

Nos. 17-3752, 18-1253, 19-1129, and 19-1189

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY,

Plaintiffs-Appellees,

v.

PRESIDENT, UNITED STATES OF AMERICA; SECRETARY,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY,
U.S. DEPARTMENT OF THE TREASURY; U.S. DEPARTMENT OF THE
TREASURY; SECRETARY, U.S. DEPARTMENT OF LABOR; and
U.S. DEPARTMENT OF LABOR,

Defendants-Appellants,

and

LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,

Intervenor-Defendant-Appellant.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

**JOINT APPENDIX
Vol. 1 (pp. 1-125)**

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TABLE OF CONTENTS

Volume 1

Notice of Appeal of the Federal Defendants (Case No. 18-1253) (dkt. no. 68)	1
Notice of Appeal of Defendant-Intervenor the Little Sisters of the Poor (Case No. 17-3752) (dkt. no. 61).....	4
Opinion (interim rules) (dkt. no. 59).....	7
Order (enjoining interim rules) (dkt. no. 60).....	51
Notice of Appeal of the Federal Defendants (Case No. 19-1189) (dkt. no. 139)	53
Notice of Appeal of Defendant-Intervenor the Little Sisters of the Poor (Case No. 19-1129) (dkt. no. 138).....	56
Opinion (final rules) (dkt. no. 136)	59
Order (enjoining final rules) (dkt. no. 135)	124

Volume 2

Docket Sheet	126
Complaint (dkt. no. 1).....	165
Amended Complaint (dkt. no. 89).....	198
Declaration of Kathryn Kost (dkt. no. 90-13).....	234
Declaration of Cynthia H. Chuang (dkt. no. 90-14)	267
Declaration of Carol S. Weisman (dkt. no. 90-15).....	277
Declaration of Samantha F. Butts (dkt. no 90-17).....	288

Declaration of Seth A. Mendelsohn (dkt. no 90-18)	297
Declaration of Leesa Allen (dkt. no 90-19)	301
Declaration of Dayle Steinberg (dkt. no 90-20)	307
Declaration of Sarah Adelman (dkt. no. 90-21).....	314
Declaration of Philip Gennace (dkt. no. 90-22)	319
Declaration of Elizabeth Coulter (dkt. no. 90-23)	324
Supplemental Declaration of Kathryn Kost (dkt. no. 118-3).....	331
Declaration of Mother Superior Marie Vincente (dkt. no. 19-2)	334
Spreadsheet from Administrative Record (Litigating Entities) (dkt. no. 90-24)	350
Spreadsheet from Administrative Record (Accommodation) (dkt. no. 90-25)	357
Spreadsheet from Administrative Record (Litigating Entities) (Bates nos. 00805059-00805065).....	384
Transcript of Preliminary-Injunction Hearing (interim rules) (dkt. no. 69)	391
Declaration and Excerpts from Exhibit to Declaration of Sharita Gruberg (ex. 20 at preliminary-injunction hearing)	645
Transcript of Preliminary-Injunction Hearing (final rules) (dkt. no. ____)	673

Volume 3

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017)*	804
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017)*	848
Comments on Interim Final Rules (dkt. no. 90-26)	873
Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018)	882
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018)	937
Executive Order No. 13,798 (May 4, 2017) (dkt. no. 90-11)	977
Health Resources & Services Administration, Women’s Preventive Services Guidelines (2016) (dkt. no. 90-10)	979
Health Resources & Services Administration, Women’s Preventive Services Guidelines (2011) (dkt. no. 90-9)	984
Excerpts from Institute of Medicine, <i>Clinical Preventive Services for Women: Closing the Gaps</i> (2011) (dkt. no. 90-8)	987
Ashley H. Snyder et al., <i>The Impact of the Affordable Care Act on Contraceptive Use and Costs Among Privately Insured Women</i> (2018) (dkt. no. 90-16)	1036

* “Public inspection” copies of the interim final rules were attached to the complaint. For ease of reference and citation, we have included in the appendix the interim rules as published in the Federal Register.

**THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No. 2:17-cv-04540 (WB)
	)	
DONALD J. TRUMP, in his official	)	
capacity as President of the United States;	)	
ALEX M. AZAR II, in his official	)	
capacity as Secretary of Health and	)	
Human Services; UNITED STATES	)	
DEPARTMENT OF HEALTH AND	)	
HUMAN SERVICES; STEVEN T.	)	
MNUCHIN, in his official capacity as	)	
Secretary of the Treasury; UNITED	)	
STATES DEPARTMENT OF THE	)	
TREASURY; RENE ALEXANDER	)	
ACOSTA, in his official capacity as	)	
Secretary of Labor; and UNITED STATES	)	
DEPARTMENT OF LABOR,	)	
	)	
Defendants. ¹	)	
	)	

NOTICE OF APPEAL

PLEASE TAKE NOTICE that the Defendants hereby appeal to the United States Court of Appeals for the Third Circuit from the Court's preliminary injunction opinion [ECF No. 59] and order [ECF No. 60], which were both issued on December 15, 2017.

Dated: February 6, 2018

Respectfully Submitted,

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¹ Pursuant to Fed. R. Civ. P. 25(d), Alex M. Azar II is substituted as a defendant in his official capacity for Eric D. Hargan.

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CERTIFICATE OF SERVICE

I hereby certify that, on February 6, 2018, a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

DATED this 6th day of February, 2018.

s/ Justin M. Sandberg
JUSTIN M. SANDBERG
Senior Trial Counsel
United States Department of Justice

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA,

Plaintiff,

v.

DONALD J. TRUMP, *et al.*

Defendants,

LITTLE SISTERS OF THE POOR SAINTS
PETER AND PAUL HOME,

Proposed Defendant-Intervenor.

Civil No. 17-CV-4540-WB

PROTECTIVE NOTICE OF APPEAL

Notice is hereby given that the Little Sisters of the Poor Saints Peter and Paul Home (the “Little Sisters”), Proposed Defendant-Intervenor in the above-captioned case, hereby appeals to the United States Court of Appeals for the Third Circuit from the Court’s Order (ECF Nos. 59 and 60) granting Plaintiff’s request for a preliminary injunction, entered in this action on December 15, 2017. The Little Sisters file this protective notice in order to protect their rights in the event that intervention is granted after the time for appeal has expired.

Dated: December 15, 2017

Respectfully submitted,

/s/ Mark Rienzi

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**Admission pro hac vice pending*

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

Dated: December 15, 2017

/s/ Mark Rienzi
Mark Rienzi

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**COMMONWEALTH OF
PENNSYLVANIA ,
Plaintiff,**

v.

**DONALD J. TRUMP, DONALD J.
WRIGHT, UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES, STEVEN T.
MNUCHIN, UNITED STATES
DEPARTMENT OF THE TREASURY,
RENE ALEXANDER ACOSTA AND THE
UNITED STATES DEPARTMENT OF
LABOR,
Defendants.**

CIVIL ACTION

NO. 17-4540

OPINION

The interests at stake in this litigation are great, but the issues that must be decided here on Plaintiff’s Motion for a Preliminary Injunction are narrow. This case implicates access to healthcare, religious freedom, women’s rights, and executive power. However, the Court currently addresses only two precise questions: Did the Defendants here follow the proper procedure in issuing new rules that greatly expand exemptions to the law requiring health plans to cover women’s preventive services at no cost, and do the new rules contradict the text of the statute that they are meant to interpret?

Plaintiff, the Commonwealth of Pennsylvania (“Commonwealth”), seeks to enjoin enforcement of two Interim Final Rules (“New IFRs”), referred to as the Moral Exemption Rule and the Religious Exemption Rule, modifying the Affordable Care Act. The New IFRs were issued by the Departments of Health and Human Services, the Department of Treasury, and the

Department of Labor on October 6, 2017. They permit employers to opt out of providing no-cost contraceptive coverage on the basis of sincerely held religious beliefs or sincerely held moral convictions. The parties here have vastly different perspectives on the import of the New IFRs. The Defendants assert that they are meant to permit a small number of religious objectors to opt out of covering contraceptive services in their employer-sponsored health plans because the requirement to provide contraceptive coverage imposes a substantial burden on their exercise of religion. Quite to the contrary, the Commonwealth argues that the Rules allow almost any employer to withhold insurance coverage for contraceptive services from their female employees, thus impacting millions of women – all in contravention of the Affordable Care Act and the United States Constitution.

The Commonwealth has sued President Donald J. Trump, United States Secretary of Health and Human Services Donald J. Wright,¹ United States Secretary of the Treasury Steven T. Mnuchin, and United States Secretary of Labor Rene Alexander Acosta in their official capacities, as well as each of their agencies (collectively, “Defendants”). It now seeks to enjoin the Defendants from enforcing the New IFRs for a variety of constitutional and statutory violations. For the reasons explained below, the Motion for a Preliminary Injunction shall be granted.

I. Background²

In March 2010, Congress enacted the Affordable Care Act. *See* Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010). The ACA included a provision called the Women’s Health Amendment, which mandated that group health plans and

¹ Eric D. Hargan substitutes Donald J. Wright pursuant to Rule 25(d) of the Federal Rules of Civil Procedure.

² The factual statements found here and elsewhere in the opinion constitute this Court’s findings of fact, as required under Rule 52(a) of the Federal Rules of Civil Procedure, regardless of any heading or lack thereof.

health insurance issuers offering group or individual health insurance provide coverage for preventive health services and screenings for women without cost-sharing responsibilities. The preventive services that must be covered include, “with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).” *See* 42 U.S.C. § 300gg-13(a)(4). Thus, Congress left the decision about which preventive care and screenings should be covered by the ACA up to the HRSA, which is an agency of the Department of Health and Human Services (HHS).

The HRSA commissioned the Institute of Medicine (“the Institute”) to issue recommendations identifying what specific preventive women’s health services should be covered under the ACA’s mandate. *See* 77 Fed. Reg. 8725-26. The Institute is an arm of the National Academy of Sciences, an organization that Congress established for the explicit purpose of furnishing advice to the federal government. *See Pub. Citizen v. Dep’t of Justice*, 491 U.S. 440, 460 n.11 (1989). The Institute, in turn, convened a committee of sixteen members (the “Committee”), including specialists in disease prevention, women’s health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. The Committee defined preventive health services to include measures “shown to improve well-being and/or decrease the likelihood or delay the onset of a targeted disease or condition.” Institute, *Clinical Prevention Services for Women: Closing the Gaps* 23 (2011) (“Institute Report”).

On July 19, 2011, the Institute, through the Committee, issued a comprehensive report that identified health services that should be covered under the Women’s Health Amendment. *Id.* at 8-12. It recommended that the ACA cover “the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women

with reproductive capacity.” *Id.* at 109-10. The Committee considered: (1) the prevalence of unintended pregnancy in the United States; (2) potential health risks of pregnancy; (3) that decreased intervals between pregnancies lead to an “increased risk of adverse pregnancy outcomes”; (4) the effectiveness of contraceptives in preventing unintended pregnancy; (5) the health benefits of contraceptives for other diseases and conditions; and (6) the barrier to contraceptive access presented by its cost. *See id.* at 104-10.

Original Religious Exemption

On August 1, 2011, HRSA adopted the Institute’s recommendations in guidelines, which required, among other things, that plans must cover all FDA-approved contraceptive methods (“Contraceptive Mandate”). 45 C.F.R. § 147.130(a)(1)(iv); 29 C.F.R. § 2590.715-2713(a)(1)(iv); 26 C.F.R. § 54.9815-2713(a)(1)(iv). This requirement applied to all health insurers offering individual or group insurance, as well as all group health plans, with the exception of certain “grandfathered” plans. *See* 29 C.F.R. § 2590.715-1251. Simultaneously, the Departments of HHS, Labor, and the Treasury (“the Agencies” or “Defendant Agencies”) also promulgated an Interim Final Rule (“IFR”) exempting certain religious employers from providing contraceptive services (“Original Religious Exemption”). *See* 76 Fed. Reg. 46621. To take advantage of that exemption, an employer must: (1) have the inculcation of religious values as its purpose; (2) primarily employ people who share its religious tenets; (3) primarily provide services to persons who share its religious tenets; and, (4) be a church, its integrated auxiliary, or a convention or association of a church, all of which are exempt from taxation under 26 U.S.C. § 501(a). *See id.* at 46623.

Second Religious Exemption and Accommodation Process

Following several legal challenges to the Contraceptive Mandate, the Agencies began to consider changes to the religious exemptions. In March 2012, they issued an Advanced Notice of Proposed Rulemaking concerning a potential accommodation process for religious objectors to the Contraceptive Mandate. 77 Fed. Reg. 16501. After a comment period, they then issued a Notice of Proposed Rulemaking proposing changes to the definition of religious organizations in the exemption and creating an accommodation process for religious objectors to the Contraceptive Mandate. 78 Fed. Reg. 8456. The Agencies published final regulations on July 2, 2013 (“Second Religious Exemption”). See 78 Fed. Reg. 39870. These regulations redefined a religious employer to only refer to churches, their integrated auxiliaries, and conventions or associations of churches, eliminating the need to fulfill the first three requirements of the prior regulations of the exemption. Upon a covered entity claiming the exemption, the provider or administrator would then have to provide the legally required contraceptive services directly to women covered under the employer’s plan (“Accommodation Process”).

Third Religious Exemption and Accommodation Process

Following enactment of the ACA and the Second Religious Exemption, the Supreme Court granted certiorari to decide whether the Contraceptive Mandate violated the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1 (RFRA). In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Supreme Court concluded that applying the Contraceptive Mandate to closely held corporations violated RFRA. In *Wheaton Coll. v. Burwell*, 134 S. Ct. 2806 (2014), the Court identified an alternative process by which Wheaton College could comply with the Contraceptive Mandate without informing its health insurer or third-party administrator: The Court permitted Wheaton College to “inform[] the Secretary of Health and Human Service in writing that it . . . has religious objections to providing coverage for

contraceptive services. *Id.* at 2807. In response to *Hobby Lobby* and *Wheaton College*, the Agencies issued a third set of IFRs to augment the Accommodation Process to comply with the Supreme Court’s orders. *See* 79 Fed. Reg. 51092, 51118 (expanding the Accommodation Process to include for-profit corporations and to adjust the Accommodation Process). The Agencies finalized the IFRs on July 14, 2015 (“Third Religious Exemption”). *See* 80 Fed. Reg. 41318, 41324.

One year later, the Supreme Court granted certiorari to decide whether the Accommodation Process violated RFRA. The question before the Supreme Court was whether the requirement to notify plaintiffs’ insurers of their religious objections substantially burdened their exercise of religion in violation of RFRA. The Supreme Court did not address the question head on. Rather, it vacated the judgments of the courts of appeals and remanded the cases to provide the parties “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans ‘receive full and equal health coverage, including contraceptive coverage.’” *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016). The Agencies then issued a Request for Information (“RFI”) seeking public comment on options for modifying the Accommodation Process in light of *Zubik*. *See* 81 Fed. Reg. 47741. On January 9, 2017, the Department of Labor announced that it was unable to develop an approach that could “resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” Department of Labor, *FAQs about Affordable Care Act Implementation Part 36* (Jan. 9, 2017).

Executive Order 13798: “Promoting Free Speech and Religious Liberty”

On May 4, 2017, President Trump issued an Executive Order “Promoting Free Speech and Religious Liberty.” Exec. Order No. 13798, 82 Fed. Reg. 21675. The Order directed the Agencies to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [the Women’s Health Amendment.]” *Id.* § 3.

Fourth Religious Exemption and Accommodation Process

The Agencies issued the New IFRs on October 6, 2017, citing a goal of being “consistent with the President’s Executive Order and the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs.” See 82 Fed. Reg. 47792 (“Religious Exemption Rule”); 82 Fed. Reg. 47838 (“Moral Exemption Rule”). The New IFRs embodied two exemptions to the Contraceptive Mandate. First, under the Religious Exemption Rule, any non-profit or for-profit entity, whether closely held or publicly traded, may claim the exemption based on sincerely held religious beliefs. Second, under the Moral Exemption Rule, any non-profit or for-profit entity, so long as it is closely held, may claim the exemption based on sincerely held moral convictions.

The Religious Exemption and Moral Exemption Rules make significant changes from prior exemptions. First, the new rules greatly expand the scope of who may opt out of the Contraceptive Mandate. Second, the rules render the Accommodation Process optional. Third, they eliminate requirements to provide notice of an intent to take advantage of either exemption. In other words, entities that stop providing contraceptive care “do not need to file notices or certifications of their exemption and [the Exemption Rules] do not impose any new notice requirements on them.”³ See 82 Fed. Reg. 47850, 47858. Fourth, the New IFRs permit

³ The Employee Retirement Income Security Act of 1974 (ERISA) still requires group health plans to notify plan participants of any change in coverage at least 30 or 60 days in advance. See 77 Fed. Reg. 8667.

employers to opt out of coverage on the basis of “sincerely held” religious beliefs and moral convictions.

The Agencies issued the new rules as IFRs and requested post-issuance comments by December 5, 2017, 60 days after they were issued. The Commonwealth filed this suit in the interim seeking to enjoin enforcement of the New IFRs because: (1) they fail to comply with the notice-and-comment procedures required by the Administrative Procedure Act (“APA”), 5 U.S.C. § 551, *et seq.*; (2) they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in violation of the substantive provisions of the APA, 5 U.S.C. § 706(2)(A); (3) they violate Title VII of the Civil Rights Act, 42 U.S.C. § 2000-2(a); (4) they violate the Equal Protection Guarantee of the Fifth Amendment, U.S. Const. amend. V; and, (5) they violate the Establishment Clause. U.S. Const. amend. I.

II. Standing

A threshold question is whether the Commonwealth has standing. Standing is a litigant’s ticket to federal court. It is a constitutional requirement, “limit[ing] the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); U.S. Const. art. III, § 2, cl. 2. The Commonwealth contends that it is properly before the Court because the New IFRs are causing, or will imminently cause, direct harm to its sovereign, quasi-sovereign and proprietary interests. Additionally, it asserts that it has *parens patriae* standing to protect the health, safety and well-being of its residents in ensuring that they enjoy access to healthcare services. The Defendants, on the other hand, contend that the Commonwealth has not suffered any legal wrong that would allow it to step foot into federal court.

“No principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *Raines v. Byrd*, 521 U.S. 811, 818 (1997). The doctrine of standing ensures that federal judicial power is properly limited to these cases or controversies. *See Finkleman v. Nat’l Football League*, 810 F.3d 187, 203 (3d Cir. 2016). Thus, if a plaintiff lacks standing, the case must be dismissed. *See id.* at 195. And, as Plaintiff, the Commonwealth has the burden of establishing that it has standing. *See Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 411-12 (2013).

To do so, it must satisfy “the irreducible constitutional minimum of standing,” which “contains three elements.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). First, the Commonwealth must have suffered an “injury in fact,” defined as “an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” *Id.* (internal quotation marks and citations omitted). Second, the Commonwealth must show that there is a “causal connection between the injury and the conduct complained of.” *Id.* That is, the injury must be “fairly traceable” to the “challenged action of the defendant.” *Id.* Third, the Commonwealth must show that it is “likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Id.* at 561 (internal quotation marks omitted). “Each element [of standing] must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Id.* Thus, because the Commonwealth here seeks a preliminary injunction, it must adduce evidence demonstrating more than a mere possibility of injury in support of standing. *Doe v. Nat’l Bd. of Med. Exam’rs*, 199 F.3d 146, 152 (3d Cir. 1999).

a. Special Solicitude

This standing inquiry must be made in the context of a clear recognition that States, like the Commonwealth here, “are not normal litigants for the purposes of invoking federal jurisdiction.” *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). Accordingly, a State is “entitled to special solicitude in [the] standing analysis” if it has: (1) a procedural right that authorizes it to challenge the conduct at issue; and, (2) a “stake in protecting its quasi-sovereign interests.” *Massachusetts*, 549 U.S. at 520; *see also Texas v. United States*, 809 F.3d 134, 151 (5th Cir. 2015), *aff’d by an equally divided Court*, 136 S. Ct. 2271 (2016).

In determining whether the Commonwealth has met these conditions, both *Massachusetts v. EPA* and *Texas v. United States* are instructive. In *Massachusetts v. EPA*, Massachusetts sued the Environmental Protection Agency (EPA), alleging that global warming was “the most pressing environmental challenge of our time,” and that the EPA had “abdicated its responsibility under the Clean Air Act” when it failed to issue rules regulating the emission of greenhouse gases coming from cars. 549 U.S. at 505. The EPA challenged Massachusetts’ standing to bring the suit because greenhouse gas emissions are a widespread and generalized harm not unique to any specific plaintiff. *See id.* at 517. The Supreme Court nonetheless held that Massachusetts had special solicitude in the standing inquiry to challenge the EPA’s inaction: First, Massachusetts had a procedural right under the relevant statute, the Clean Air Act, which allowed it to “challenge agency action unlawfully withheld.” *Id.* (citing 42 U.S.C. § 7607(b)(1)). Second, Massachusetts had a quasi-sovereign interest – a “well-founded desire to preserve its sovereign territory” from the effects of global warming. *Id.* at 519. Indeed, Massachusetts “own[ed] a great deal of the ‘territory alleged to be affected.’” *Id.*; *see also id.* at 522 (affidavits noting that “rising seas have already begun to swallow Massachusetts’ coastal land.”). After

concluding that Massachusetts was entitled to special solicitude in the standing analysis, the Supreme Court ultimately held that it had Article III standing to sue the EPA based on an injury to its territory that stemmed from global warming. *See id.* at 526.

In *Texas v. United States*, the Fifth Circuit, relying on *Massachusetts v. EPA*, similarly concluded that Texas, as a State, was entitled to special solicitude in seeking to enjoin implementation of the Deferred Action for Parents of Americans and Lawful Permanent Residents program (DAPA). 809 F.3d at 154. In that case, non-citizens in Texas could apply for a driver's license if they presented "documentation issued by the appropriate United States agency that authorizes the applicant to be in the United States." *See id.* at 155 (quoting TEX. TRANSP. CODE § 521.142(a)). DAPA would have permitted at least 500,000 non-citizens to qualify for these driver's licenses. *Id.* Because Texas subsidized its licenses, it would have lost money for each license issued to a DAPA beneficiary. *Id.* Texas therefore sought injunctive relief to prevent DAPA's implementation. *See id.* at 149.

Applying the *Massachusetts v. EPA* framework, the Fifth Circuit first considered whether Texas had a procedural right to challenge DAPA. It concluded that Texas' use of the APA to challenge an "affirmative decision" made by a federal agency was similar to Massachusetts' use of the judicial review provision in the Clean Air Act to challenge the EPA's inaction. *Id.* at 152. Second, as to Texas' quasi-sovereign interest, the Fifth Circuit held that DAPA imposed "substantial pressure" on the State to change its laws to avoid bearing further costs from subsidizing additional driver's licenses. *See id.* at 153. The Fifth Circuit thus concluded that Texas had special solicitude in suing the federal government under the APA for injunctive relief. *Id.* at 154-55.

On writ of certiorari, the Supreme Court summarily affirmed the Fifth Circuit’s decision without opinion but with a notation that the affirmance was “by an equally divided Court.” *United States v. Texas*, 136 S. Ct. 2271 (2016) (per curiam). Notably, one question certified by the Supreme Court included whether Texas had standing. *See United States v. Texas*, 136 S. Ct. 906 (2016) (granting petition for writ of certiorari for, among other things, whether Texas had standing). Affirmances by an equally divided Supreme Court typically do not constitute binding precedent. *See Eaton v. Price*, 364 U.S. 263, 264 (1960). However, when the Supreme Court is equally divided on an issue of subject matter jurisdiction, it has determined that the proper course is to remand the issue of jurisdiction to a lower court. *See Silliman v. Hudson River Bridge Co.*, 66 U.S. 582, 584-85 (1861). In other words, if the Supreme Court were equally divided on whether Texas had standing to enjoin DAPA, it would have remanded that issue to the Fifth Circuit. The Supreme Court did not and instead affirmed the Fifth Circuit. It therefore follows logically that a majority of the Supreme Court decided that Texas had standing to pursue its APA claim.⁴

There is no daylight between the 2015 Texas suit against the federal government and the current Commonwealth suit against the federal government. Like Texas, the Commonwealth challenges agency action in issuing regulations – here, the New IFRs. *See Texas*, 809 F.3d at 152. It is all the more significant that the Commonwealth, like Texas before it, sues to halt *affirmative* conduct made by a federal agency. *See id.* Whereas *Massachusetts v. EPA* concerned regulatory inaction – the EPA’s order denying a rulemaking petition – the Commonwealth’s case here challenges regulatory action that, it contends, affects its legally cognizable interests. *See* 549 U.S. at 514. Thus, it is especially appropriate to accord the

⁴ Even if the affirmance by an equally divided Supreme Court as it relates to subject matter jurisdiction were not binding, the Court is persuaded by the reasoning of the Fifth Circuit in *Texas v. United States* as it pertains to state standing.

Commonwealth “special solicitude.” *Texas*, 809 F.3d at 152-53. Furthermore, like Texas and Massachusetts, the Commonwealth seeks to protect a quasi-sovereign interest – the health of its women residents. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 600-01 (1982) (holding that a State has a “quasi-sovereign interest in the health and wellbeing – both physical and economic – of its residents in general.”). As the Commonwealth observes, contraceptives offer significant health benefits, including the prevention of unintended pregnancies, and the treatment of menstrual disorders, acne or hirsutism, and pelvic pain. This quasi-sovereign interest in safeguarding the health and wellbeing of its women residents is inextricably intertwined with the Commonwealth’s alleged future fiscal injury that, as will be discussed later, goes to the heart of its Article III standing. *See Texas*, 809 F.3d at 153 (concluding that DAPA affected quasi-sovereign interest by “imposing substantial pressure” on Texas to change its laws to avoid losing more money from driver license subsidies). According to the Commonwealth (and as addressed more fully below), the Agencies’ New IFRs will allow more employers to exempt themselves from the ACA’s Contraceptive Mandate. Consequently, the Commonwealth contends that Pennsylvanian women will seek state-funded sources of contraceptive care. Such a course of action will likely cause the Commonwealth to expend more funds to protect its quasi-sovereign interest in ensuring that women residents receive adequate contraceptive care. The Commonwealth, then, meets the two conditions outlined in *Massachusetts v. EPA* and shall be accorded special solicitude in the standing analysis.

b. Article III Standing

As previously stated, the three pillars of standing are injury in fact, causation, and redressability. *Lujan*, 504 U.S. at 560. First, an agency rule that has “a major effect on the states’ fises” is sufficient to find injury in fact. *Texas*, 809 F.3d at 152; *id.* at 155 (Texas

“satisfied the first standing requirement by demonstrating that it would incur significant costs in issuing driver’s licenses to DAPA beneficiaries.”); *see also Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (holding that Wyoming had Article III standing because it undisputedly suffered a “direct injury in the form of a loss of specific tax revenues”); *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (“While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.”).

The New IFRs will likely inflict a direct injury upon the Commonwealth by imposing substantial financial burdens on State coffers. Specifically, the Commonwealth will have to increase its expenditures for State and local programs providing contraceptive services. This is not a speculative harm. As the Defendants themselves noted in issuing one of the New IFRs, “there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women.” 82 Fed. Reg. 47803. As more women residents of the Commonwealth are deprived of contraceptive services through their insurance plans and turn to these State and local programs, the Commonwealth will likely make greater expenditures to ensure adequate contraceptive care. And although Defendants point out that the Commonwealth has not yet identified a woman resident of Pennsylvania who has lost contraceptive coverage as a result of the New IFRs, the Commonwealth need not sit idly by and wait for fiscal harm to befall it. *See McNair v. Synapse Group Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) (“When, as in this case, prospective relief is sought, the plaintiff must show that he is “likely to suffer future injury” from the defendant’s conduct.”) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983)). As the New IFRs themselves estimate, they will cause at least 31,700 women to lose contraceptive coverage. 82 Fed. Reg. 47821.

Indeed, the Commonwealth's affidavits confirm that its women residents will come to rely more on State-funded sources. The Acting Executive Deputy Secretary for the Commonwealth's Department of Human Services concludes that it would not be unreasonable to expect women who do not receive contraceptive care from their insurers to rely on government-funded programs. *See* Decl. of Leesa Allen ¶ 23 ("Allen Decl."). The Executive Deputy Insurance Commissioner for the Commonwealth echoes a similar view, expecting women who lose contraceptive coverage to seek coverage from State-funded programs (or pay for the contraceptives themselves). *See* Decl. of Seth A. Mendelsohn ("Medelsohn Decl.") ¶ 15. The CEO of Planned Parenthood Southeastern Pennsylvania also expects that, as a result of the New IFRs, many low-income women will have to rely on government-funded programs to obtain contraceptive care. *See* Decl. of Dayle Steinberg ("Steinberg Decl.") ¶¶ 24-25. The Commonwealth has furthermore provided evidence from a doctor who practices in Pennsylvania acknowledging that she directs uninsured, low-income women to State programs for contraceptive services. *See* Tr. 177-78. At bottom, just as Texas' estimated loss due to DAPA supported injury in fact, so too does the Commonwealth's estimated loss due to the New IFRs support injury in fact. *See Texas*, 809 F.3d at 155.

Second, the Commonwealth's financial injury is "fairly traceable" to issuance of the New IFRs. By their terms, they expand the scope of the existing religious exemption rule as well as allow employers a new rationale for refusing to provide employees with contraceptive coverage if the refusal is "based on sincerely held moral convictions." In short, the New IFRs allow more employers to stop providing contraceptive coverage. And as the Commonwealth's various affidavits show, State officials expect that once employers take advantage of the New IFRs more women residents will seek contraceptive care through State-funded programs. The

Commonwealth has thus shown a causal connection between the New IFRs and its financial injury.

Defendants, however, cite to *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976), and argue that the injury is not “fairly traceable” to the New IFRs because the Commonwealth’s fiscal injury is “self-inflicted.” According to Defendants, the Commonwealth cannot shoot itself in the foot and then hobble into federal court by premising injury in fact on costs that flow from *elective* State programs that offer contraceptive care services to residents.

Pennsylvania v. New Jersey is distinguishable. In that case, Pennsylvania voluntarily gave tax credits to Pennsylvania residents who paid taxes in New Jersey. *Id.* at 663. Pennsylvania proceeded to sue New Jersey, contending that the New Jersey tax injured Pennsylvania’s fiscs and was constitutionally impermissible. *Id.* at 662. The Supreme Court found that Pennsylvania lacked standing because the injuries to its fiscs were “self-inflicted,” resulting, as they did, from a decision of its state legislature. *Id.* at 664. Pennsylvania was not allowed to “complain about damage inflicted by its own hand” when it enacted a law that incorporated the legislative choices of New Jersey. *Id.* The harm could have been avoided if Pennsylvania simply changed the law so that it no longer extended credits for taxes paid to New Jersey. *See id.* Here, by contrast, funding for the Commonwealth’s programs does not explicitly incorporate the legislative choices of the federal government. Rather, the Commonwealth’s described injuries flow from the unilateral decision by the Agencies to issue the New IFRs, which will likely cause Pennsylvanian women to seek contraceptive care from other sources, particularly state-funded sources. Consequently, the injunction that the Commonwealth seeks – to enjoin that unilateral federal agency decision – is untethered to any state law that the Commonwealth itself has enacted. *See Texas*, 809 F.3d at 158 (“The fact that Texas sued in

response to a significant change in the defendants' policies shows that its injury is not self-inflicted.”).

Third, the Commonwealth has satisfied the redressability requirement. Because the Commonwealth is asserting a procedural right under the APA to protect its interests, it “can assert that right without meeting all the normal standards for redressability and immediacy.” *See Massachusetts*, 549 U.S. at 517-18. If, as here, the litigant is “vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.” *Id.* at 518. Enjoining the Agencies' New IFRs based on APA claims should prompt them to reconsider the propriety of the Religious and Moral Exemptions Rules, “which is all a plaintiff must show when asserting a procedural right.” *Texas*, 809 F.3d at 161. In sum, the Commonwealth has shown that it has standing to pursue injunctive relief through its APA claims based on an injury to its fisci.⁵

III. Legal Standard

As the Commonwealth has standing to pursue a preliminary injunction, the next step is to determine whether one is appropriate. A preliminary injunction is an extraordinary remedy; it “should be granted only in limited circumstances.” *American Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1426-27 (3d Cir. 1994). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The “failure to establish any element . . . renders a preliminary injunction

⁵ Because the Commonwealth has identified an imminent, direct injury to its state coffers that result from the New IFRs, the Court does not need to address whether it has sovereign or *parens patriae* standing.

inappropriate.” *NutraSweet Co. v. Vit-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999). The movant bears the burden of showing that these four factors weigh in favor of granting the injunction. *See Opticians Ass’n of Am. v. Indep. Opticians of Am.*, 920 F.2d 187, 192 (3d Cir. 1990).

While the movant must show that each of these factors weighs in favor of granting an injunction, an injunction might be appropriate where a movant makes a particularly strong case on some factors, but not others. Thus, “courts must *balance* the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.” *Reilly v. City of Harrisburg*, 858 F.3d 173, 177-78 (3d Cir. 2017), *as amended* (June 26, 2017) (quoting *Winter*, 555 U.S. at 24). “[I]n a situation where factors of irreparable harm, interests of third parties and public considerations strongly favor the moving party, an injunction might be appropriate even though plaintiffs did not demonstrate as strong a likelihood of ultimate success as would be generally required.” *Constructors Ass’n of W. Pa. v. Kreps*, 573 F.2d 811, 815 (3d Cir. 1978). In addition, the court must weigh “[a]ll of [the four preliminary injunction] factors . . . together in the final decision and the strength of the plaintiff’s showing with respect to one may affect what will suffice with respect to another.” *Marxe v. Jackson*, 833 F.2d 1121, 1128 (3d Cir. 1987). The Third Circuit recently clarified in *Reilly* that a “movant for preliminary equitable relief must meet the threshold for the first two ‘most critical’ factors [– likelihood of success and irreparable harm]. If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief.” *Reilly*, 858 F.3d at 179. “How strong a claim on the merits is enough depends on the balance of the harms: the more net harm

an injunction can prevent, the weaker the plaintiff's claim on the merits can be while still supporting some preliminary relief." *Id.*

a. Likelihood of Success on the Merits

In demonstrating the likelihood of success on the merits, a plaintiff need not show that it is more likely than not that he will succeed. *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc). Instead, a plaintiff must "show[] a reasonable probability of success on the merits." *American Express Travel Related Svcs., Inc. v. Sidamon-Eristoff*, 669 F.3d 359, 366 (3d Cir. 2012). This requires a showing "significantly better than negligible, but not necessarily more likely than not." *Reilly*, 858 F.3d at 179.

Because "courts should be extremely careful not to issue unnecessary constitutional rulings," *American Foreign Serv. Ass'n v. Garfinkel*, 490 U.S. 153, 161 (1989) (per curiam), the Court addresses the statutory claims at issue – that Defendants violated the notice-and-comment procedures of the APA and that the New IFRs are "arbitrary, capricious, or not in accordance with law" – and finds it unnecessary, at this juncture, to proceed to the constitutional issues.

i. Administrative Procedure Act

1. Procedural Safeguards

The APA provides any interested party the right to participate in the rulemaking process by submitting data, views or arguments. See 5 U.S.C. § 553. "The APA provisions reflect a judgment by Congress that the public interest is served by a careful and open review of proposed administrative rules and regulations." *Phila. Citizens in Action v. Schweiker*, 669 F.2d 877, 881 (3d Cir. 1982). "Section 553 was enacted to give the public an opportunity to participate in the rule-making process. It also enables the agency promulgating the rule to educate itself before

establishing rules and procedures which have a substantial impact on those regulated.” *Texaco, Inc. v. Fed. Power Comm’n*, 412 F.2d 740, 744 (3d Cir. 1969).

Accordingly, prior to promulgating regulations, administrative agencies must follow a procedure called “notice and comment rulemaking.” See 5 U.S.C. § 553. First, an agency must issue a general notice of proposed rulemaking. See 5 U.S.C. §§ 552(b), 553(b). Then the agency must “give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments. . . .” *Id.* § 553(c). Last, “[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.” *Id.* Defendants bypassed each of these procedures when issuing the New IFRs.

The APA requires a court to set aside agency action “found to be . . . without observance of procedure required by law.” 5 U.S.C. § 706(2)(D). Thus, if Defendants did not comply with notice and comment provisions, the Court must preliminarily enjoin Defendants from enforcing the New IFRs unless there is a statutorily countenanced reason for their non-compliance. See *Minard Run Oil Co. v. U.S. Forest Serv.*, 2009 WL 4937785, at *34 (W.D. Pa. 2009), *aff’d*, 670 F.3d 236 (3d Cir. 2011).

Although “[e]xemption from the terms of the Administrative Procedure Act are not lightly to be presumed. . . ,” *Marcello v. Bonds*, 349 U.S. 302, 310 (1955), there are limited exceptions to the requirement that all rules must be issued pursuant to notice-and-comment rulemaking. Defendants contend that two of those exceptions apply here. First, they argue that Congress expressly and impliedly authorized the Secretaries of HHS, Labor, and the Treasury to bypass notice and comment rulemaking with respect to the New IFRs. 5 U.S.C. § 559. Second, they argue that there is no need for notice-and-comment rulemaking because they have found

“good cause” that the notice and comment procedure is, in this instance, “impracticable, unnecessary, or contrary to the public interest.” *Id.* § 553(b)(B).

i. Statutory Authorization to Bypass Notice and Comment

At the outset, it should be noted that the ACA contains no provision expressly authorizing the Defendant Agencies or their respective Secretaries to bypass the APA’s notice and comment requirements, and indeed, Defendants cite none. Rather, in justifying their sidestep of the strictures of the notice and comment procedure, they find express and implied authorizations for their actions through various statutes *besides* the ACA. Defendants’ argument, matryoshkanesque in its construction, proceeds as follows: In 1996, Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191 (1996), which regulates group health plans and some individual health insurance policies. HIPAA amended certain provisions of the United States Code to provide that “[t]he [respective] Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this [chapter.]” See 29 U.S.C. § 1191c; 26 U.S.C. § 9833; 42 U.S.C. § 300gg-92.⁶ In 2010, Congress passed the ACA, which also amended those same sections of the United States Code to require health plans to cover certain preventive women’s services. HHS interpreted the preventive service requirement to include contraceptive services. The requirement to provide contraceptive services was thus codified in the chapters of the United States Code as modified by HIPAA in 1996. Thus, according to Defendants, HIPAA’s amendments, which permit issuance of IFRs “appropriate to carry out this [chapter],” also encompass authorization to issue IFRs to carry out the ACA.

⁶ Specifically, HIPAA amended various portions of ERISA, which is administered by the Secretary of Labor, the Internal Revenue Code, which is administered by the Secretary of Treasury, and the Public Health Services Act, which is administered by the Secretary of Health and Human Services.

The argument is creative, but not supported by law. As to express authorization, in order to authorize an agency to bypass notice and comment, a subsequent statute must be clear that it abrogates the APA. See 5 U.S.C. § 559; *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18 (D.D.C. 2010). And as *Coalition for Parity* held, the provision of HIPAA that Defendants here rely on says nothing about overruling the APA, let alone notice and comment procedures. *Id.* HIPAA, then, does not provide express authorization to bypass the notice and comment requirements of the APA in this case. See *id.*

As to implied authorization, the relevant standard to determine if Congress *sub silentio* allowed an agency to avoid notice and comment is “whether Congress has established procedures so clearly different from those required by the APA that it must have intended to displace the norm.” *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998). Defendants rely on two cases, *Asiana Airlines* and *Methodist Hospital of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994), for the proposition that Congress has impliedly authorized the Agencies here to bypass notice and comment and issue IFRs.

In both *Asiana Airlines* and *Methodist Hospital*, the D.C. Circuit held that certain IFRs could be issued without complying with notice and comment, but both cases are inapposite. The statutory language from those cases, involving respectively the Federal Aviation Reauthorization Act and the Social Security Amendments of 1983, expressly abrogated APA notice and comment procedures because Congress, through its use of the mandatory word “shall” in both pieces of legislation, commanded the agencies to issue interim final rules. See *Asiana Airlines*, 134 F.3d at 395 (“the Administrator **shall** publish . . . interim final rule[s]”) (citing 49 U.S.C. § 45301(b)(2)) (emphasis added); *Methodist Hosp.*, 38 F.3d at 1236 n.18 (“[t]he Secretary **shall** cause to be published . . . a notice of the interim final DRG prospective payment rates . . .

without the necessity for consideration of comments. . . .”) (citing 97 Stat. 168-69) (emphasis added). By contrast, the HIPAA provision here states that a “Secretary **may** promulgate any interim final rules as the Secretary determines are appropriate. . . .” See 29 U.S.C. § 1191c; 26 U.S.C. § 9833; 42 U.S.C. § 300gg-92 (emphasis added). The use of the term “may” is permissive rather than mandatory. See *Barlow v. Collins*, 397 U.S. 159, 165-66 (1970) (statute authorizing Secretary of Agriculture to promulgate regulations “as he may deem proper” does not preclude judicial review).⁷ There is, accordingly, no support in HIPAA for the Agencies’ avoidance of the notice and comment procedure.

ii. *Good Cause Exception to Bypass Notice and Comment*

The second exception to notice-and-comment rulemaking permits agencies to utilize IFRs “for good cause.” See 5 U.S.C. § 553. More specifically, the APA provides that notice and comment may be waived “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” *Id.* The “circumstances justifying reliance on the good cause exception are ‘indeed rare’ and will be accepted only after the court has examined closely proffered rationales justifying the elimination of public procedures.” *Natural Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 764 (3d Cir. 1982). The Third Circuit has cautioned that the good cause exception should be “narrowly construed.” *United States v. Reynolds*, 710 F.3d 498, 507 (3d Cir. 2013) (citations omitted).

Since the APA requires agencies availing themselves of the good cause exception to state their “finding[s] and a brief statement of reasons” for good cause “in the rules issued,” the Court

⁷ *Asiana Airlines* and *Methodist Hospital* are further distinguishable still. In both cases, Congress imposed an expeditious timetable on the agencies in issuing the IFRs which justified bypassing notice and comment. See *Methodist Hosp.*, 38 F.3d at 1237; *Asiana Airlines*, 124 F.3d at 398. By contrast, the supposed statutory authorization in HIPAA provides no timetable for the Agencies to issue IFRs.

will examine the proffered “good cause” reasons as stated in the New IFRs. *See* 82 Fed. Reg. at 47813-15; 82 Fed. Reg. at 47855-59. First, the Agencies found that excessive delay caused by notice and comment rulemaking would be contrary to public interest. *Id.* Second, the Agencies determined that the New IFRs were important to resolve ongoing litigation and ease the burdens imposed by them in order to prevent “continued uncertainty, inconsistency, and cost.” *Id.* Third, the Agencies determined that they had already received significant comments in past rounds of rulemaking as well as from the 2016 RFI, and therefore there was no need to repeat the notice-and-comment process again. *Id.* These arguments are considered *seriatim*.

As to their “excessive delay” justification, the Agencies contend that, because the Accommodation Process (in their view) violated RFRA, it was a matter of urgency to issue the New IFRs without going through the APA’s time-consuming notice and comment process.⁸ *See id.* However, urgency is not sufficient in the absence of a deadline imposed by Congress, the executive, or courts. *See Reynolds*, 710 F.3d at 511 (“Our prior decisions have recognized urgency alone as sufficient only when a deadline imposed by Congress, the executive, or the judiciary requires agency action in a timespan that is too short to provide a notice and comment period.”). None of the three branches of government have imposed any urgent deadline that could support circumventing notice and comment rulemaking. First, Congress has not spoken on this issue. Second, far from compelling any immediate action, President Trump’s Executive

⁸ The Agencies also justify their use of IFRs rather than regulations promulgated through APA’s proscribed procedures by reference to their use of IFRs in three earlier updates to regulations concerning the Women’s Health Amendment. This fact does not, of course, warrant a conclusion that the New IFRs were appropriately issued – the facts of one case do not necessarily transfer wholesale to another. Defendants argue that as the D.C. Circuit upheld the Defendants’ use of IFRs in *Priests for Life v. U.S. Dep’t of Health and Human Servs.*, 772 F.3d 229, 276 (D.C. Cir. 2014), *vacated on other grounds*, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), this Court should do so here. In that case, however, the D.C. Circuit reasoned that good cause existed to bypass notice and comment because “the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, [] present virtually identical issues, . . . the modifications made in the interim final rule are minor,” and the Supreme Court “obligat[ed] [HHS] to take action.” *Id.* By contrast, the issues presented in the New IFRs are not identical to prior regulations, they make significant changes in the law, and the Supreme Court did not require immediate action.

Order 13798 merely asks the Secretaries to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive care mandate.”

Executive Order 13798 § 3. Last, the Supreme Court has not imposed any deadline or called for urgent action either. In fact, the Supreme Court remanded the latest challenge to the Accommodation Process to give the parties “an opportunity to arrive at an approach going forward.” *Zubik*, 136 S. Ct. at 1560. Though Defendants cite many cases in which courts have pressured them to resolve uncertainty regarding the Contraceptive Mandate, none of those courts have imposed any actual deadlines for issuing regulations.

“The desire to eliminate uncertainty, by itself, cannot constitute good cause.” *Reynolds*, 710 F.3d at 510. Even if it could, the Agencies’ stated need to resolve uncertainty is undercut by the request, contained in the New IFRs, for post-issuance comments regarding “whether these regulations expanding the exemption should be made permanent or subject to modification.” *See* 82 Fed. Reg. at 47814-15; 82 Fed. Reg. at 47855-56. The request for comments particularly as to whether the New IFRs should be modified “implicitly suggests that the rule[s] will be reconsidered [and] means the level of uncertainty is, at best, unchanged. . . .” *Reynolds*, 710 F.3d at 511.

The Agencies stated in the New IFRs that the clarity offered by the expanded exemptions will decrease insurance costs; they hypothesize that groups with grandfathered health plans will wish to make changes to other components of their health plans in order to reduce costs, while still avoiding coverage for contraceptive services. *See* 82 Fed. Reg. 47815, 47856. Under the ACA, as long as grandfathered plans do not make any changes to their health coverage, they need not cover women’s preventive services. However, the New IFRs do not cite a single comment from an employer with a grandfathered plan which suggests that they will make

changes to health plans in light of the new agency interpretation.⁹ This is merely speculation, unsupported by the record.

Last, the Agencies asserted in the New IFRs that notice and comment was unnecessary because the Agencies considered past comments and requested post-issuance comments. The Agencies received multiple rounds of comments on the first set of interim final regulations in 2010, on the interim final regulations in 2011, on the proposed changes to the religious employer exemption in 2012 and 2013, on the modifications to the Accommodation Process in 2015, and on the RFI issued in July 2016. And the Agencies received over 54,000 public comments in response to the July 2016 RFI which sought ways to expand the Accommodation Process.

Defendants cite no case, and research has not disclosed any, finding that notice and comment is unnecessary where an agency has received ample commentary on its prior interpretations of the same law. In fact, the significance of this issue and the outpouring of public comments reflect the opposite: the overwhelming public interest demonstrates that notice and comment is critical. “The unnecessary prong of the exception . . . ‘is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.’” *Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001) (quoting *South Carolina v. Block*, 558 F. Supp. 1004, 1016 (D.S.C. 1983)). The significance of this litigation and the stakes involved, including

⁹ Indeed, a search of “grandfather” in the hundreds of thousands of pages of the Administrative Record filed with the Court does not reveal a single comment from a policy holder with a grandfathered health plan who sought to change their health coverage without risking their grandfathered status. During Oral Argument, the Court asked Defendants to find comments in the Administrative Record demonstrating that group health plans with grandfathered status sought to change their health plans without forgoing their grandfathered status. Defendants admitted that they “have identified no particular comments.” Tr. 206. Instead, Defendants looked outside of the Administrative Record and cited just two cases from 2012 in which the litigating parties wanted to retain their grandfathered health plans without covering contraceptive services. See *Roman Catholic Archdiocese of Atlanta v. Sebelius*, No. 1:12-CV-03489-WSD (N.D. Ga. 2014); *Diocese of Fort Wayne-S. Bend, Inc. v. Sebelius*, 988 F. Supp. 2d 958 (N.D. Ind. 2013). However, neither case shows that those entities sought to change their coverage in order to maintain their grandfathered status in 2017.

hundreds of lawsuits, and several appeals to the Supreme Court, belies the Agencies' purported reliance on the "unnecessary," good cause exception for notice and comment.

The Agencies also assert that their provision for a post-issuance commentary period does away with the need for pre-issuance notice and comment. They solicited comments for 60 days following the issuance of the New IFRs. *See* 82 Fed. Reg. at 47792. None of the cases that Defendants cite support that position. Instead, each of them stand for the proposition that an agency may seek post-issuance commentary only if and only *after* having shown that it had good cause to avoid notice and comment rulemaking, a situation that is not present here.¹⁰

There are several reasons why post-issuance comments do not comply with the notice and comment provisions of the APA. First, there is nothing in the APA that provides for post-issuance commentary. Second, participants are less likely to influence agency action in later stages of the agency decision-making process. This is especially the case where an agency has already issued interim rules which suggest that it has decided what federal policy should be. Post-issuance commentary does not ameliorate the need for notice and comment because by the time agencies issue interim rules, they are less likely to heed public input. *See United States v. Johnson*, 632 F.3d 912, 929 (5th Cir. 2011) ("[P]arties will have a greater opportunity for influencing agency decision making if they participate at an early stage."). Last, permitting post-issuance commentary *carte blanche* would write the notice and comment requirements out of the APA. *See id.*; *United States v. Gould*, 568 F.3d 459, 479 (4th Cir. 2009) ("[R]equesting post-promulgation comments makes a sham of the APA's rulemaking procedures."); *Paulsen v.*

¹⁰ In *Petry v. Block*, 737 F.2d 1193 (D.C. Cir. 1984), the D.C. Circuit held that the Department of Agriculture had good cause to avoid notice and comment rulemaking before it held that remand to the agency for further proceedings was unnecessary in light of a post-promulgation comment period. In *Republic Steel Corp v. Costle*, 621 F.2d 797 (6th Cir. 1980), another case cited by Defendants, the court countenanced post-promulgation comments *after* finding good cause for avoiding notice-and-comment. Prior to *Petry*, the D.C. Circuit has held that "[p]ermitting submission of views after the effective date is no substitute for the right of interested persons to make their views known to the agency." *State of N.J., Dep't of Env'tl. Prot. v. U.S. Env'tl. Prot. Agency*, 626 F.2d 1038, 1049 (D.C. Cir. 1980). *Petry* did not alter this rule.

Daniels, 413 F.3d 999, 1005 (9th Cir. 2005) (“[I]t is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later.”).

Grasping at straws, Defendants argue that even if a single justification “standing alone” does not constitute good cause, the “combined effect” of several factors justified the Agencies’ reliance on the good cause exception. An underlying assumption of this argument is that “[e]ach of the factors” provides at least some support for a finding that the Agencies had good cause to dispense with notice and comment. They do not. The three proffered factors to dispense with notice and comment offer no support. There was no deadline, much less an urgent one, to implement new rules. The New IFRs did not resolve any uncertainty and, as this case demonstrates, have not prevented ongoing litigation. And the blizzard of prior comments that the Agencies have received in past rounds of notice and comment rulemaking actually demonstrates that further comments are necessary given the public interest in this matter.

Certainly, an inquiry into whether an agency has “properly invoked ‘good cause’ proceeds case-by-case, sensitive to the totality of the factors at play.” *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984). And a court may consider the “combined effect” of multiple factors, which standing alone might not suffice to demonstrate “good cause.” See *Nat’l Women, Infants, & Children Grocers Ass’n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 107 (D.D.C. 2006). But Defendants’ arguments – even when viewed in their totality – provide no support for their proposition.¹¹

¹¹ Defendants’ failure to follow the APA’s notice and comment procedures was also not “harmless.” “[T]he ‘utter failure’ to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure.” *Reynolds*, 710 F.3d at 516. Rather, failure to abide by notice and comment rulemaking will only be found harmless in instances such as “when the administrative record demonstrates that the conclusion reached in the administrative rule was the only possible conclusion.” *Id.* at 518. This is not the case here. In addition, the Defendant Agencies have never sought comments on whether publicly traded companies should be allowed to opt out of the Contraceptive Mandate for sincerely held religious reasons, whether a “moral exemption” should apply to the Mandate for all closely held corporations, or whether to exempt entities from additional notice requirements before opting out of providing contraceptive coverage for their employees.

For the above reasons, it is likely that the Commonwealth will succeed on its claim that the Defendants did not follow proper procedures in issuing the New IFRs.

2. Substantive Provision

Under the APA, an administrative rule has no legal effect if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). Pursuant to this standard, it is likely that the Commonwealth will also succeed on its substantive challenge against the New IFRs because they contradict the text of the statute that they purport to interpret.

While an agency’s interpretation of a statute is generally accorded great deference, an interpretation that conflicts with the statute’s plain language is not. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *Chevron* and its progeny dictate the appropriate framework for analyzing whether an agency’s interpretation of a statute is permissible. First, a court must determine whether *Chevron* applies. *Chevron* deference is only appropriate in situations where Congress delegated rulemaking authority to a particular agency. *See Swallows Holding, Ltd. v. C.I.R.*, 515 F.3d 162, 168 (3d Cir. 2008). Next, “if the statutory language is clear and unambiguous, our inquiry ends and the plain meaning of the statute governs the action.” *Id.* at 170. While review of an agency’s interpretation under the “arbitrary and capricious” standard is decidedly narrow, an agency may not exercise its authority in a manner “inconsistent with the administrative structure that Congress enacted into law.” *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000). Last, “[i]f the statute is ambiguous on the point, we defer at step two to the agency’s interpretation so long as the construction is ‘a reasonable policy choice for the agency to make.’” *National Cable & Telecommunications Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron*, 467 U.S. at 845).

i. *Scope of HHS' Statutory Authority*

The takeaway is that *Chevron* deference does not extend to all agency action. In *United States v. Mead*, the Supreme Court explained that *Chevron* deference is only appropriate in situations where “Congress would expect the agency to be able to speak with the force of law.” 553 U.S. 218, 229 (2001). Here, Congress delegated authority to the HRSA, a division of HHS, to interpret the scope of “preventive care” as defined by the ACA. The problem is that HHS, the Department of Labor, and the Department of Treasury have, through the New IFRs, interpreted the statute in a manner inconsistent with its text.

It bears mentioning, at this time, the remarkable breadth of the New IFRs. They are the proverbial exception that swallows the rule. The New IFRs permit various entities, on the basis of sincerely held religious beliefs or moral convictions, to opt out of providing contraceptive coverage – coverage that, under the text of the ACA as interpreted by the HRSA in August 2011, is supposedly mandatory. The Religious Exemption Rule allows all non-profit and for-profit entities, whether closely held or publicly traded, to deny contraceptive coverage based on sincerely held religious beliefs. The Moral Exemption Rule allows any non-profit or for-profit organization that is not publicly traded to deny contraceptive coverage for its employees for any sincerely held moral conviction. This means that boards of closely held corporations can vote, or their executives can decide, to deny contraceptive coverage for the corporation’s women employees not just for religious reasons but also for any inchoate – albeit sincerely held – moral reason they can articulate. Who determines whether the expressed moral reason is sincere or not or, for that matter, whether it falls within the bounds of morality or is merely a preference choice, is not found within the terms of the Moral Exemption Rule. If one assumes that it is the Agency Defendants – or, indeed, any agency – then the Rule has conjured up a world where a

government entity is empowered to impose its own version of morality on each one of us. That cannot be right. It “run[s] afoul of this country’s vast history of legislative protections that single out and safeguard religious freedom *but not moral philosophy*.” *Real Alternatives, Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338, 350 (3d Cir. 2017) (emphasis added).

A simple hypothetical illustrates the insidious effect of the Moral Exemption Rule. It would allow an employer with a sincerely held moral conviction that women do not have a place in the workplace to simply stop providing contraceptive coverage. And, it may do so in an effort to impose its normative construct regarding a woman’s place in the world on its workforce, confident that it would find solid support for that decision in the Moral Exemption Rule. It is difficult to comprehend a rule that does more to undermine the Contraceptive Mandate or that intrudes more into the lives of women.

ii. The Text of the ACA

Before analyzing whether the Agencies had authority to create the Moral and Religious Exemption Rules, a brief aside to RFRA is necessary. RFRA provides that government action cannot “substantially burden” the exercise of religion. It states that laws passed after 1993 are subject to RFRA “unless such law explicitly excludes such application. . . .” 42 U.S.C. § 2000bb-3(b). The ACA was passed after 1993 and is thus subject to RFRA.¹² In *Hobby Lobby*, the Supreme Court held that the ACA does not explicitly exclude application of RFRA. *See Hobby Lobby*, 134 S. Ct. at 2775 n.30. It follows that any exception to the ACA required by RFRA is permissible. Bearing that in mind – and putting the issue of RFRA’s application to the New

¹² Congress enacted RFRA in 1993 in response to *Employment Div., Dep’t of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990), which held that “the Constitution does not require judges to engage in a case-by-case assessment of the religious burdens imposed by facially constitutional laws.” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2000).

IFRs on ice for now – the Court turns whether there is any language in the text of the ACA itself that would authorize the Agencies to issue the New IFRs – and concludes that there is not.

Congress created only a single exemption from the ACA’s statutory mandate to cover women’s preventive care and that is for “grandfathered health plans.” 42 U.S.C. § 18011(e). “When Congress provides exceptions in a statute . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth.” *United States v. Johnson*, 529 U.S. 53, 58 (2000). Given that there is no religious or moral exemption in the explicit text of the statute and there is one for grandfathered health plans, it cannot be assumed that Congress authorized the Agencies to create any additional exemptions.

The fact that the statute does not contain language specifically precluding the Agency Defendants from developing exemptions does not change this result. Even absent the maxim that the inclusion of an exemption in a statute must be interpreted to mean that Congress intended no additional exemptions, “[n]ot every silence is pregnant.” *Burns v. United States*, 501 U.S. 129, 136 (1991). Here, the mandatory language “shall” – found in the ACA’s requirement that covered health plans “shall cover . . . with respect to women, such additional preventive care” as provided for in the HRSA guidelines – indicates quite the opposite: no exemptions created by HHS are permissible (unless they are required by RFRA). “An inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent.” *Id.* That conclusion carries particular weight here, because, in 2012, Congress explicitly rejected an attempt to add to the ACA an exemption similar to the Moral and Religious Rules. See S. Amdt. 1520, 112th Cong. (2011-2012); see also *Brown & Williamson*, 529 U.S. at 147 (rejection of an agency’s interpretation by Congress is a factor courts consider when determining the meaning of a statute).

Nevertheless, Defendants argue that the textual structure of the ACA permits HHS to proscribe the “manner or reach of the coverage.” They compare two subsections of the ACA, both of which provide for no-cost preventive care and screenings. The first concerns children, the second, women. Defendants then focus on the language in each subsection which authorizes the agency to issue guidelines regarding that subsection.¹³ The subsection concerning children refers to “preventive care and screenings provided for in the comprehensive guidelines” from the HRSA. 42 U.S.C. § 300gg-13(a)(3). In contrast, the subsection concerning women refers to “such additional preventive care and screenings . . . **as** provided for in the comprehensive guidelines” from the HRSA. 42 U.S.C. § 300gg-13(a)(4) (emphasis added). Defendants note that the word “as” precedes the words “provided for in the comprehensive guidelines” in the women’s subsection, but not the children’s subsection. Proceeding from the statutory maxim that statutes should be interpreted, if possible, to give each word operative effect, *see Walters v. Metropolitan Educ. Enter., Inc.*, 519 U.S. 202, 209 (1997), Defendants conclude that the inclusion of the word “as” in the women’s subsection means that HRSA may determine not only the services covered by the ACA, but also the manner or reach of that coverage.

This extrapolation from the statutory inclusion of the word “as” must, pursuant to another principle of statutory interpretation, be analyzed by looking to the dictionary definition of the

¹³ The full text of the two subsections are as follows:

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for – [the following services] . . .

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings **provided** for in the comprehensive guidelines supported by the Health Resources and Services Administration;

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) **as provided for** in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

42 U.S.C. § 300gg-13(a)(3)–(4) (emphasis added).

word. See *Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 200 (3d Cir. 2015). The term “as” in this context is “[u]sed to indicate that something happens during the time when something else is taking place.” As, Oxford English Dictionary Online, June 2017. At the time Congress passed the ACA, the HRSA had already promulgated guidelines interpreting children’s preventive care. The HRSA had not promulgated such guidelines for women’s preventive care. Thus, the ACA requires coverage “provided for” in HRSA guidelines for children’s care and “as provided for” in HRSA guidelines for women’s care. Giving effect to the use of the word “as” leads to the conclusion that the “as” is used in anticipation of HRSA issuing such guidelines and not to the conclusion that the ACA implicitly provides the Agencies with the authority to create non-statutory exemptions.

In sum, the ACA contains no statutory language allowing the Agencies to create such sweeping exemptions to the requirements to cover “preventive services,” which, as interpreted by those same agencies, include mandatory no-cost coverage of contraceptive services. Nor does any rule of statutory construction warrant these exemptions.

iii. Religious Freedom and Restoration Act

The Agency Defendants also argue that they were compelled by RFRA to create the Religious Exemption Rule. It should be noted at the outset that they specifically do not propound this argument with respect to the Moral Exemption Rule. Thus, since the text of the statute is clear that non-statutory exemptions are not permitted, and Defendants admit that RFRA provides no support for it, the Moral Exemption Rule is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” under the APA. 5 U.S.C. § 706(2)(A). As set forth below, upon consideration of Defendants’ argument regarding RFRA, the Court reaches the same conclusion with respect to the Religious Exemption Rule.

a. RFRA Does Not Support the Agencies’ Interpretation

Turning now – finally – to the RFRA issue. One of the reasons the Agencies gave for issuing the New IFRs is that the Accommodation Process imposes a substantial burden on the exercise of religion. The Accommodation Process, as discussed earlier, allows religious objectors to notify their healthcare administrator of their religious objection, and the administrator would then have to provide the legally required contraceptive services directly to women covered under the employer’s plan. The Agencies’ stated belief that the Accommodation Process now imposes a substantial burden on the exercise of religion led them to create the broader exemptions set forth in the New IFRs. *See* 82 Fed. Reg. 47800. But their view that the Accommodation Process imposes a substantial burden on the exercise of religion has been specifically rejected by the Third Circuit, which found exactly to the contrary in *Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015), *vacated and remanded on other grounds sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016).¹⁴ There, the Third Circuit decisively and clearly held that the Accommodation Process does **not** impose a “substantial burden” under RFRA. And, in *Real Alternatives*, it reaffirmed that the Accommodation Process does not impose a substantial burden on religious exercise. *See* 867 F.3d at 356 n.18 (“[W]e continue to believe . . . that the regulation at issue . . . did not impose a substantial burden.”). Therefore, the Agency Defendants’ interpretation of RFRA – that issuance of the Religious Exemption Rule is proper because the “substantial burden” that the Accommodation Process places on a person’s exercise of religion – is erroneous as a matter of

¹⁴ While *Zubik* subsequently vacated *Geneva College*, it did so on other grounds. The Supreme Court expressly stated that “the Court does not decide whether petitioners’ religious exercise has been substantially burdened. . . .” *Zubik*, 136 S. Ct. at 1561.

law. *See Williams v. Meltzler*, 132 F.3d 937, 946 (3d Cir. 1997) (on questions of law, administrative judgment is subject to plenary judicial review).¹⁵

Defendants make much of having issued exemptions under prior regulations. For example, the Original Religious Exemption allowed churches and their integrated auxiliaries to opt out of the Contraceptive Mandate. However, the Supreme Court has held that exemptions like the one for churches and their integrated auxiliaries are required under RFRA and the First Amendment’s free exercise protections. *See Hobby Lobby*, 134 S. Ct. at 2794 & n.14 (citing cases requiring exemptions for certain religious organizations). In *Real Alternatives*, the Third Circuit confirmed that the Original Religious Exemption was plainly required by federal and constitutional law in holding that exemptions and accommodations “may be extended to houses of worship and religious denominations without applying to all nonprofit entities in order to ‘alleviate significant governmental interference with the ability of religious organizations to define and carry out their religious missions.’” 867 F.3d at 352 (quoting *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327 (1987)). In contrast, the New IFRs are not required under RFRA because the Third Circuit – twice now – has foreclosed the Agencies’ legal conclusion that the Accommodation Process imposes a substantial burden.

¹⁵ Although the Agencies asserted in the New IFRs that “[t]he Departments believe that agencies charged with administering a statute or associated regulations or guidance that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining how to avoid the imposition of such burden,” 82 Fed. Reg. 47800, Defendants now suggest otherwise. Defendants concede that the Agencies’ interpretations of RFRA are not entitled to deference under RFRA. *See* Tr. 45 (“We are not arguing that the Agencies are entitled to *Chevron* deference writ large.”). In any event, the Agencies’ opinion is foreclosed by *Snoqualmie Indian Tribe v. F.E.R.C.*, 545 F.3d 1207 (9th Cir. 2008), in which the Ninth Circuit held that an agency’s interpretation of RFRA is not accorded deference. They do argue that deference is appropriate for the Agencies’ opinion that the Contraceptive Mandate does not serve a compelling interest as applied to religious objectors. However, this is beside the point because this question only becomes relevant if a court finds, first, that a government action imposes a substantial burden on the exercise of religion. As noted, the Accommodation Process does not impose a substantial burden on the exercise of religion so the Court need not conduct the compelling state interest analysis.

For these reasons, the Commonwealth has shown a likelihood of success on the merits of its APA claim that the New IFRs are arbitrary, capricious, and contrary to established law.

b. Irreparable Harm

As explained earlier, the second factor to consider in deciding the Commonwealth's motion is whether it has demonstrated that it is likely to suffer irreparable harm in the absence of a preliminary injunction. "Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with the characterization of injunctive relief as 'an extraordinary remedy' that may be awarded only upon a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 21& 22 ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction.").

The Commonwealth asserts that it will suffer two harms in the absence of an injunction: First, significant damage to the Commonwealth's fiscal integrity; and second, harm to the health, safety, and wellness of the Commonwealth's female residents.

The Commonwealth offered the testimony of Doctors Carol Weisman, Samantha Butts, and Cynthia Chuang, as well as several declarations and exhibits to support its allegation of irreparable harm. From this testimony and from other evidence and affidavits in the record, the Court finds that it is likely that the New IFRs will result in direct and irreparable harm to the Commonwealth's fiscal integrity: The Commonwealth will become obligated to shoulder much of the burden of providing contraceptive services to those women who lose it because their health plans will opt out of coverage. See Steinberg Decl. ¶¶ 27-29; Medelsohn Decl. ¶ 15. Such women will seek contraceptive services elsewhere and, as Defendants noted in issuing the New IFRs, may turn to "multiple Federal, State, and local programs that provide free or

subsidized contraceptives for low-income women” as alternative coverage. *See* 82 Fed. Reg. 47813, 47850. These programs in the Commonwealth include Medicaid, called “Medical Assistance,” which relies on funding from both the State and federal governments; Family Planning Services Program; and the Commonwealth’s network of clinics funded under the Title X grant program. *See* Allen Decl. ¶¶ 3-18; Steinberg Decl. ¶ 16. Indeed, Dr. Chuang testified that she counsels patients without coverage for contraceptive services to seek coverage from Medicaid. Tr. 177-78. As women in Pennsylvania lose contraceptive coverage through their health insurance plans and turn to State programs, it is likely that the Commonwealth will bear the added financial burden occasioned by the increase in women who need contraceptive care coverage. *See* Decl. of Seth A. Mendelsohn ¶ 15; Allen Decl. ¶ 23.

Of course, “loss of money” is generally insufficient to merit a preliminary injunction because “monetary damages . . . are capable of ascertainment and award at final judgment. . . .” *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989). Here, however, the Commonwealth will not be able to recover any economic damages traceable to the implementation of the New IFRs. This is because a party – including the Commonwealth – may not seek monetary damages from the federal government. *See* 5 U.S.C. § 702 (providing that the federal government is immune from a suit for money damages). Therefore, if the New IFRs are ultimately struck down, the Commonwealth will be unable to recoup the money it expends on contraceptive care in the interim. In such circumstances, a preliminary injunction is appropriate. *See, e.g., N.J. Retail Merchants*, 669 F.3d at 388 (holding that a preliminary injunction is appropriate where a movant could not recover damages from a State due to sovereign immunity).

The Commonwealth’s harm is not merely speculative; it is actual and imminent. *See Adams v. Freedom Forge Corp.*, 204 F.3d 475, 488 (3d Cir. 2000). The New IFRs estimate that

at least 31,700 women will lose contraceptive coverage under the New Rules – and, as Plaintiff and amici persuasively argue, there are reasons to believe the number is significantly higher. See 82 Fed. Reg. 47,821. Thus, the only serious disagreement is not whether the Commonwealth will be harmed, but *how much* the Commonwealth will be harmed. Though Defendants argue that the Commonwealth has not identified any individual who has lost coverage already, there is no need to wait for the axe to fall before an injunction is appropriate, particularly where Defendants have estimated that it is about to fall on tens of thousands of women.¹⁶ And the financial burden is impending. The Commonwealth anticipates that on January 1, 2018, when open enrollment begins for health plans regulated by ERISA, some health plans will remove no-cost contraceptive services pursuant to the New IFRs, and it is likely that Pennsylvanian women will seek contraceptive services through services funded by the State fisc.

While the legal harm to the integrity of the State fisc is important to obtain a preliminary injunction, of parallel importance is the significant harm to the Commonwealth's interest in protecting the health, safety, and well-being of its citizens. See *In re Oxycontin Antitrust Litig.*, 821 F. Supp. 2d 591, 601 (S.D.N.Y. 2011) (citing *Alfred L. Snapp*, 458 U.S. at 601-02). The potential harm faced by Pennsylvanian women and across the nation is enormous and irreversible. As employers take advantage of the New IFRs, access to no-cost contraceptive services for many women will be severely curtailed.

The Commonwealth's concern is that absent available cost-effective contraception, women will either forego contraception entirely or choose cheaper but less effective methods – individual choices which will result in an increase in unintended pregnancies. That, in turn, will inflict economic harm on the Commonwealth because unintended pregnancies are more likely to

¹⁶ Since the New IFRs eliminate requirements to notify HHS of any decision to opt out, it is nearly impossible to know whether employers have already availed themselves of the New IFRs.

impose additional costs on Pennsylvania's State-funded health programs. *See* Steinberg Decl., ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

The record evidence in support of this position is compelling. Contraceptives are, without question, effective at preventing unintended pregnancies. *See* Institute Report at 106. Eighty five percent of women who do not use any form of contraceptive services and who do not want to become pregnant, become pregnant in one year. *See id.* Those women who do use contraception are far less likely to have an unplanned pregnancy. *Id.* But, even for those who do use contraception, there is some chance of an unplanned pregnancy higher or lower depending upon the chosen contraceptive method. For example, a pamphlet issued by the Centers for Disease Control entitled "Effectiveness of Family Planning Methods" shows there are 6 to 12 pregnancies per 100 women who are on the contraceptive pill in any given year. *See* Exh. 17. Yet, for those who have an Intrauterine Device ("IUD") implanted there is less than one pregnancy per 100 women per year. *Id.* Thus, it is clear that an IUD is more effective than the pill at preventing unintended pregnancy. A reasonable conclusion from that is women, all else being equal, would make the contraceptive choice of an IUD rather than the pill. But, three doctors testified that an IUD can be cost-prohibitive for many women because it has higher upfront costs than the contraceptive pill. Tr. 90; 132-33; 176-78. Dr. Butts testified that, prior to the implementation of the ACA's Contraceptive Mandate, it was common for her patients not to have prescribed IUDs implanted, but since the Contraceptive Mandate, use of IUDs has increased dramatically. Tr. 132; 153. She testified that after the Mandate went into effect, making no-cost contraception services available to all women, the number of her patients who

declined an IUD dropped significantly. *Id.* Meanwhile, she recorded a five-fold increase in the number of IUDs she inserted in the course of her medical practice. Tr. 153.

Dr. Chuang and Dr. Weisman also testified about a study (“MyNewOptions Study”) they and others conducted between 2014 and 2016 of more than 900 Pennsylvanian women who were actively avoiding pregnancy. Reviewing insurance claims data, they found that the number of women using IUDs and other implants – contraceptive methods that carry the highest up-front costs but are the most effective – doubled in two years after the Contraceptive Mandate took effect. Tr. 178-87. Meanwhile, the number of women who did not use contraceptive services decreased by roughly 50% in the two years following the Mandate’s effect.¹⁷ *Id.* Doctors Chuang, Weisman, and Butts all attributed these changes to the effect of the Contraceptive Mandate, Tr. 90; 134; 187, and concluded that with the reduction in no-cost contraceptive insurance that will result from employer utilization of the New IFRs, more women will lose no-cost contraceptive coverage and the cost of their contraceptive services, to them, will rise. *See* Tr. 94. Thus, women will likely forgo contraceptive services or seek out less expensive and less effective types of contraceptive services in the absence of no-cost insurance coverage. *See id.*; Weisman Decl. ¶ 47; Chuang Decl. ¶¶ 36-39. Indeed, women cite cost as a significant factor in determining whether to purchase contraceptive services and which contraceptive services to use. *See* Adam Sonfield, *What is at Stake with the Federal Contraceptive Coverage Guarantee?* 20 Guttmacher Policy Review 8, 9 (2017).

¹⁷ Defendants cited a study from the Guttmacher Institute which found no changes in contraceptive use patterns among sexually active women. *See* Bearak, J.M. and Jones, R.K., “Did Contraceptive Use Patterns Change after the Affordable Care Act? A descriptive analysis,” 27 *Women’s Health Issues* 316 (Guttmacher Inst. May-June 2017). Unlike the MyNewOptions Study presented by Plaintiff, the Guttmacher study used survey data, which is less reliable than the claims data used in the MyNewOptions study. And, unlike the MyNewOptions study, the Guttmacher study did not focus on Pennsylvania where the rate of unintended pregnancy is significantly greater than the national average, and which is the focus of the preliminary injunction.

The real life consequences, as amici point out, are significant: roughly 41% of unintended pregnancies in America are caused by inconsistent use of contraceptives.¹⁸ These problems are particularly acute in Pennsylvania, where the rate of unintended pregnancy is 53%, significantly higher than the national average. Tr. 152. The negative effects of even a short period of decreased access to no-cost contraceptive services are irreversible.

c. Balance of the Equities

The third factor that the Commonwealth must show is that the balance of the equities tips in favor of granting a preliminary injunction. “Balancing the equities” is jurisprudential “jargon for choosing between conflicting public interests.” *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1943) (Frankfurter, J., concurring). Here, Congress has already struck the balance: Its passage of the Women’s Health Amendment was to bridge the significant gender gap in healthcare costs between men and women. Senator Feinstein explained that “[w]omen of childbearing age spend 68 percent more in out-of-pocket health care costs than men.” 155 Cong. Rec. 29302. And part of this problem stems from unintended pregnancies – an issue faced only by women. Senator Durbin explained that the purpose of the Women’s Health Amendment was to “expand health insurance coverage to the vast majority of [the 17 million women of reproductive age in the United States who are uninsured and] . . . reduce unintended pregnancies.” *Id.* at 26768. Where, as here, “Congress itself has struck the balance, has defined

¹⁸ The Contraceptive Mandate also affects women’s health in other contexts as well. The Institute’s Report, which recommended no-cost contraceptive coverage under the ACA, explained that contraceptive services are used to treat menstrual disorders, acne, hirsutism, and pelvic pain, in addition to assisting family planning and birth spacing. See Institute Report at 107. Contraceptive services are essential for women who face high-risk pregnancies or those for whom pregnancy may lead to significant complications. Even a short period of interrupted coverage will lead to irreparable harm because, as the Institute Report notes, women face severe complications, including death, from high-risk pregnancy. Dr. Butts also testified that decreased access to contraceptives will “increase pain and suffering for women who have [disorders such as pelvic pain and other medical conditions] . . . and to the extent that some of those unintended pregnancies are in women with very serious medical disorders for whom pregnancy may be contraindicated [it] can increase risks in a life-threatening way.” Tr. 140.

the weight to be given the competing interests, a court of equity is not justified in ignoring that pronouncement under the guise of exercising equitable discretion.” *Youngstown Sheet*, 343 U.S. at 609-10.

Here, given the Commonwealth’s clear interest in securing the health and well-being of its women residents and containing its costs for contraceptive services, the balance of the equities heavily weighs in its favor. Defendants’ assertion that there is “inherent harm to an agency in preventing it from implementing regulations that Congress found to be in the public interest to direct that agency to develop” does not change that balance. Defendants will not be prejudiced by a preliminary injunction. If the New IFRs were issued in violation of applicable law, they will have suffered no harm. If Defendants ultimately prevail, then a preliminary injunction will have merely delayed their preferred regulatory outcome.

d. Public Interest

When considering the public interest, a court is limited to evaluating “how such interest and conveniences are affected by the selection of an injunction over other enforcement mechanisms.” *United States v. Oakland Cannabis Buyers’ Co-op.*, 532 U.S. 483, 498 (2001). Here, a preliminary injunction is unquestionably in the public interest because it maintains the status quo pending the outcome of a trial on the merits. The New IFRs permit any entity to opt out of coverage within 30 to 60 days’ notice to plan members. A trial on the merits will not conclude in that short span. A preliminary injunction will maintain the status quo: those with exemptions or accommodations prior to October 6, 2017 will maintain their status, those with injunctions preventing enforcement of the Contraceptive Mandate will maintain their injunctions, but those with coverage will maintain their coverage as well.

IV. Conclusion

Plaintiff, the Commonwealth of Pennsylvania, has demonstrated that it has met all four factors necessary to obtain a preliminary injunction. In this case, the Commonwealth is likely to succeed on the merits of its two APA claims; the Commonwealth is likely to suffer serious and irreparable harm in the absence of a preliminary injunction; the balance of the equities tips in favor of granting an injunction, and the public interest favors granting it as well. After weighing these four factors, as stated above, the Court concludes that a preliminary injunction is warranted. The Commonwealth's Motion for Preliminary Injunction will be granted and Defendants shall be enjoined from enforcing the New IFRs.

An appropriate order follows.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

December 15, 2017

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**COMMONWEALTH OF
PENNSYLVANIA ,
Plaintiff,**

v.

**DONALD J. TRUMP, DONALD J.
WRIGHT, UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES, STEVEN T.
MNUCHIN, UNITED STATES
DEPARTMENT OF THE TREASURY,
RENE ALEXANDER ACOSTA AND THE
UNITED STATES DEPARTMENT OF
LABOR,
Defendants.**

CIVIL ACTION

NO. 17-4540

ORDER

AND NOW, this 15th day of December, 2017, upon consideration of the Commonwealth of Pennsylvania's Motion for a Preliminary Injunction (ECF No. 9), Defendants' Response thereto (ECF No. 15), Plaintiff's Reply in Support thereof (ECF No. 30), the Administrative Record (ECF Nos. 23 & 47), Briefs of the Amici Curiae (ECF Nos. 34, 35 & 36), and following a Hearing on Plaintiff's Motion on December 14, 2017, **IT IS HEREBY ORDERED** that the Motion is **GRANTED**.

It is **FURTHER ORDERED** that Defendants Eric D. Hargan, as Acting Secretary of the United States Department of Health and Human Services (substituted pursuant to Rule 25(d) of the Federal Rules of Civil Procedure); the United States Department of Health and Human Services; Steven T. Mnuchin, as Secretary of the United States Department of Treasury; the United States Department of Treasury, Rene Alexander Acosta, as Secretary of the United States

Department of Labor; and the United States Department of Labor;¹ and their officers, agents, servants, employees, attorneys, designees, and subordinates, as well as any person acting in concert or participation with them, are hereby **ENJOINED** from enforcing the following Interim Final Rules pending further order of this Court:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act described at 82 Fed. Reg. 47792; and
2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act described at 82 Fed. Reg. 47838.

The Court has considered the issue of security pursuant to Rule 65(c) of the Federal Rules of Civil Procedure and determines that Defendants will not suffer any financial loss that warrants the need for the Plaintiff to post security. After considering the facts and circumstances of this case, the Court finds that security is unnecessary and exercises its discretion not to require the posting of security in this situation.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

¹ In light of the constitutional concerns associated with enjoining the President of the United States for a claim under the Administrative Procedure Act, this injunction does not apply to the President. *See Franklin v. Massachusetts*, 505 U.S. 788, 801 (1992).

**THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

V.

Civil Action No. 2:17-cv-04540 (WB)

DONALD J. TRUMP, in his official capacity as President of the United States; ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, in his official capacity as Secretary of the Treasury; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, in his official capacity as Secretary of Labor; and UNITED STATES DEPARTMENT OF LABOR, *et al.*,

Defendants.

NOTICE OF APPEAL

PLEASE TAKE NOTICE that Federal Defendants Alex M. Azar II, Secretary of the United States Department of Health and Human Services, R. Alexander Acosta, Secretary of the United States Department of Labor, Steven Mnuchin, Secretary of the United States Department of Treasury, the U.S. Department of Health and Human Services, the United States Department of Labor, and the United States Department of the Treasury hereby appeal to the United States Court of Appeals for the Third Circuit from the Court's preliminary injunction order [ECF No. 135] and opinion [ECF No. 136], which were both issued on January 14, 2019.

DATED: January 23, 2019

Respectfully submitted,

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Assistant Director, Federal Programs Branch

/s/ Justin M. Sandberg

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CERTIFICATE OF SERVICE

I hereby certify that, on January 23, 2019, a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

DATED this 23d day of January, 2019.

s/ Justin M. Sandberg
JUSTIN M. SANDBERG
Senior Trial Counsel
Unite States Department of Justice

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA
and STATE OF NEW JERSEY,

Plaintiffs,

v.

DONALD J. TRUMP, *et al.*

Defendants,

LITTLE SISTERS OF THE POOR SAINTS
PETER AND PAUL HOME,

Defendant-Intervenor.

Civil No. 2:17-CV-04540-WB

**DEFENDANT-INTERVENOR'S
NOTICE OF APPEAL**

NOTICE OF APPEAL

Notice is hereby given that the Little Sisters of the Poor Saints Peter and Paul Home, Defendant-Intervenor in the above-captioned case, hereby appeals to the United States Court of Appeals for the Third Circuit from the Court's Order and Opinion (ECF Nos. 135 and 136) granting Plaintiffs' Second Motion for a Preliminary Injunction, entered on January 14, 2019.

Dated: January 14, 2019

Respectfully submitted,

/s/ Mark Rienzi

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Counsel for Defendant-Intervenor

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

Dated: January 14, 2019

/s/ Mark Rienzi

Mark Rienzi

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**COMMONWEALTH OF
PENNSYLVANIA AND STATE OF NEW
JERSEY,**

CIVIL ACTION

Plaintiffs,

NO. 17-4540

v.

**DONALD J. TRUMP, ALEX M. AZAR II,
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
STEVEN T. MNUCHIN, UNITED
STATES DEPARTMENT OF THE
TREASURY, RENE ALEXANDER
ACOSTA, THE UNITED STATES
DEPARTMENT OF LABOR, AND THE
UNITED STATES OF AMERICA,**

Defendants,

**LITTLE SISTERS OF THE POOR
SAINTS PETER AND PAUL HOME,**

Defendant-Intervenor.

OPINION

Table of Contents

I.	Background	3
A.	Contraceptive Mandate	3
B.	Regulatory Action to Accommodate Religious Objections.....	4
C.	<i>Hobby Lobby & Wheaton College</i>	6
D.	Regulatory Response to <i>Hobby Lobby & Wheaton College</i>	7
E.	<i>Zubik</i> Remand & Impasse	8
F.	2017 IFRs & First Preliminary Injunction	9
G.	2018 Final Rules & Second Motion for Preliminary Injunction.....	12
II.	Analysis.....	13
A.	Standing	13
1.	Special Solitude.....	15

2. Article III Standing	18
B. Venue	20
C. Preliminary Injunction	23
1. Legal Standard	23
2. Likelihood of Success on the Merits.....	24
a. APA Procedural Claim	24
i. Inadequate Response to Comments	25
ii. IFRs Taint the Final Rules	27
b. APA Substantive Claim	34
i. The ACA.....	35
ii. RFRA	42
3. Irreparable Harm	52
4. Balance of the Equities	55
5. Public Interest	56
D. Remedy	57

Plaintiffs, the Commonwealth of Pennsylvania and the State of New Jersey (collectively “the States”), have sued the United States of America, President Donald J. Trump, the United States Secretary of Health and Human Services Alex M. Azar II, the United States Secretary of the Treasury Steven T. Mnuchin, and the United States Secretary of Labor Rene Alexander Acosta in their official capacities, as well as each of their agencies (collectively “Defendants”), seeking to enjoin enforcement of two Final Rules that grant exemptions to the Affordable Care Act’s requirement that health plans cover women’s preventive services. The Final Rules “finalize” two Interim Final Rules, which Defendants issued in October 2017 and which this Court enjoined soon thereafter, *see Pennsylvania v. Trump*, 281 F. Supp.3d 553, 585 (E.D. Pa. 2017). On November 15, 2018, while their appeal of that preliminary injunction was pending, Defendants promulgated the Final Rules currently before the Court. The States move to enjoin enforcement of the Final Rules arguing that, like the IFRs before them, the Final Rules violate a variety of constitutional and statutory provisions. For the reasons set forth below, Plaintiffs’

Second Motion for a Preliminary Injunction shall be granted.

I. Background¹

Although the relevant factual and procedural history of this dispute has been laid out at length before, *see id.* at 560-64, that background information is recounted here for the sake of clarity.

A. Contraceptive Mandate

In March 2010, Congress enacted the Affordable Care Act. *See* Patient Protection and Affordable Care Act (“ACA”), Pub L. No. 111-148, 124 Stat. 119 (2010). A provision of the ACA, the Women’s Health Amendment, mandated that insurance providers cover preventive health services and screenings for women without cost-sharing responsibilities. Specifically, the Women’s Health Amendment requires that “[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [“HRSA”] for purpose of this paragraph.” 42 U.S.C. § 300gg-13(a)(4). This requirement applies to all health insurers offering individual or group insurance, as well as all group health plans, with an exception for certain “grandfathered” plans. 42 U.S.C. § 18011 (exempting “grandfathered” plans); *see also* 29 C.F.R. § 2590.715-1251 (2010).

Rather than enumerate the preventive services to be covered by the mandate, Congress delegated that decision to HRSA, which is an agency of Defendant Department of Health and Human Services (“HHS”). HRSA, in turn, commissioned the then-named Institute of Medicine

¹ The factual statements found here and elsewhere in the opinion constitute this Court’s findings of fact, as required under Rule 52(a) of the Federal Rules of Civil Procedure, regardless of any heading or lack thereof.

(“the Institute”), to convene a panel of experts to provide recommendations.² On July 19, 2011, the Institute issued its report, recommending that the ACA cover “the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.” Institute of Medicine, *Clinical Prevention Services for Women: Closing the Gaps*, at 109-10 (2011).

On August 1, 2011, HRSA issued its preventive care guidelines (“2011 Guidelines”), which adopted the Institute’s recommendations. See HRSA, *Women’s Preventive Services Guidelines*, available at <https://www.hrsa.gov/womens-guidelines/index.html>.³ The 2011 Guidelines hewed to the Institute’s report, defining preventive care to include all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling.” *Id.* Under the Women’s Health Amendment, “non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing.” *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). Thus these interlocking statutory and regulatory requirements created the so-called “Contraceptive Mandate.”

B. Regulatory Action to Accommodate Religious Objections

At the same time, and based on “considerable feedback,” HHS, the Department of Labor, and the Department of the Treasury (collectively “the Agencies”) found it was “appropriate that HRSA, in issuing [the 2011] Guidelines, take[] into account the effect on the religious beliefs of

² The Institute, renamed the National Academy of Medicine in 2015, is an arm of the National Academy of Sciences, an organization that Congress established for the explicit purpose of furnishing advice to the federal government. See *Pub. Citizen v. Dep’t of Justice*, 491 U.S. 440, 460 n.11 (1989).

³ The Guidelines were updated in 2016 but continue to define “preventive services” to include contraceptive services and counseling. See *Updating the HRSA-Supported Women’s Preventive Services Guidelines*, 81 Fed. Reg. 95,148, 95,149 (Dec. 27, 2016).

certain religious employers if coverage of contraceptive services were required.” *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011). The Agencies therefore provided HRSA with “additional discretion to exempt certain religious employers from the Guidelines where contraceptive services are concerned.” *Id.*

On August 1, 2011, the Agencies promulgated an interim final rule exempting certain religious employers from providing contraceptive services. *Id.* Under the exemption, a “religious employer” could be exempt from the Contraceptive Mandate only if it: (1) had the inculcation of religious values as its purpose; (2) primarily employed people who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a church, its integrated auxiliary, or a convention or association of a church exempt from taxation under the Internal Revenue Code. *Id.* On February 15, 2012, after considering more than 200,000 responses to this interim final rule, the Agencies issued a final rule adopting the “religious employer” definition. 77 Fed. Reg. at 8,725.

On March 21, 2012, the Agencies issued a notice of proposed rulemaking requesting comments on “alternative ways of providing contraceptive coverage without cost sharing in order to accommodate non-exempt, non-profit religious organizations with religious objections to such coverage.” *Certain Preventive Services Under the Affordable Care Act*, 77 Fed. Reg. 16,501, 16,503 (March 21, 2012). After receiving and considering over 400,000 comments, the Agencies issued their final rule on July 2, 2013. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 39,870, 39,871 (July 2, 2013). The final rule had two noteworthy effects.

First, the rule “eliminate[ed] the first three prongs and clarif[ied] the fourth prong of the

definition” of “religious employer” adopted in 2012. *Id.* at 39,874. Under the new definition, an entity qualified as a “religious employer” so long as it “is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii)” of the Internal Revenue Code, which applies to “churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.” *Id.*

Second, the rule established an accommodation for “eligible organizations” with religious objections to providing contraceptive coverage. *Id.* The rule defined an “eligible organization” as one that: “(1) [o]pposes providing coverage for some or all of the contraceptive services required to be covered . . . ; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria.” *Id.* An eligible organization was required to provide a copy of the self-certification to its insurance provider, which then would provide contraceptive coverage to the organization’s employees. *Id.* at 39,876. Thus an eligible organization that self-certified as such was “not required to contract, arrange, pay, or refer for contraceptive coverage,” but its “plan participants and beneficiaries [would] still benefit from separate payments for contraceptive services without cost sharing or other charge,” consistent with the Contraceptive Mandate. *Id.* at 39,874.

C. Hobby Lobby & Wheaton College

Meanwhile, a host of legal challenges to the Contraceptive Mandate progressed through the federal courts, several of which eventually reached the Supreme Court.

On June 30, 2014, the Supreme Court issued its opinion in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). There, three closely-held corporations challenged the Contraceptive Mandate. *Id.* at 2765. The Supreme Court held that the application of the Contraceptive Mandate to the organizations violated the Religious Freedom Restoration Act, 42

U.S.C. § 2000bb-1 (“RFRA”), because the Contraceptive Mandate imposed a substantial burden on the plaintiffs’ religious exercise and was not the “least restrictive means” of guaranteeing cost-free access to certain methods of contraception. 134 S. Ct. at 2780-82. The Supreme Court found the existence of the accommodation supported its conclusion that the Contraceptive Mandate was not the “least restrictive means”: “HHS itself has demonstrated that it has at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs. . . . HHS has already established an accommodation for nonprofit organizations with religious objections.” *Id.* at 2782. Nevertheless, the Supreme Court refrained from deciding “whether an approach of this type”—meaning the accommodation—“complies with RFRA for purposes of all religious claims.” *Id.*

A few days later, the Supreme Court issued an order in a related case, *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014) (per curiam). There, Wheaton College, an organization eligible for the accommodation, sought an injunction “on the theory that its filing of a self-certification form [would] make it complicit in the provision of contraceptives by triggering the obligation for someone else to provide the services to which it objects.” *Id.* at 2808 (Sotomayor, J., dissenting). The Supreme Court granted the injunction, permitting Wheaton College to “inform[] the Secretary of Health and Human Services in writing that it . . . has religious objections to providing coverage for contraceptive services”—that is, the college did not have to “use the [self-certification] form prescribed by the [g]overnment.” *Id.* at 2807 (per curiam). The Supreme Court warned, however, that the “order should not be construed as an expression of the Court’s views on the merits.” *Id.*

D. Regulatory Response to *Hobby Lobby* & *Wheaton College*

The Agencies responded to *Hobby Lobby* and *Wheaton College* by issuing a notice of

proposed rulemaking “amend[ing] the definition of an eligible organization [for purposes of the accommodation] to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered.” *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,118, 51,121 (Aug. 27, 2014). Furthermore, the Agencies issued an interim final rule, effective immediately, that provided “an alternative process” for eligible organizations to self-certify “consistent with the Wheaton order.” *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,092, 51,094-96 (Aug. 27, 2014). On July 14, 2015, the Agencies issued a rule that finalized the extended accommodation and alternative self-certification process. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 80 Fed. Reg. 41,318, 41,323-24 (July 14, 2015).

E. *Zubik* Remand & Impasse

On May 16, 2016, the Supreme Court issued its third decision regarding the Contraceptive Mandate. In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), several organizations eligible for the accommodation challenged the self-certification process on the grounds that the requirement to submit a notice either to their insurer or the federal government violated RFRA. *Id.* at 1559. The Supreme Court declined to reach the merits of the dispute, requesting instead “supplemental briefing from the parties addressing ‘whether contraceptive coverage could be provided to petitioners’ employees, through petitioners’ insurance companies, without any such notice from petitioners.’” *Id.* at 1559-60. After the parties agreed that “such an option [was] feasible,” the Supreme Court remanded to afford them “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans receive full and equal health

coverage, including contraceptive coverage.” *Id.* at 1560 (internal quotation marks omitted). Again, though, the Court “express[ed] no view on the merits of the cases,” and refrained from “decid[ing] whether petitioners’ religious exercise has been substantially burdened, whether the [g]overnment has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest.” *Id.*

Following the remand the Agencies reached an impasse. After reviewing over 50,000 comments submitted in response to a request for information, the Agencies concluded that there was “no feasible approach . . . at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” Dep’t of Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4 (2016), available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf>.

F. 2017 IFRs & First Preliminary Injunction

On May 4, 2017, President Donald Trump issued an Executive Order entitled “Promoting Free Speech and Religious Liberty.” Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017). The Order directed the Agencies to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [the Women’s Health Amendment].” *Id.* at § 3.

On October 6, 2017, aiming to be “[c]onsistent with the President’s Executive Order and the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs,” *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792, 47,799 (Oct. 13, 2017), the Agencies issued two, new IFRs, referred to as the Religious Exemption IFR and the Moral

Exemption IFR. *See id.* at 47,792 (“Religious Exemption IFR”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838, 47,838 (Oct. 13, 2017) (“Moral Exemption IFR”) (collectively, “the IFRs”).

The IFRs made several significant changes to the prior exemption and accommodation framework.⁴ For one, the Moral Exemption IFR made the exemption available to “additional entities”—including for-profit entities that are not publicly traded—that object based on “sincerely held *moral* convictions,” without any need for the objection to be grounded in a *religious* objection to contraception. 82 Fed. Reg. at 47,862 (emphasis added). Second, the Religious Exemption IFR significantly broadened the scope of the religious exemption to encompass any non-profit or for-profit entity, whether closely held or publicly traded. 82 Fed. Reg. at 47,810. Third, the IFRs “likewise” expanded eligibility for the accommodation, allowing entities with sincerely held religious or moral convictions to take advantage of the accommodation process. 82 Fed. Reg. at 47,813; 82 Fed. Reg. at 47,849. Fourth, the IFRs made “the accommodation process optional for eligible organizations,” such that entities taking advantage of the accommodation would “not be required to comply with a self-certification process.” 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850. Finally, the IFRs eliminated the requirement to provide notice of an intent to take advantage of the exemption or accommodation—entities that stop providing contraceptive care “do not need to file notices or

⁴ The following is not an exhaustive list of the changes enacted by the IFRs, and subsequently the Final Rules. For example, the IFRs also changed the level at which exemptions are to be applied. So, whereas before the availability of an exemption was to be “determined on an employer by employer basis,” the IFRs provide that an exemption “will be determined on a plan basis.” 82 Fed. Reg. at 47,810. The effect of this change, according to the States, is that an employer may disregard the Contraceptive Mandate by adopting a group health plan “established or maintained” by an objecting organization, *id.*, even if the employer itself does not hold a sincere religious or moral objection to contraception.

certifications of their exemption.” 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850. Thus the IFRs permit entities with religious or moral objections to forgo providing contraceptive coverage to employees without “fil[ing] notices or certifications of their exemption.” 82 Fed. Reg. at 47,838.⁵

The IFRs became effectively immediately. 82 Fed. Reg. at 47,815; 82 Fed. Reg. at 47,855. Rather than engage in advance notice-and-comment procedures, the Agencies requested post-promulgation comments be submitted by December 5, 2017, 60 days after the IFRs went into effect. 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838. The Commonwealth filed suit in the interim seeking to enjoin enforcement of the IFRs, arguing: (1) they failed to comply with the notice-and-comment procedures required by the APA, 5 U.S.C. § 551, *et seq.*; (2) they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in violation of the substantive provisions of the APA, 5 U.S.C. § 706(2)(A); (3) they violate Title VII of the Civil Rights Act, 42 U.S.C. § 2000e-2, *et seq.*; (4) they violate the Equal Protection Guarantee of the Fifth Amendment, U.S. Const. amend. V; and, (5) they violate the Establishment Clause, U.S. Const. amend. I.⁶ This Court granted the preliminary injunction, finding the Commonwealth was likely to succeed on its claims that the IFRs violated both the procedural and substantive strictures of the APA; it did not, however, reach the merits of the other statutory or constitutional claims. *See Pennsylvania*, 281 F. Supp.3d at 585.⁷

⁵ The IFRs note that ERISA requires certain disclosures: “[u]nder ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document.” 82 Fed. Reg. at 47,838.

⁶ The State of New Jersey was not party to the original Complaint, and thus, not a party to the first motion for a preliminary injunction either.

⁷ Following this Court’s issuance of a preliminary injunction, several other district courts issued decisions regarding the propriety of the IFRs. *See California v. Health & Human Servs.*, 281 F. Supp.3d 806, 832 (N.D. Cal. 2017) (enjoining the IFRs for violating the procedural requirements of the APA only), *aff’d in part, vacated in part*,

Defendants subsequently appealed the decision and moved to stay proceedings while the appeal was pending, which this Court granted.⁸

G. 2018 Final Rules & Second Motion for Preliminary Injunction

On November 15, 2018, while their appeal of the preliminary injunction was pending before the Third Circuit, the Agencies promulgated two new rules that “finalize[d]” the IFRs. *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,536, 57,536 (Nov. 15, 2018) (“Final Religious Exemption”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592, 57,592 (Nov. 15, 2018) (“Final Moral Exemption”). “In response to public comments,” the Agencies made “various changes” to the Final Rules “to clarify the intended scope of the language” in the IFRs. 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593. The changes, however, were largely “non-substantial technical revisions.” 83 Fed. Reg. at 57,567. Defendants assert such changes “do not alter the fundamental substance of the exemptions set forth in the IFRs.” The Final Rules were scheduled to take effect on January 14, 2019. 83 Fed. Reg. at 57,567; 83 Fed. Reg. at 57,592.

The Commonwealth then sought to lift the stay to challenge the Final Rules. The Court granted the motion,⁹ and Pennsylvania—now joined by New Jersey—filed an Amended

remanded sub nom., *California v. Azar*, 911 F.3d 558, 566 (9th Cir. 2018) (upholding the lower court’s conclusion on the merits, but striking down the remedy as overbroad); *Massachusetts v. Health & Human Servs.*, 301 F. Supp.3d 248, 266 (D. Mass. 2018) (finding State lacked standing to challenge the IFRs), *app. docketed*, No. 18-1514 (1st Cir. June 6, 2018).

⁸ Following the Commonwealth’s initial motion for a preliminary injunction, Defendant-Intervenor Little Sisters filed a motion to intervene. The Court denied that motion. *See Pennsylvania v. Trump*, 2017 WL 6206133, at *1 (E.D.Pa. Dec. 8, 2017). On appeal, however, the Third Circuit reversed, remanding the case to permit intervention. *See Pennsylvania v. President United States of Am.*, 888 F.3d 52, 62 (3d Cir. 2018). The Court duly vacated its prior ruling and granted Defendant-Intervenor Little Sisters’ motion.

⁹ While the filing of a notice of appeal is generally “an event of jurisdictional significance—it confers jurisdiction on the court of appeals and divests the district court of its control over those aspects of the case involved in the appeal,” *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982),—“[a]n appeal from the grant or denial of a

Complaint and a Second Motion for a Preliminary Injunction, seeking to enjoin enforcement of the Final Rules.¹⁰ The States argue the Final Rules: (1) failed to comply with the notice-and-comment procedures required by the APA; (2) are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in violation of the substantive provisions of the APA; (3) violate Title VII of the Civil Rights Act; (4) violate the Equal Protection Guarantee of the Fifth Amendment; and, (5) violate the Establishment Clause. It is to the merits of these contentions that the Court now turns.

II. Analysis¹¹

A. Standing

A threshold question is whether the States have standing. Standing is a litigant’s ticket to federal court—a constitutional requirement that “limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The States contend that they are properly before the Court because the Final Rules will imminently cause direct harm to their sovereign, quasi-sovereign and proprietary interests. Additionally, they assert that they have *parens patriae* standing to protect the health, safety and well-being of their residents in ensuring that they enjoy access to healthcare services. Defendants, on the other hand, contend that the States have not suffered any legal wrong that would allow them to get through the turnstile into federal court.

preliminary injunction does not divest the trial court of jurisdiction or prevent it from taking other steps in the litigation while the appeal is pending,” 11A Wright & Miller, Fed. Prac. & Pro. § 2962 (3d ed.); see also *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 268 (3d Cir. 2005) (observing that the district court retains the power to “modify or grant injunctions” following an appeal).

¹⁰ The Third Circuit stayed Defendants’ appeal pending the resolution of the Second Motion for a Preliminary Injunction. *Pennsylvania v. President United States of Am.*, No. 17-3752 (3d Cir. Jan. 9, 2019).

¹¹ This section and all others afterwards includes the Court’s legal conclusions as required under Rule 52(a) of the Federal Rules of Civil Procedure.

“No principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 37 (1976). The doctrine of standing “is part of this limitation.” *Id.*; see also *Finkleman v. Nat’l Football League*, 810 F.3d 187, 203 (3d Cir. 2016). “[T]he irreducible constitutional minimum of standing contains three elements.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). First, a plaintiff must have suffered an “injury in fact,” which is “an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” *Id.* (internal quotation marks and citations omitted). Second, a plaintiff must show that there is a “causal connection between the injury and the conduct complained of”—that is, the injury must be “fairly traceable” to the “challenged action of the defendant.” *Id.* (internal quotation marks omitted). Third, a plaintiff must show that it is “likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Id.* at 561 (internal quotation marks omitted).

As “[t]he party invoking federal jurisdiction,” the States “bear[] the burden of establishing these elements.” *Id.* And, “[s]ince they are not mere pleading requirements but rather an indispensable part of the plaintiff’s case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Id.* “[A]t the preliminary injunction stage, allegations are”—without more—“not enough to support standing;” rather, the States must “adduce[] evidence demonstrating more than a mere possibility” that the elements of standing are met. *Doe v. Nat’l Bd. of Med. Exam’rs*, 199 F.3d 146, 152-53 (3d Cir. 1999).

1. Special Solitude

This standing inquiry must be made with recognition that States, like Pennsylvania and New Jersey here, “are not normal litigants for the purposes of invoking federal jurisdiction.” *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). They are “entitled to special solicitude in [the] standing analysis” if they have: (1) a procedural right that authorizes them to challenge the conduct at issue; and, (2) a “stake in protecting [their] quasi-sovereign interests.” *Id.* at 520; *see also Texas v. United States*, 809 F.3d 134, 151 (5th Cir. 2015), *aff’d by an equally divided Court*, 136 S. Ct. 2271 (2016) (per curiam).

In determining whether the States have met these conditions, both *Massachusetts v. EPA* and *Texas v. United States* are instructive. In *Massachusetts v. EPA*, Massachusetts sued the Environmental Protection Agency (“EPA”), alleging that the EPA had “abdicated its responsibility under the Clean Air Act” when it failed to issue regulations regarding the emission of certain greenhouse gases. 549 U.S. at 505. The EPA challenged Massachusetts’ standing to bring the suit, arguing greenhouse gas emissions are a widespread and generalized harm not unique to any specific plaintiff. *Id.* at 517. The Supreme Court nonetheless held that Massachusetts had special solicitude in the standing inquiry to challenge the EPA’s inaction: First, Massachusetts had a procedural right under the relevant statute, the Clean Air Act, which allowed it to “challenge agency action unlawfully withheld.” *Id.* (citing 42 U.S.C. § 7607(b)(1)). Second, Massachusetts had a quasi-sovereign interest—a “well-founded desire to preserve its sovereign territory” from the effects of global warming because Massachusetts “own[ed] a great deal of the territory alleged to be affected.” *Id.* at 519 (internal quotation marks omitted); *see also id.* at 522 (noting affidavits asserting that “rising seas have already begun to swallow Massachusetts’ coastal land.”). After concluding that Massachusetts was entitled to special

solicitude in the standing analysis, the Supreme Court ultimately held that it had Article III standing to sue the EPA based on the injury to its territory stemming from global warming. *Id.* at 526.

In *Texas v. United States*, the Fifth Circuit, relying on *Massachusetts v. EPA*, similarly concluded that Texas and a multitude of other States were entitled to special solicitude in seeking to enjoin implementation of the Deferred Action for Parents of Americans and Lawful Permanent Residents program (“DAPA”). 809 F.3d at 154-55. There, non-citizens in Texas could apply for a driver’s license if they presented “documentation issued by the appropriate United States agency that authorizes the applicant to be in the United States.” *Id.* at 155 (internal quotation marks omitted). DAPA would have permitted at least 500,000 non-citizens to qualify for these driver’s licenses. *Id.* Because Texas subsidized its licenses, it would have lost money for each license issued to a DAPA beneficiary. *Id.* Texas therefore sought injunctive relief to prevent DAPA’s implementation. *See id.* at 149.

The Fifth Circuit applied the *Massachusetts v. EPA* framework and concluded that Texas was entitled to special solicitude. First, the Fifth Circuit considered whether the States’ challenge was similar in kind to the challenge brought by Massachusetts, and concluded that it was. Both suits turned on the construction of a federal statute that specifically provided for a procedural right to judicial review, and Texas’ use of the APA to challenge an “affirmative decision” made by a federal agency was comparable to Massachusetts’ use of the judicial review provision in the Clean Air Act to challenge the EPA’s inaction. *Id.* at 152. Second, as to the quasi-sovereign interest, the Fifth Circuit held that DAPA imposed “substantial pressure” on Texas to change its laws to avoid bearing further costs from subsidizing additional driver’s licenses. *Id.* at 153. The Fifth Circuit thus concluded that Texas, and its fellow plaintiff States,

warranted special solicitude in their suit against the federal government under the APA. *Id.* at 154-55.¹²

The Fifth Circuit’s reasoning in *Texas v. United States* is persuasive here. Here as there, the States bring suit under the APA to challenge an affirmative action by the federal government. *See Texas*, 809 F.3d at 152. And, the Final Rules—like DAPA—“affect[] the [S]tates’ ‘quasi-sovereign’ interest by imposing substantial pressure on them to change their laws.” *Id.* Specifically, they put pressure on provisions of the States’ laws that provide state-funded contraceptive care to low-income citizens. As the States show, the Final Rules permit more employers to exempt themselves from the Contraceptive Mandate, which would result in more of the States’ women seeking state-funded sources of contraceptive care. The harm to the States’ fiscs are “intrusions . . . analogous to pressure to change the law,” *id.*, implicating the States’ quasi-sovereign interests. *See also Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982) (holding that a State has a “quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general.”). The States, then, meet the two conditions outlined in *Massachusetts v. EPA* and shall be accorded special solicitude in the standing analysis.

¹² Defendants here question the binding effect of *Texas v. United States* beyond the facts of that case, given that the Supreme Court summarily affirmed the Fifth Circuit’s decision “by an equally divided Court.” *United States v. Texas*, 136 S. Ct. 2271 (2016) (per curiam). While an affirmance by an equally divided Supreme Court typically does not constitute binding precedent, *see Eaton v. Price*, 364 U.S. 263, 264 (1960), where the Supreme Court is equally divided on an issue of subject matter jurisdiction, it has determined that the proper course is to remand the issue of jurisdiction to a lower court. *See Silliman v. Hudson River Bridge Co.*, 66 U.S. 582, 584-85 (1861). In other words, if the Supreme Court were equally divided on whether Texas had standing to challenge DAPA, it would have remanded that issue to the Fifth Circuit. The Supreme Court did not, and instead affirmed the Fifth Circuit, indicating that a majority of the Supreme Court decided that Texas had standing to pursue its APA claim. Certainly, if the Supreme Court had determined that Texas did not have standing, it would not have had jurisdiction to hear the case. Even if the affirmance by an equally divided Supreme Court as it relates to subject matter jurisdiction were not binding, the Court is persuaded by the reasoning of the Fifth Circuit in *Texas v. United States* as it pertains to State standing.

2. Article III Standing

While the States are entitled to special solicitude in the standing analysis, they must nevertheless meet the “irreducible constitutional minimum of standing”—namely, injury in fact, causation, and redressability. *Lujan*, 504 U.S. at 560. In its initial challenge to the IFRs, the Commonwealth satisfied this burden, *see Pennsylvania*, 281 F. Supp.3d at 569, and the same is true of the States’ challenge to the Final Rules. *See also California*, 911 F.3d at 571 (finding another group of States had standing to challenge the IFRs).

First, the Final Rules inflict a direct injury upon the States by imposing substantial financial burdens on their coffers. An agency rule that has “a major effect on the states’ fisces” is sufficient to find injury in fact. *Texas*, 809 F.3d at 152; *id.* at 155 (“[Texas] satisfied the first standing requirement by demonstrating that it would incur significant costs in issuing driver’s licenses to DAPA beneficiaries.”); *see also Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (holding that Wyoming had Article III standing because it undisputedly suffered a “direct injury in the form of a loss of specific tax revenues”); *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (“While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.”). If the Final Rules go into effect, the States will have to increase their expenditures for State funded programs that provide contraceptive services. This is not a speculative harm. As Defendants themselves noted in issuing the IFRs, “there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women.” 82 Fed. Reg. at 47,803. As more of the States’ women residents are deprived of contraceptive services through their insurance plans and turn to these State funded programs, the States will be pressed to make greater expenditures to ensure adequate contraceptive care. *See Mendelsohn Decl.* ¶ 15; *Steinberg Decl.* ¶¶ 24-25. And

although Defendants point out that the States have not yet identified a woman resident who has lost contraceptive coverage due to the Final Rules, the States need not sit idly by and wait for fiscal harm to befall them. *See McNair v. Synapse Group Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) (“When, as in this case, prospective relief is sought, the plaintiff must show that he is ‘likely to suffer *future* injury’ from the defendant’s conduct.”) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (emphasis added)). At bottom, just as Texas’ estimated loss due to DAPA supported a finding that Texas suffered an injury in fact, so too does the States’ estimated loss due to the Final Rules support a finding that the States have suffered an injury in fact. *See Texas*, 809 F.3d at 155.

Second, the States’ financial injury is “fairly traceable” to the issuance of the Final Rules. By their terms, the Final Rules expand the scope of the existing religious exemption rule and allow entities a new rationale for refusing to provide employees with contraceptive coverage if the refusal is “based on sincerely held moral convictions,” 83 Fed. Reg. at 57,593. Thus, the Final Rules allow more entities to stop providing contraceptive coverage, which will result in more women residents seeking contraceptive care through State-funded programs. *See Mendelsohn Decl.* ¶ 15; *Steinberg Decl.* ¶¶ 24-25. The States have thus shown a causal connection between the Final Rules and their financial injury.

As the Court previously explained, *Pennsylvania v. New Jersey*, 426 U.S. 660 (1976), is not to the contrary. *See also California*, 911 F.3d at 574 (finding *Pennsylvania* did not bar States’ challenge to the IFRs on a similar theory of standing). In that case, Pennsylvania voluntarily gave tax credits to Pennsylvania residents who paid taxes in New Jersey, and then proceeded to sue New Jersey, contending that the New Jersey tax injured Pennsylvania’s fiscs and was constitutionally impermissible. *Pennsylvania*, 426 U.S. at 662-63. The Supreme Court

found that Pennsylvania lacked standing because the injuries to its fisci were “self-inflicted,” resulting, as they did, from a decision of its state legislature to enact a law that incorporated the legislative choices of New Jersey. *Id.* at 664. Here, by contrast, the States’ laws funding contraceptive care do not “directly and explicitly” tie the States’ finances to another sovereign’s law. *California*, 911 F.3d at 574. Rather, the States’ described injuries flow from the unilateral decision by the Agencies to issue the Final Rules. *See id.* (finding *Pennsylvania* did control in an analogous challenge); *cf. Texas*, 809 F.3d at 158 (“The fact that Texas sued in response to a significant change in the [federal government’s] policies shows that its injury is not self-inflicted.”). The States have therefore met the traceability requirement.

Finally, the States have satisfied the redressability requirement. As to the States’ procedural claims, enjoining the Final Rules could prompt the Agencies “to reconsider the program, which is all a plaintiff must show when asserting a procedural right.” *Texas*, 809 F.3d at 161; *see also Massachusetts*, 549 U.S. at 518 (noting that where, as here, a litigant is “vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant”). And, as for the States’ substantive claims, enjoining the Final Rules “would prevent [the States’] injury altogether.” *Texas*, 809 F.3d at 161.

In sum, the States have established the irreducible constitutional minimum of standing to challenges the Final Rules in federal court.¹³

B. Venue

The next question to address is whether the States’ choice of venue—the Eastern District of Pennsylvania—is proper. Notwithstanding Defendants’ argument to the contrary, it is.

¹³ Because the States have identified an imminent, direct injury to its state coffers that would result from the Final Rules, there is no need to address whether they have *parens patriae* standing.

Defendants' argument is grounded in the structure of the venue statute, Section 1391(e)(1) of which provides that in a civil action against an officer of the United States, venue lies "in any judicial district in which . . . the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1). Section 1391(c) defines a party's residence "[f]or all venue purposes," and distinguishes between three, and only three, categories of litigants: "a natural person," "an entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated," and "a defendant not resident in the United States." *Id.* at § 1391(c). Because Pennsylvania is neither a natural person nor a non-resident, Defendants argue it must be treated as an entity for purposes of determining residency. Section 1391(c)(2) provides that "if a plaintiff," an entity "shall be deemed to reside . . . only in the judicial district in which it maintains its principal place of business." *Id.* Thus, according to Defendants, Pennsylvania resides only in the Middle District—the district that encompasses Harrisburg, the state capital—because that is where Pennsylvania maintains its principal place of business.

While inventive, Defendants' interpretation of Section 1391(c) is ultimately unpersuasive. *See California*, 911 F.3d at 570 (rejecting the argument); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp.2d 1301, 1328 (N.D. Ala. 2005) (rejecting a similar argument for an earlier version of the venue statute). Defendants' argument hinges on the assumption that, because Section 1391(c) refers to only three categories of litigants and because a state is neither a natural person nor a non-resident, a state must necessarily be "an entity" for purposes of the venue statute. There are, however, several issues with that assumption.

First, the statute explicitly refers to an entity's incorporation status, indicating "that the term [entity] refers to some organization, not a state." *California*, 911 F.3d at 570. The legislative history confirms that Congress was contemplating "unincorporated associations, such

as partnerships and labor unions, and other entities with capacity to sue in their common name,” when it defined the residency of unincorporated entities in Section 1391(c). H.R. Rep. No. 112-10, at 21 (2011). There is no indication, however, that Congress intended for that provision to dictate the residency of sovereign States by equating a State with an “unincorporated association[]” like a labor union.

Second, Congress explicitly distinguishes between States and entities within Section 1391. Compare 28 U.S.C. § 1391(c) (defining the residency of an “entity”), with *id.* at § 1391(d) (“Residency of corporations in States with multiple districts”). “Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation marks and citations omitted). Thus, courts typically “refrain from concluding . . . that the differing language in [] two subsections [of a statute] has the same meaning in each.” *Id.* Here, Congress’s differentiation between “an entity” and “States” within Section 1391 indicates that Congress did not intend to include the latter within the definition of the former.

Finally, reading Section 1391 as Defendants suggest would yield an absurd result. As several courts have observed, an interpretation that “limit[s] residency to a single district in the state would defy common sense,” because “[a] state is ubiquitous throughout its sovereign borders.” *California*, 911 F.3d at 570; *Alabama*, 382 F. Supp.2d at 1329 (“[C]ommon sense dictates that a state resides throughout its sovereign borders”).¹⁴

Thus, the Court will follow the lead of the Ninth Circuit in concluding that “the statute . .

¹⁴ The unreported district court cases that Defendants rely upon are not to the contrary. See *Gaskin v. Pennsylvania*, 1995 WL 154801, at *1 (E.D. Pa. Mar. 30, 1995); *Bentley v. Ellam*, 1990 WL 63734, at *1 (E.D. Pa. May 8, 1990). Both *Gaskin* and *Bentley* discuss the residency of state agencies or officials, which is different in kind from the residency of a sovereign State itself.

. dictates that a state with multiple judicial districts ‘resides’ in every district within its borders.” *California*, 911 F.3d at 570. Venue is therefore proper in the Eastern District of Pennsylvania.¹⁵

C. Preliminary Injunction

Because the States have established standing to bring their claims into federal court and that this is a proper venue to hear those claims, the Court now turns to the merits of the preliminary injunction motion.

1. Legal Standard

A preliminary injunction is an extraordinary remedy; it “should be granted only in limited circumstances.” *American Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1426-27 (3d Cir. 1994). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v. NRDC*, 555 U.S. 7, 20 (2008). The first two are the “most critical factors: [a movant] must demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief.” *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017), *as amended* (June 26, 2017) (internal quotation marks omitted). “If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor

¹⁵ Section 1391(e) also provides that venue is proper in a civil action against an officer of the United States, where “a substantial part of the events or omissions giving rise to the claim occurred.” 28 U.S.C. § 1391(e). Because the Court finds Pennsylvania resides throughout the State, it need not address the States’ alternative argument that venue is proper because “a substantial part of the events” giving rise to their claim occurred here.

Relatedly, New Jersey’s residency does not bear on the question of because “in an action against the federal government or an agent thereof [t]here is no requirement that all plaintiffs reside in the forum district.” *Exxon Corp. v. FTC*, 588 F.2d 895, 899-90 (3d Cir. 1978); *Superior Oil Co. v. Andrus*, 656 F.2d 33, 37 n.7 (3d Cir. 1981) (“[O]nly one plaintiff need satisfy the residency requirement of [Section 1391(e)].”).

of granting the requested preliminary relief.” *Id.*

2. Likelihood of Success on the Merits

In demonstrating the likelihood of success on the merits, a plaintiff need not show that it is more likely than not that it will succeed. *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc). Instead, all a plaintiff must show is “a *likelihood* of success on the merits (that is, a reasonable chance, or probability, of winning) to be granted relief.” *Id.* (emphasis in original).

a. APA Procedural Claim

The States argue that the Final Rules should be enjoined because Defendants failed to comply with the procedural requirements of the APA.

The APA generally requires that, when promulgating regulations, administrative agencies meet a set of procedural requirements, called notice-and-comment rulemaking. *See* 5 U.S.C. § 553. Agencies must: issue a general notice of proposed rulemaking, *see id.* at § 553(b); “give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments . . .” *id.* at § 553(c); and, “[a]fter consideration of the relevant matter presented, . . . incorporate in the rules adopted a concise general statement of their basis and purpose,” *id.*

Notice-and-comment rulemaking serves two distinct purposes—it both “give[s] the public an opportunity to participate in the rule-making process,” and “enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated.” *Texaco, Inc. v. Fed. Power Comm’n*, 412 F.2d 740, 744 (3d Cir. 1969). Nevertheless, there are limited exceptions to the requirement that all rules be issued pursuant to notice-and-comment rulemaking, such as when an agency has “good cause” to

forgo the strictures of notice-and-comment rulemaking, 5 U.S.C. § 553(b), or when a subsequent act of Congress abrogates the APA's procedural requirements, *id.* at § 559.

In issuing the IFRs, the Agencies failed to meet the various requirements of notice-and-comment rulemaking. *See Pennsylvania*, 281 F. Supp.3d at 570. Defendants argued, however, that the IFRs were not procedurally invalid because they fell under one (or more) of the limited exceptions to notice-and-comment rulemaking. *Id.* at 571. The Court found otherwise and enjoined the IFRs for violating the procedural strictures of Section 553. *Id.* at 576; *see also California*, 281 F. Supp.3d at 829 (enjoining the IFRs for violating the procedural requirements of the APA), *aff'd in part, vacated in part, California*, 911 F.3d at 575 (upholding the conclusion that the IFRs violated the APA).

While Defendants continue to maintain that the IFRs were procedurally valid,¹⁶ they now argue that, even assuming the IFRs were procedurally improper, the subsequent action taken by the Agencies in promulgating the Final Rules satisfied notice-and-comment requirements, and thus the Final Rules comply with the APA. The States' response is two-fold. First, they argue that the Agencies notice-and-comment procedures fell short of the APA's requirements because the Agencies did not adequately respond to significant comments in their statement of the basis and purpose of the Final Rules. Second, the States contend that, no matter the Agencies' subsequent actions, the procedural defects that characterized the issuance of the IFRs fatally taint the Final Rules. These arguments are considered *seriatim*.

i. Inadequate Response to Comments

The States argue that the Agencies' issuance of the Final Rules failed to meet the

¹⁶ The Court, for the reasons stated in its prior opinion, again finds the Agencies' position unpersuasive, *see Pennsylvania*, 281 F. Supp.3d at 570, and therefore declines Defendants' invitation to revisit its prior holding. *See Hayman Cash Register Co. v. Sarokin*, 669 F.2d 162, 165 (3d Cir. 1982) ("Under the law of the case doctrine, once an issue is decided, it will not be relitigated in the same case, except in unusual circumstances.").

requirements of notice-and-comment rulemaking by not responding to all “vital questions[] raised by comments which are of cogent materiality.” *United States v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). The APA requires federal agencies to “consider and respond to significant comments received during the period for public comment.” *Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199, 1203 (2015). The requirement, however, is not “particularly demanding.” *Nazareth Hosp. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 747 F.3d 172, 185 (3d Cir. 2014) (quoting *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993)). All that is required is a response that “‘demonstrates that the [agency] considered and rejected’ the arguments.” *Id.* (quoting *Covad Commc’ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006)).

The States contend that the Agencies failed to clear this relatively low bar, pointing to several examples of comments that purportedly received an inadequate response: comments that discuss the scientific evidence of the harm to the health and economic security of women that would result from the Final Rules, 83 Fed. Reg. at 57,555-56; comments that assert the broad religious and moral exemptions will cause women to lose contraceptive coverage, *id.* at 57,548-49; comments that argue the exemptions violate the ACA prohibition on regulations that create barriers to medical care, *id.* at 57,551-52; and, specifically, a comment submitted by various States—including Pennsylvania and New Jersey—regarding the medical risks associated with pregnancy, *id.* at 57,555.

For each example, however, a review of the Final Rules demonstrates that the Agencies acknowledged the comments and provided an explanation as to why the Agencies did (or did not) amend the Final Rules based on the comment. *See* 83 Fed. Reg. at 57,548, 57,551, 57,555. While the Agencies’ explanations are not always the picture of clarity, they meet the not

“particularly demanding” requirement, *Nazareth Hosp.*, 747 F.3d at 185, that the Agencies “consider and respond to significant comments received during the period for public comment,” *Perez*, 135 S. Ct. at 1203. Put differently, the Final Rules “demonstrate [to a commenter] that the [the Agencies] considered and rejected, the arguments” put forth by a commenter, which is “all that the [APA] requires.” *Nazareth Hosp.*, 747 F.3d at 185 (internal quotation marks omitted).

Thus, the States are unlikely to succeed on the merits of their argument that, in promulgating the Final Rules, the Agencies’ actions failed to meet the requirements of notice-and-comment rulemaking.¹⁷

ii. IFRs Taint the Final Rules

The States maintain that, even if the Agencies complied with the requirements of notice-and-comment rulemaking in promulgating the Final Rules, the failure to do so in promulgating the IFRs fatally infected the process such that the Final Rules should also be held invalid.

Generally, “the period for comments after promulgation cannot substitute for the prior notice and comment required by the APA.” *Sharon Steel. Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979). The Circuit courts however, diverge on the procedural validity of a final rule that follows an IFR promulgated in a procedurally flawed manner—that is, the question of whether a “procedural defect that taints the original, interim-final rule carr[ies] over to the succeeding final rule.” Kristin E. Hickman & Mark Thomson, *Open Minds and Harmless Errors: Judicial Review of Postpromulgation Notice and Comment*, 101 Cornell L. Rev. 261, 267 (2016) (discussing various approaches taken by the Circuit courts); compare *Salman Ranch, Ltd. v. Comm’r*, 647 F.3d 929, 940 (10th Cir. 2011) (“While the . . . temporary regulations were issued

¹⁷ The States’ argument is limited to the claim that the Agencies failed to adequately respond to significant comments. The States do not argue, for example, that the notice provided was inadequate. See 5 U.S.C. § 552(b).

without notice and comment, now that the regulations have issued in final form [after notice and comment], these arguments are moot . . .”) (internal quotation marks omitted), *rev’d on other grounds, Salman Ranch, Ltd. v. Comm’r*, 566 U.S. 971 (2012), with *Air Transp. Ass’n of Am. v. Dep’t of Transp.*, 900 F.2d 369, 379 (D.C. Cir. 1990) (“Although we have suggested that there might be circumstances in which ‘defects in an original notice [could] be cured by an adequate later notice’ and opportunity to comment, we have emphasized that we could reach such a conclusion only upon a compelling showing that ‘the agency’s mind remain[ed] open enough at the later stage.’ The FAA has not come close to overcoming the presumption of closed-mindedness in this case.”) (quoting *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988)), *vacated on other grounds*, 498 U.S. 1077 (1991). For its part, the Third Circuit has evidenced a deep skepticism towards the curative powers of post-promulgation notice-and-comment procedures, *see NRDC v. EPA*, 683 F.2d 752, 767-68 (3d Cir. 1982); *United States v. Reynolds*, 710 F.3d 498, 519 (3d Cir. 2013); *accord Sharon Steel. Corp.*, 597 F.2d at 381, which warrants a conclusion that the States are likely to succeed on the claim that the procedural faults that characterized the issuance of the IFRs fatally tainted the Final Rules such that the issuance of the Final Rules violated the APA.

The Third Circuits’ decision most directly on point is *NRDC v. EPA*. There, the NRDC challenged EPA action that indefinitely postponed the effective date of certain Clean Water Act amendments. *NRDC*, 683 F.2d at 757. The EPA did not engage in notice-and-comment procedures before acting to postpone the implementation of the amendments.¹⁸ *Id.* at 756. After NRDC initiated litigation challenging the agency’s action, the EPA issued a notice of proposed

¹⁸ The EPA argued that the initial action to postpone was not a “rule” under the APA, and thus did not require notice-and-comment procedures. *NRDC*, 683 F.2d at 761. The Third Circuit rejected that argument, holding the EPA’s action postponing the effective date qualified as a rule, requiring notice-and-comment procedures. *Id.*

rulemaking, seeking comments on whether the agency should issue a rule further postponing the effective date. *Id.* at 757. After going through notice-and-comment procedures, the EPA then issued a final rule implementing some of the amendments, while further postponing the most controversial bits. *Id.* Nevertheless, NRDC maintained its challenge to the EPA’s initial action to postpone the effective date. The Third Circuit rejected the EPA’s argument that its notice-and-comment procedures *after* the initial action to postpone “cured” any failure to engage in such procedures *before* the initial action, and held the initial action postponing the effective date was procedurally invalid. *Id.* at 767.

Critical to this dispute, however, the Third Circuit further held that, even though the NRDC did not challenge the final rule—that is, the rule promulgated following notice-and-comment procedures—the final rule “was likewise invalid.” *Id.* at 768. The court of appeals explained that the appropriate remedy for the EPA’s failure to engage in notice-and-comment rulemaking before taking its initial action required holding *both* the initial action and the subsequent, final rule “ineffective.” *Id.* at 767. EPA’s notice-and-comment procedures “could not serve as the procedural mechanism” for the final rule because “that rulemaking [could not] replace one on the question of whether the amendments should be postponed in the first place.” *Id.* That is, if the EPA had engaged in notice-and-comment procedures before initially acting to postpone the effective date, then “the question to be decided in the [subsequent] rulemaking”—the rulemaking that complied with notice-and-comment procedures—“would have been whether the amendments . . . should be suspended, and not whether they should be further postponed.” *Id.* The Third Circuit warned that:

To allow the APA procedures in connection with the further postponement to substitute for APA procedures in connection with an initial postponement would allow EPA to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action

without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued. . . . We cannot countenance such a result.

Id.

That reasoning applies with equal force here. The Agencies issued the IFRs without engaging in notice-and-comment rulemaking. As in *NRDC*, the issuance of the procedurally defective IFRs fundamentally changed the “question to be decided in the [subsequent] rulemaking”—instead of asking whether substantial expansions to the exemption and accommodation should be made *at all*, the Agencies solicited comments on whether those changes should be *finalized*. Thus, the subsequent “rulemaking on [finalizing the IFRs] could not serve as the procedural mechanism,” for the Final Rules because “that rulemaking [could not] replace one on the question of whether” the Agencies should broaden the existing exemption and accommodation “in the first place.” *Id.* The Agencies are, in essence, engaging in precisely the behavior that the Third Circuit warned against in *NRDC*: “substitute[ing] post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures . . . by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued.” *Id.* The Court, like the Third Circuit, “cannot countenance such a result.” *Id.*

Defendants and Defendant-Intervenor advance several arguments to the contrary, none of which are ultimately persuasive. For one, Defendants argue that *NRDC* is not on all fours with this case and so “provides no support for the Plaintiffs’ procedural challenge.” Defendants are correct that *NRDC* differs factually from the case at hand: there the *NRDC* challenged only the initial action, here the States challenged both the IFRs and the Final Rules. But, even though the plaintiff did not challenge the final rule in *NRDC*, the Third Circuit held both the initial action to

postpone and the subsequent rule procedurally invalid. In reaching that determination, the Third Circuit rejected the notion—advanced by the Agencies here—that subsequent notice-and-comment rulemaking procedures “cured” the failure to engage in such procedures “in the first place.” *Id.* at 767-78. Both the holding and the reasoning given for that holding are binding on this Court. *See Tate v. Showboat Marina Casino P’ship*, 431 F.3d 580, 582 (7th Cir. 2005) (Posner, J.) (“[T]he holding of a case includes, besides the fact and the outcome, the reasoning essential to that outcome.”); *see also IFC Interconsult, AG v. Safeguard Int’l Partners, LLC*, 438 F.3d 298, 311 (3d Cir. 2006) (quoting Judge Posner’s definition approvingly). Because the Third Circuit’s reasoning invalidating the subsequent rule was essential to the holding, and because that reasoning applies with equal force to the promulgation of the Final Rules, that reasoning controls here.

Next, Defendants argue that the States suffered no procedural injury because they had an opportunity to submit a comment in response to the IFRs, an opportunity that the States “admit” to taking advantage of. The problem for Defendants is that the EPA made the exact argument to the Third Circuit in *NRDC*, which the court of appeals flatly rejected. *NRDC*, 683 F.2d at 768. As the Third Circuit explained, it did not matter that “notice and comment were provided in connection with the proposal that the amendments be further postponed, and *NRDC* was able to make all of the arguments in connection with the further postponement that *NRDC* would have made in connection with the initial postponement.” *Id.* The problem was that the initial, procedurally defective action fundamentally changed the question to be presented in the subsequent rulemaking, prejudicing *NRDC*, which ““must come hat-in-hand and run the risk that the decisionmaker is likely to resist change.”” *Id.* at 768 (quoting *Sharon Steel*, 597 F.2d at 381). Here, the procedurally invalid IFRs similarly changed the question to be presented in the

subsequent rulemaking, prejudicing the States' ability to have their comments heard by an impartial decisionmaker. *Cf. Wagner Elec. Corp. v. Volpe*, 466 F.2d 1013, 1020 (3d Cir. 1972) ("Section [553(b)] of the [APA] requires notice *before* rulemaking, not after. The right of interested persons to petition for the issuance, amendment or repeal of a rule, granted in [5 U.S.C. § 553(e)], is neither a substitute for nor an alternative to compliance with the mandatory notice requirements of [5 U.S.C. § 553(b)].") (emphasis in original).

Defendant-Intervenor's attempt to distinguish away the reasoning of *NRDC* fares no better. It argues the court of appeals' reasoning does not control because, while "unique circumstances" existed in *NRDC* "to establish prejudice," no such circumstances are present here. Specifically, Defendant-Intervenor argues that the Third Circuit invalidated the final rule in *NRDC* because of the "asymmetry between using an interim rule to repeal a rule promulgated with prior notice and comment," whereas, here, the Final Rules are not "an abrupt change in federal policy" because the Final Rules do not rescind the Contraceptive Mandate. According to Defendant-Intervenor, that makes this case "readily distinguishable from *NRDC*."

The argument is premised on a misreading of *NRDC*. The Third Circuit did not invalidate the EPA action because of the degree of change affected by the procedurally invalid action. Rather, it held that the subsequent notice-and-comment rulemaking "[could not] replace [a rulemaking] on the question of whether the amendments should be postponed in the first place." *NRDC*, 683 F.2d at 768. More fundamentally, the court of appeals did not rest its decision on the existence of any "unique circumstances," as Defendant-Intervenor suggests. Instead, the Third Circuit voiced a general admonition against the practice of using post-promulgation procedures to cure pre-promulgation procedural flaws. *Id.* As discussed, the reasoning underpinning that warning informs the result here.

Defendant-Intervenor also advances an altogether different argument. It points out that the Agencies “created the [Contraceptive] Mandate via a series of IFRs without notice and comment,” suggesting that the Final Rules are procedurally valid because the Agencies followed similar procedures in the past. The Court rejected a version of this argument last go around. See *Pennsylvania*, 281 F. Supp.3d at 573 n.8. Whether a party could have brought a successful challenge to the procedures followed in the past is not before the Court—what is at issue here is whether the procedures the Agencies followed in issuing the Final Rules violated the APA. *Id.* (explaining that the IFRs were “not identical to prior regulations” because “they make significant changes in the law, and the Supreme Court did not require immediate action”). The same flawed reasoning characterizes Defendant-Intervenor’s related argument that invalidating the Final Rules would “cast a pall on thousands of regulations,” because, according to the Government Accountability Office, 35% of all major rules were finalized with post-IFR notice-and-comment procedures. Obviously, those regulations are not currently before this Court, and, accordingly, the Court is not asked—and thus, cannot decide—whether the specific procedures employed in promulgating those regulations were defective.

The States are likely to prevail on their claim that the issuance of the Final Rules violated the procedural requirements of the APA in that the procedural defect that characterized the IFRs fatally tainted the issuance of the Final Rules. That is so, regardless of whether the procedure followed by the Agencies in the Final Rules may otherwise meet the requirements of notice-and-comment rulemaking.¹⁹

¹⁹ As noted, other courts of appeals employ other approaches when evaluating whether a procedural defect in an interim-rule fatally infects a final rule issued after notice-and-comment procedures are followed—one example being the “open mind” approach. See, e.g., *Air Transp. Ass’n of Am.*, 900 F.2d at 379 (employing the “open mind standard”). While it has never adopted this approach, the Third Circuit in *Reynolds* indicated that whether a promulgating agency “maintained a flexible and open-minded attitude towards” an interim rule is a relevant consideration in determining whether an APA violation occurred generally. 710 F.3d at 519.

b. APA Substantive Claim

The States also contend that the Final Rules violate the substantive requirements of the APA. As the Court has previously noted, the breadth of the exemptions set out in the IFRs, and now the Final Rules, is remarkable. The Final Religious Exemption allows all non-profit and for-profit entities, whether closely held or publicly traded, to deny contraceptive coverage based on sincerely held religious beliefs. The Final Moral Exemption allows any non-profit or for-profit organization that is not publicly traded to deny contraceptive coverage for its employees for any sincerely held moral conviction.

The APA's substantive requirements command that an administrative rule must be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). "It is well settled that an agency may only act within the authority granted to it by statute." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 108 (2d Cir. 2018). Because "administrative agencies may act only pursuant to authority delegated to them by Congress," an agency must "point to something" in a statute that "gives it the authority"

Even under the more flexible "open mind standard," however, the States would likely succeed on the merits of their procedural claim. As the D.C. Circuit has explained, while "defects in an original notice could be cured by an adequate later notice and opportunity to comment," the remedial measures cure the earlier lapses only if the promulgating agency makes "a compelling showing that the agency's mind remained open enough at the later stage." *Air Transp. Ass'n of Am.*, 900 F.2d at 379 (internal quotation marks omitted). That is, "it is the agency's burden to persuade the court that it has accorded the comments a full and fair hearing." *Advocates for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288, 1292 (D.C. Cir. 1994). Courts that use this approach have established that an agency can demonstrate open-mindedness by making changes to a final rule in response to public comments, or giving careful consideration to comments submitted in response to a proposed rule. *Air Transp. Ass'n of Am.*, 900 F.2d at 380; see also *Advocates for Highway & Auto Safety*, 28 F.3d at 1292.

Here, the Agencies have not made a "compelling showing" that they kept an open mind at the later stages of the rulemaking process. Most notably, while the Agencies made some changes to the Final Rules based on public comments, those rules were largely "non-substantial technical revisions," 83 Fed. Reg. at 57,567, that Defendants concede "do not alter the fundamental substance of the exemptions set forth in the IFRs." Indeed, the Final Rules and the preambles that accompany them "demonstrate[] a single-minded commitment to the substantive result reached," *Reynolds*, 710 F.3d at 519—to wit, expanding the exemption and accommodation. Because the Agencies' actions indicate closed-mindedness on "the very subject matter about which [they] w[ere] to keep an 'open mind,'" *id.*, the States would likely prevail on their procedural claim even under the more lenient open mind standard.

to take the specific action at issue. *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (internal quotation marks omitted).

Defendants cite two potential fonts of statutory authority to issue the Final Rules. First, they assert that the ACA includes a broad delegation of authority to the Agencies, permitting them to issue the Final Rules. Second, with specific regard to the Religious Exemption, Defendants assert that RFRA not only authorizes the Agencies to create a religious exemption to the Contraceptive Mandate, but in fact *requires* that the Agencies issue the broad exemption contained within the Final Religious Exemption.

As explained below, both arguments fail. The Final Rules—just as the IFRs before them—exceed the scope of the Agencies’ authority under the ACA, and, further, cannot be justified under RFRA. As a result, the Final Rules must be set aside.²⁰

i. The ACA

To reiterate for purposes of clarity, the ACA requires that group health plans and insurance issuers “shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for-- . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a). It is uncontroverted here that, pursuant to this provision, HRSA has—and by extension the Agencies have—the delegated authority to define what “preventive care” is; that in 2011, HRSA issued guidelines defining “preventive care” to include contraceptives; and that the Final Rules do not purport to remove contraceptives from the coverage mandate. 83 Fed Reg. at 57,537. In light of these provisions, *what* must be provided under the ACA’s “preventive care”

²⁰ Defendants argue that any finding that they lack statutory authority to enact the Final Rules necessarily calls into doubt their ability to enact the 2011 religious exemption, which extended to religious entities such as churches and their auxiliaries. Whatever the merits of that argument, the 2011 religious exemption is not before this Court.

requirement is clear—all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling,” 77 Fed. Reg. at 8,725—as is *who* must provide it—any “group health plan” or “health insurance issuer offering group or individual health insurance coverage,” 42 U.S.C. § 300gg-13(a).

The Agencies, however, contend that the authority to define *what* preventive care will be covered includes a congressional delegation of authority to carve out exceptions to *who* must provide preventive coverage. More specifically, Defendants argue that the Women’s Health Amendment necessarily grants them the authority to exempt employers and healthcare plan sponsors from the coverage requirement, based on religious or moral objections to the Mandate. Thus, the precise question at issue is whether the ACA permits the Agencies to develop the exemptions set forth in the Final Rules.

When the scope of the authority delegated to an agency is challenged, that challenge is generally addressed under the analytical framework prescribed by *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). That is because, “[n]o matter how it is framed, the question a court faces when confronted with an agency’s interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority.” *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (emphasis removed); *see also Am. Farm Bureau Fed’n v. EPA*, 792 F.3d 281, 295 (3d Cir. 2015) (applying *Chevron* framework to resolve “[w]hether an [agency] interpretation falls within the scope of authority that Congress has delegated”) (internal punctuation omitted).

There are two steps to the *Chevron* analysis. Step One asks “whether Congress has directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842. “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give

effect to the unambiguously expressed intent of Congress.” *Id.* at 842-43. But, “[i]f the statute is ambiguous on the point,” Step Two requires “defer[ence] . . . to the agency’s interpretation so long as the construction is ‘a reasonable policy choice for the agency to make.’” *National Cable & Telecomm. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron*, 467 U.S. at 845).

Here, as noted, the ACA provides that any “group health plan” or “health insurance issuer offering group or individual insurance coverage *shall*, at a minimum provide coverage for” “preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a) (emphasis added). On its face, the Women’s Health Amendment does not contemplate exceptions or exemptions to the “preventive care” coverage mandate—much less delegate authority to the Agencies to create such exemptions.²¹ Rather, the statute directs that all specified health plans and insurance issuers “shall” cover “preventive care,” however defined. “Shall” is a mandatory term that “normally creates an obligation impervious to judicial [or agency] discretion.” *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Thus, by stating that the specified plans “shall” provide coverage for “preventive care,” the statute sets forth who is bound by the coverage mandate (any “group health plan” or “health insurance issuer offering group or individual insurance coverage”), while delegating to the Agencies the task of defining what counts as “preventive care.” The statute further underscores the importance of the Contraceptive Mandate, by stipulating that the specified health plans must provide preventive care coverage “at a minimum” and without “any cost sharing requirements.”

²¹ As discussed further *infra*, the ACA, in sections outside the Women’s Health Amendment, does provide one very specific exception to its broader coverage mandate, for grandfathered health plans. See 42 U.S.C. § 18011. The ACA insurance requirements also do not apply to employers with fewer than 50 employees. See 26 U.S.C. § 4980H(c)(2).

Nonetheless, the Agencies assert that they hold the authority to issue the far-reaching exemptions to the Contraceptive Mandate set out in the Final Rules. They argue that the statement “as provided for in comprehensive guidelines supported by [HRSA]” contemplates a broad delegation of authority, that permits the Agencies not only to define preventive care, but also the manner and reach of “preventive care” coverage. 42 U.S.C. § 300gg-13(a). Effectively, the Agencies’ argument is that the statute authorizes them to carve out, contrary to the express remits of the statute, categories of entities who need not provide preventive care coverage. But such a grant of authority is inconsistent with the statute’s text. Congress has already answered *who* must provide preventive care coverage: any “group health plan” or “health insurance issuer offering group or individual insurance coverage.” To permit the Agencies to disrupt this mandate contradicts the plain command of the text.

There are further textual reasons to doubt that the phrase “as provided for in comprehensive guidelines supported by [HRSA]” permits such an extensive delegation. True enough, the statute speaks to “*comprehensive* guidelines,” which suggests a broad scope. But the delicate term *support* undermines this contention: it strains credulity to say that by granting HRSA the authority to “support” guidelines on “preventive care,” Congress necessarily delegated to HRSA the authority to subvert the “preventive care” coverage mandate through the blanket exemptions set out in the Final Rules.

MCI Telecommunications Corp. v. American Telephone & Telegraph Co., 512 U.S. 218 (1994), is instructive. In that case, the Supreme Court rejected an agency’s assertion of authority—similar to the assertion here—to create exceptions to statutory requirements. *Id.* at 234. There, the statutory scheme at issue required that “[e]very common carrier . . . shall . . . file” tariffs, and also granted the Federal Communications Commission (“FCC”) the authority to

“modify any requirement made by or under the authority of this section.” *Id.* at 224 (quoting 47 U.S.C. § 203). The FCC asserted that the grant of authority to “modify” the statutory requirements permitted it to eliminate the filing requirement for certain entities altogether. The Supreme Court firmly rejected this view, finding that the FCC’s authority to “modify” statutory requirements did not allow the FCC to make “basic and fundamental changes” to the command of the statute. *Id.* at 225. In a passage particularly on point here, the Supreme Court reasoned that “[i]t is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to ‘modify’ rate-filing requirements.” *Id.* at 231.

The logic of *M.C.I.* compels the conclusion that Congress’s limited delegation to the Agencies does not include authority to create broad exemptions to the Contraceptive Mandate. In *M.C.I.*, the Court held that the agency could not create exceptions for statutorily mandated filing requirements—despite the fact that, there, the text explicitly authorized the agency to “modify” statutory requirements. Here, the statute presents no authority at all to “modify” or waive statutory requirements. As in *M.C.I.*, if Congress intended to grant the Agency such broad authority, it has the means available to it to do so. See *Whitman v. Am. Trucking Ass’n*, 531 U.S. 457, 468 (2001) (“Congress . . . does not . . . hide elephants in mouseholes.”).

Defendants argue to the contrary that the text and structure of the ACA permit the Agencies to issue the Final Rules, primarily thanks to the use of the word “as” in the Women’s Health Amendment. They note that the Women’s Health Amendment follows immediately after—and differs slightly from—another subsection of the ACA that speaks to preventive care coverage, for children. Specifically, the Women’s Health Amendment mandates coverage for

“preventive care and screenings . . . **as provided for in** comprehensive guidelines supported by [HRSA],” while the subsection pertaining to children mandates coverage for “preventive care and screenings **provided for in the** comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a)(3)–(4) (emphasis added). Proceeding from the statutory maxim that statutes “must be interpreted, if possible, to give each word some operative effect,” *Walters v. Metro. Educ. Enter., Inc.*, 519 U.S. 202, 209 (1997), Defendants conclude that the inclusion of the word “as” in the women’s subsection means that HRSA may determine not only the services covered by the ACA, but also the manner or reach of that coverage.

The impact of the word “as” in this instance can be determined by “look[ing] to dictionary definitions to determine the ordinary meaning of a word,” while bearing in mind that “statutory language must be read with reference to its statutory context.” *Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 200 (3d Cir. 2015) (internal quotation marks omitted). The term “as” in this context could mean “[u]sed in comparisons to refer to the extent or degree of something,” “[u]sed to indicate that something happens during the time when something else is taking place,” or “[u]sed to indicate by comparison the way that something happens or is done.” *As*, Oxford English Dictionary Online (January 2018), <https://en.oxforddictionaries.com/definition/as>.

Defendants argue for either the first or third of these definitions, asserting that the “as” here means something like “as you like it.” However, the statutory context indicates that the second definition is the most appropriate. When Congress passed the ACA, HRSA had already promulgated guidelines defining children’s preventive care. HRSA had not yet promulgated such guidelines for women’s preventive care. Thus, the ACA requires coverage “provided for in *the*” preexisting HRSA guidelines for children’s care. The use of the article “the” demonstrates that Congress referred to particular, extant guidelines governing children’s preventive care.

Giving effect to the use of the word “as” with regard to the Women’s Health Amendment leads to the conclusion that Congress used “as” here to indicate that the HRSA guidelines would be *forthcoming*, i.e. in anticipation of HRSA issuing guidelines—not to the conclusion that the ACA implicitly provides the Agencies with the authority to create exemptions.

Further, even if the word “as” is read to “indicate by comparison” the “extent,” “degree” or “way” the Agencies may promulgate guidelines, that definition does not help Defendants, for the following reason. The most natural comparison available in the statute—as Defendants recognize—would be to the pre-ACA children’s health preventive services guidelines. And comparing the children’s guidelines to the women’s guidelines ultimately undermines Defendants’ reading of the statute. That is because the children’s guidelines simply define a list of “preventive care” services—that is, *what* must be covered. See HHS, *Preventive Care Benefits for Children*, available at <https://www.healthcare.gov/preventive-care-children>. They do not include any exemptions to that coverage; indeed, the children’s guidelines do not speak at all to *who* must provide that coverage. And that makes sense because Congress already defined the *who*: any “group health plan” or “health insurance issuer offering group or individual insurance coverage”—the same plans that “shall” cover women’s preventive services without cost sharing. Thus if Congress employed “as” here to create a comparison to the children’s care guidelines, then Congress assuredly did not intend to permit HRSA to craft exemptions to the types of preventive care that would be required. Rather, Congress intended that HRSA would create a parallel set of guidelines, setting forth the types of “preventive care” to be covered, without exception.

The conclusion that the Women’s Health Amendment does not grant HRSA the power to create exemptions is bolstered by other provisions of the ACA. Congress created only a single

exemption from the ACA’s statutory mandate to cover women’s preventive care, for “grandfathered health plans.” 42 U.S.C. § 18011(e)(3). In accordance with the *expressio unius est exclusio alterius* principle, “[w]hen Congress provides exceptions in a statute . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth.” *United States v. Johnson*, 529 U.S. 53, 58 (2000). The fact that there is no religious or moral exemption in the explicit text of the statute, while there is an exemption for grandfathered health plans, militates against finding that Congress authorized the Agencies to create any additional exemptions. Indeed, that interpretation is supported by the legislative history, given that, in 2012, Congress explicitly rejected an attempt to add to the ACA an exemption similar to that contained in the Final Rules. *See* 158 Cong. Rec. S1165 (Mar. 1, 2012); *see also Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147 (2000) (rejection of an agency’s interpretation by Congress is a factor courts consider when determining the meaning of a statute).

For these reasons, the ACA prohibits HRSA from exempting entities from providing such coverage as set forth in the Final Rules. Accordingly, the Final Rules violate the APA and fail at *Chevron*’s Step One.

ii. RFRA

Defendants argue that, even if the ACA does not grant the Agencies authority to issue the Final Rules, RFRA independently enables the Agencies to issue the Final Religious Exemption.²² They assert that the Contraceptive Mandate cannot be brought into accord with RFRA by anything less than the provisions contained in the Final Religious Exemption, and that, as such,

²² It should be noted at the outset that Defendants specifically do not propound this argument with respect to the Final Moral Exemption. Nor could they. RFRA protects a person’s “exercise of religion,” and does not speak to broader moral convictions. 42 U.S.C. § 2000bb-1(a). Thus, because neither the ACA nor RFRA grant the Agencies the authority for it, the Final Moral Exemption must be invalidated.

RFRA “required” the promulgation of the rule. But it is the courts, not the Agencies, that determine RFRA’s reach. And the Final Religious Exemption goes far beyond RFRA’s command.

Congress enacted RFRA in 1993 following the Supreme Court’s decision in *Employment Div., Dep’t of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990). In *Smith*, the Supreme Court held that “the Constitution does not require judges to engage in a case-by-case assessment of the religious burdens imposed by facially constitutional laws,” and thus strict scrutiny did not apply to Free Exercise challenges to laws of general applicability. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2000). Prior to *Smith*, in decisions such as *Sherbert v. Verner*, 374 U.S. 398 (1963), courts employed “a balancing test that took into account whether the challenged action imposed a substantial burden on the practice of religion, and if it did, whether it was needed to serve a compelling government interest,” *Hobby Lobby*, 134 S. Ct. at 2760. With RFRA, Congress sought to restore the pre-*Smith* judicial standard. See 42 U.S.C. § 2000bb(b)(1) (stating that a purpose of the statute is “to restore the compelling interest test as set forth in *Sherbert v. Verner*, 374 U.S. 398 (1963) and *Wisconsin v. Yoder*, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened”); see also *Gonzales*, 546 at 424, 430-31.

In accordance with this goal, RFRA provides that the “Government shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability,” unless “it demonstrates that application of the burden to the person--(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. § 2000bb-1(a)-(b). Accordingly, RFRA has two components. First, the government is prohibited from placing a substantial

burden on religious exercise. If government action does not impose a substantial burden on religion, then RFRA is not implicated. However, if it does, the government action must be struck down unless it is the least restrictive means of furthering a compelling interest.

Despite Defendants' contention that the Agencies may determine what RFRA demands with respect to the ACA, RFRA provides, to the contrary, that it is the courts that are charged with determining RFRA's application. RFRA "explicitly provides a private cause of action," *Mack v. Warden Loretto FCI*, 839 F.3d 286, 301 (3d Cir. 2016), which permits an aggrieved individual to obtain "Judicial Relief," and contemplates them doing so in a "judicial proceeding," 42 U.S.C. § 2000bb-1(c). More specifically, RFRA states that, "[a] person whose religious exercise has been burdened . . . may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." *Id.* RFRA thus commits to the courts the task of determining whether generally applicable laws violate a person's religious exercise: "RFRA . . . plainly contemplates that *courts* would recognize exceptions—that is how the law works. . . . RFRA makes clear that it is the obligation of the courts to consider whether exceptions are required under the test set forth by Congress." *Gonzales*, 546 U.S. at 434 (emphasis in original).

Nevertheless, the Agencies contend that they are independently required to assess how RFRA bears on the Contraceptive Mandate and that their authority to promulgate the Final Religious Exemption flows from that obligation. In years past, the Agencies asserted that the accommodation did not impose a substantial burden on any entity's religious exercise and that guaranteeing cost-free contraceptive coverage did serve several compelling government interests. The Agencies now take the obverse positions: that the accommodation constitutes a substantial burden on the religious exercise of objecting employers and that the contraceptive mandate does

not serve “any compelling interest.” Indeed, they go further—arguing that this new set of views “in itself, is dispositive,” as a matter of law. In essence, they have taken on the quintessentially judicial tasks of determining whether the application of the Contraceptive Mandate to objecting entities constitutes a substantial burden, whether any burden was in furtherance of a compelling government interest, and whether the accommodation was the least restrictive means of accomplishing contraceptive coverage. Having taken on those tasks, the Agencies—based on their independent assessments of these legal questions—now claim that RFRA “requires” the Final Religious Exemption.

Their position is unsustainable for a number of reasons, the foremost being that administrative agencies may not simply formulate a view of a law outside their particular area of expertise, issue regulations pursuant to that view, claim that the law requires those regulations, then seek to insulate their legal determination from judicial scrutiny. It is axiomatic that under our constitutional system, “[i]t is emphatically the province and duty of the judicial department to say what the law is.” *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). Nothing about RFRA warrants departure from this general maxim. To the contrary, RFRA specifically provides only for “Judicial Relief,” 42 U.S.C.A. § 2000bb-1(c), thereby committing interpretative authority to the courts—not to agencies. *See Gonzales*, 546 U.S. at 434; *see also Real Alternatives, Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338, 356 (3d Cir. 2017) (“[I]t is for the reviewing court to determine whether a burden is ‘substantial.’”). Indeed, in the *Hobby Lobby* decision, the Supreme Court found that agency action violated RFRA, without ever suggesting that the agency’s interpretation was entitled to deference. *See Hobby Lobby*, 134 S. Ct. at 2775-85 (analyzing whether the Contraceptive Mandate violated RFRA, without discussion of deference to agency view); *see also* Thomas W. Merrill, *Step Zero After*

City of Arlington, 83 Fordham L. Rev. 753, 759 (2014) (“[T]he [Supreme] Court has never suggested that trans-substantive statutes like the Administrative Procedure Act (APA) or the Religious Freedom Restoration Act (RFRA) should be interpreted by giving deference to agency interpretations.”).

Nevertheless, Defendants cast their new legal contentions as reasonable policy decisions within their ambit of expertise. Of course, where a statute leaves gaps for an agency to fill, the agency may change its interpretation so long as it provides a “reasoned explanation for the change.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). However, what Defendants attempt to do here is not a change of interpretation regarding an ambiguous statute they are tasked with administering. Rather, Defendants are baldly asserting—with respect to a statute that does not explicitly delegate them any authority—what RFRA “requires.” Defendants have no expertise in administering RFRA. *See Gonzales*, 546 U.S. at 434; *see also Real Alternatives*, 867 F.3d at 356; *Iglesia Pentecostal Casa De Dios Para Las Naciones, Inc. v. Duke*, 718 F. App’x 646, 653 (10th Cir. 2017) (holding that the question of whether a RFRA violation exists is “a legal determination that Congress has not exclusively entrusted to” agencies) (internal quotation marks omitted). While Defendants may change course in their legal assessment of what RFRA commands, this is not the final word. Ultimately, it is up to the courts to decide.

It is true, as Defendants point out, that there is a great deal of “legal uncertainty” about RFRA’s precise application to the Contraceptive Mandate. But on the specific question presented here—whether RFRA “requires” the Final Religious Exemption—the law is clear.

To set out Defendants’ position in greater detail, yet another review of *Hobby Lobby* is in order. There, the Supreme Court held that “[t]he contraceptive mandate, as applied to closely

held corporations, violates RFRA.” 134 S. Ct. at 2785. The Supreme Court reasoned that the Contraceptive Mandate imposed a substantial burden on the religious exercise of the plaintiffs—closely held corporations—and that the burden was not the least restrictive means of providing contraceptive coverage to women. With specific regard to the least restrictive means element, the Supreme Court explained that the Agencies had already created a less restrictive means to both ensure women had contraceptive coverage and reduce the burden on religious objectors: the accommodation. *Id.* at 2781-82. As noted, the accommodation allowed eligible religious objectors to notify their healthcare administrator of their religious objection, and the administrator would then have to provide the legally required contraceptive services directly to women covered under the employer’s plan. Because the accommodation “[did] not impinge on the plaintiffs’ religious belief that providing insurance coverage for the contraceptives at issue here violates their religion,” and still accomplished the government’s goal of providing contraceptive coverage, the Supreme Court found that the Contraceptive Mandate, as applied to the plaintiffs, was not the least restrictive means, and thus violated RFRA. *Id.* at 2782. Importantly, the Supreme Court reserved on the question of “whether an approach of this type complies with RFRA for purposes of all religious claims.” *Id.* Following *Hobby Lobby*, in *Zubik*, the Supreme Court declined to decide the question of whether the accommodation itself imposed a substantial burden on plaintiff nonprofits’ religious exercise; instead, it remanded so that the parties might come to a resolution on their own, whereby the plaintiffs’ employees could receive contraceptive coverage without the plaintiffs’ having to submit the form required by the accommodation. 136 S. Ct. at 1559-60.

Based on these rulings, Defendants assert that RFRA “requires” the Religious Exemption, because their previous attempts to satisfy RFRA with the accommodation failed.

This theory rests on three legal conclusions: (1) a blanket exemption from the Contraceptive Mandate for religious objectors strays no further than RFRA demands; (2) the accommodation did not relieve the substantial burden identified by the Supreme Court in *Hobby Lobby*; and, (3) the contraceptive mandate imposes a substantial burden on publicly traded corporations. But each of these views is either incorrect under the law—as previously determined by precedential rulings—or a significant extension of existing doctrine. Accordingly, Defendants have stepped beyond the demands of RFRA, and the Final Religious Exemption cannot be justified as a “requirement” of RFRA.

As to the first conclusion—that a blanket exemption for religious objectors goes no further than RFRA demands—a close read of *Hobby Lobby* demonstrates that the Agencies’ conclusion is incorrect. There, the Supreme Court explained that an exemption akin to the Final Religious Exemption goes beyond RFRA’s requirements. 134 S. Ct. at 2775 n.30. More specifically, prior to enacting the ACA, Congress had considered but ultimately voted down a ‘conscience amendment,’ which, like the Final Religious Exemption, enabled an employer or insurance provider to deny coverage based on its asserted religious beliefs. *Id.* The *Hobby Lobby* majority concluded it was “reasonable to believe that” Congress rejected the amendment because such a “blanket exemption” for religious objectors “extended more broadly than the . . . protections of RFRA.” *Id.* That is because “it would not have subjected religious-based objections to the judicial scrutiny called for by RFRA, in which a court must consider not only the burden of a requirement on religious adherents, but also the government’s interest and how narrowly tailored the requirement is.” *Id.* Thus, as the *Hobby Lobby* Court recognized, the blanket exemption the Agencies have set forth “extend[s] more broadly than the . . . protections of RFRA.” Plainly then, RFRA cannot “require” such a rule, which creates precisely this blanket

exemption.

As to the second conclusion—that the accommodation imposes a substantial burden on the religious exercise of objecting entities—Defendants are incorrect under the law of this circuit. While the Supreme Court has not resolved this precise issue, Third Circuit authority demonstrates that, contrary to the Agencies’ view, the accommodation does *not* impose a substantial burden. See *Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015), *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam); see also *Real Alternatives*, 867 F.3d at 356 n.18. The accommodation has been specifically upheld against a RFRA challenge by the Third Circuit, first, and directly, in *Geneva Coll.*, 778 F.3d at 442, and second, by implication, in *Real Alternatives*, 867 F.3d at 356 n.18. Defendants argue that *Geneva* is no longer good law because it was vacated by the Supreme Court in *Zubik*. But the Supreme Court in *Zubik* specifically declined to decide the merits of the RFRA challenge to the accommodation, by explicitly refraining from “decid[ing] whether petitioners’ religious exercise has been substantially burdened.” 136 S. Ct. at 1560. Instead, the Supreme Court vacated *Geneva* (and related decisions from other Circuit courts) and remanded for the express purpose of allowing the parties “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans receive full and equal health coverage, including contraceptive coverage.” *Id.*

Following *Zubik*, the Third Circuit reiterated in *Real Alternatives* that it “continue[s] to believe . . . that the regulation at issue”—the accommodation—“did not impose a substantial burden.” *Real Alternatives*, 867 F.3d at 356 n.18. Defendants characterize this statement as dicta, and indeed, the issues in the two cases were slightly distinct. In *Geneva*, nonprofits

eligible for the accommodation asserted that filling out the accommodation form “facilitated” or “triggered” the provision of contraceptives, thereby substantially burdening their religious exercise. 778 F.3d at 427. In *Real Alternatives*, employees of a secular employer similarly asserted that the Contraceptive Mandate violated RFRA because their purchase of insurance enabled the provision of contraceptives. 867 F.3d at 359. What Defendants overlook is that in *Real Alternatives* the Third Circuit reaffirmed and reapplied the reasoning of *Geneva*. In both cases, the Third Circuit found that there was no substantial burden on the plaintiffs’ religious exercise because their actions were insufficiently related to the provision of contraceptives and “an independent obligation on a third party can[not] impose a substantial burden on the exercise of religion in violation of RFRA.” *Id.* at 364 (quoting *Geneva*, 778 F.3d at 440-41).

Accordingly, applying the law of this circuit as announced in *Real Alternatives*, the accommodation does not impose a substantial burden on religious exercise.

The third conclusion—that the Contraceptive Mandate imposes a substantial burden on the religious exercise of publicly traded corporations—goes considerably beyond existing jurisprudence. In *Hobby Lobby*, the Supreme Court found that the Contraceptive Mandate imposed a substantial burden on the specific plaintiffs in that case: “closely held corporations, each owned and controlled by members of a single family.” 134 S. Ct. at 2774. It explicitly declined to extend its holding to publicly traded corporations, suggesting that publicly traded corporations would be unlikely to hold a singular, sincere religious belief:

These cases, however, do not involve publicly traded corporations, and it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable. In any event, we have no occasion in these cases to consider RFRA’s applicability to

such companies.

Id. Defendants assert that it is reasonable to include publicly traded corporations in the Religious Exemption. But, as *Hobby Lobby* makes clear, RFRA does not “require” this expansion.

Thus, even if the Agencies are correct that the accommodation imposes a substantial burden on religious employers, and that they must act, through regulation, to relieve that burden,²³ the Final Religious Exemption sweeps further than RFRA would require. The Agencies’ willingness to exceed the bounds of existing case law demonstrates that the Agencies have cast aside RFRA’s mandate for “judicial scrutiny . . . in which a *court* must consider not only the burden of a requirement on religious adherents, but also the government’s interest and how narrowly tailored the requirement is.” *Id.* at 2775 n.30 (emphasis added). Accordingly, the

²³ Defendants contend that the Final Rules—like earlier rules that created the exemption and accommodation framework—are merely the Agencies’ attempts to respond to the Supreme Court’s decisions in *Hobby Lobby*, *Wheaton College*, and *Zubik*. After each of those decisions, the Agencies promulgated generally applicable regulations that expanded or modified the exemption and accommodation framework in an attempt to bring the Agencies’ actions in line with what the Supreme Court said RFRA commands. According to Defendants, that is all that is happening here, the only difference being the States have now challenged the Agencies’ authority to do so.

Fair enough. Nonetheless, this challenge raises a fundamental question: whether RFRA grants agencies independent authority to issue regulations of general applicability, like the Final Religious Exemption. It is worth noting that the scope of affirmative authority, if any, that RFRA grants to agencies to issue regulations of general applicability—whether in response to judicial interpretations of RFRA or based on their own assessments of RFRA’s application—is distinctly undetermined. Neither *Hobby Lobby*, nor *Wheaton College*, nor *Zubik* resolved this question—nor, does it appear, has any other court. The statutory language does not provide a clear answer. On the one hand, RFRA “applies to all Federal law, *and the implementation of that law*, whether statutory or otherwise,” which could possibly be read to grant agencies some authority to promulgate regulations on a generalized basis. 42 U.S.C. § 2000bb-3(a) (emphasis added). However, RFRA is fundamentally a remedial measure, that by its terms “provide[s] a claim or defense to persons whose religious exercise is substantially burdened by government,” *id.* at § 2000bb(b)(2), in a “*judicial proceeding*” in order to “obtain appropriate relief against a government,” *id.* at § 2000bb-1(c) (emphasis added). *See also Hobby Lobby*, 134 S. Ct. at 2775 n.30; *Gonzales*, 546 U.S. at 430-31, 434. Indeed, quite recently, the federal government suggested that RFRA does not permit an agency to create exemptions to regulations absent a judicial determination, albeit in a case that did not focus on this issue in great depth. *See Iglesia Pentecostal*, 718 F. App’x at 653 (recounting federal government’s position that “[a]bsent a judicial finding that the regulation violates RFRA, neither the director of USCIS nor the AAO has any discretion to set aside any provision of those regulations.”) (brackets omitted).

Put simply, it is not clear what, if any, affirmative authority RFRA grants to agencies to issue regulations of general applicability. The parties do not point to any authority that resolves this question. Nor has independent research yielded definitive answers. While this large question looms in the background, the Court need not decide it here. Whatever the extent of an agency’s authority under RFRA, the Agencies here have exceeded it in promulgating the Final Religious Exemption.

Religious Exemption cannot be justified under RFRA.

Because neither the ACA nor RFRA confer authority on the Agencies to promulgate the Religious Exemption, the rule is invalid.²⁴

* * *

In light of these conclusions, the States have demonstrated an adequate likelihood of success on the merits in support of their motion for preliminary relief.

3. Irreparable Harm

The second factor to consider in deciding the States’ motion is whether they have demonstrated that they are likely to suffer irreparable harm in the absence of a preliminary injunction. The Supreme Court’s “frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction.” *Winter*, 555 U.S. at 22 (emphasis in original); *see id.* (“Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with the characterization of injunctive relief as an extraordinary remedy that may be awarded only upon a clear showing that the plaintiff is entitled to such relief.”). The States assert that they will suffer two forms of irreparable harm in the absence of an injunction: (1) significant damage to the States’ fiscal integrity; and (2) harm to the health, safety, and wellness of the women of Pennsylvania and New Jersey. The Court finds both sufficient to justify preliminary relief.

As to the harm to the States’ fiscal integrity, the States’ evidence demonstrates that it is likely that the Final Rules will cause direct and irreparable harm. The States will become

²⁴ Given its holding that Defendants violated the procedural and substantive provisions of the APA in issuing the Final Rules, and in view of the admonition that “courts should be extremely careful not to issue unnecessary constitutional rulings,” *American Foreign Serv. Ass’n v. Garfinkel*, 490 U.S. 153, 161 (1989) (per curiam), it is unnecessary to proceed to the constitutional issues. Similarly, because the Final Rules violate the substantive provisions of the APA for the reasons given, there is no need to reach the States’ other statutory challenges to the Final Rules.

obligated to shoulder much of the burden of providing contraceptive services to women who lose contraceptive care because their health plans take advantage of the expanded exemptions contained in the Final Rules. See Steinberg Decl. ¶¶ 27-29 (discussing Pennsylvania); Geenace Decl. ¶¶ 15-17 (discussing New Jersey). Such women will seek contraceptive services elsewhere and, as Defendants noted in issuing the IFRs, may turn to “multiple . . . State[] and local programs that provide free or subsidized contraceptives for low-income women” for alternative coverage. See 82 Fed. Reg. at 47,803. In Pennsylvania, these state funded programs include: Medicaid, called “Medical Assistance;” the Family Planning Service Program; and the Commonwealth’s network of clinics funded under the Title X grant program. See Allen Decl. ¶¶ 3-18; Steinberg Decl. ¶ 16. New Jersey funds similar programs through Medicaid, known as “NJ Family Care,” and the State’s Plan First Program. Adelman Dec. ¶¶ 9-14. As women in the States lose contraceptive coverage through their health insurance plans and turn to state-funded programs, it is likely that the States will bear the added financial burden occasioned by the increase in women who need contraceptive care coverage. See Mendelsohn Decl. ¶¶ 15-18; Allen Decl. ¶ 23; Geenace Decl. ¶¶ 15-18.

The States’ harm is not merely speculative; it is actual and imminent. The Final Rules estimate that at least 70,500 women will lose coverage. See 83 Fed. Reg. at 57,578.²⁵ Thus, the only serious disagreement is not whether the States will be harmed, but *how much*. Though Defendants argue that the States have not identified any individual who has lost coverage already, there is no need to wait for the axe to fall before an injunction is appropriate, particularly where Defendants have estimated that it is about to fall on thousands of women—and, as a corollary, on the States. See *Texas*, 809 F.3d at 186 (granting relief based on predicted

²⁵ The States argue that there is reason to believe the number is significantly higher because organizations taking advantage of the exemption need not inform the Agencies of their plan to do so.

harm to States' fiscs).

While “loss of money” is generally insufficient to merit a preliminary injunction, *see Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989), here, the harm to the States' fiscs is irreparable because they will not be able to recover any economic damages that result from the Final Rules. That is because a party—like the States here—which alleges an APA violation may not recover monetary damages from the federal government on that claim. *See* 5 U.S.C. § 702 (permitting relief “other than money damages”); *California*, 911 F.3d at 581 (finding irreparable harm in APA case on similar grounds). Therefore, if the Final Rules are ultimately struck down as violative of the APA, the States will not be able to recoup any money they expend on contraceptive care in the interim. In such circumstances, a preliminary injunction is appropriate. *See, e.g., N.J. Retail Merchants Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012) (holding that a preliminary injunction is appropriate where a movant could not recover damages from a State due to sovereign immunity).

In addition to pecuniary harm, the States also stand to suffer injury to their interest in protecting the safety and well-being of their citizens. *See Alfred L. Snapp*, 458 U.S. at 607 (observing that a State has a “quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general”). The States' witnesses explained that employers taking advantage of the Final Rules will result in more women losing no-cost contraceptive coverage. Mendelsohn Decl. ¶¶ 14-15; Adelman Decl. ¶ 20. As a result, women will likely forgo contraceptive services or seek out less expensive and less effective types of contraceptive services in the absence of no-cost insurance coverage. Weisman Decl. ¶¶ 45-48; Chuang Decl. ¶¶ 36-39; *see also* Adam Sonfield, *What is at Stake with the Federal Contraceptive Coverage Guarantee?*, 20 Guttmacher Policy Review 8, 9 (2017) (reporting that women cite cost as a

significant factor in determining whether to purchase contraceptive services and which contraceptive services to use). Disruptions in contraceptive coverage will lead to women suffering unintended pregnancies and other medical consequences. Butts Decl. ¶¶ 57-59; Institute of Medicine, *Clinical Prevention Services* at 107 (explaining that contraceptive services are used to treat menstrual disorders, acne, hirsutism, and pelvic pain, in addition to assisting family planning and birth spacing).²⁶ The negative effects of even a short period of decreased access to no-cost contraceptive services are irreversible.

The States have therefore showed that they are likely to suffer irreparable harm as a result of the Rules' impact on both the States' fiscs and the welfare of the States' citizens.

4. Balance of the Equities

The third factor is that the balance of the equities tips in favor of granting a preliminary injunction. "Balancing the equities" is jurisprudential "jargon for choosing between conflicting public interests." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1943) (Frankfurter, J., concurring). Here, Congress has already struck the balance: the Women's Health Amendment was intended to ensure women received no-cost coverage for preventive services, which includes contraceptives. As lead sponsor of the Women's Health Amendment, Senator Barbara Mikulski, explained: the amendment "leaves the decision of which preventive services a patient will use between the doctor and the patient." 155 Cong. Rec. S11988 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). Congress enacted the Women's Health Amendment to guarantee that "the decision about what is medically appropriate and medically necessary is between a woman and her doctor." *Id.* Where "Congress itself has struck the balance, [and] has

²⁶ Increased unplanned pregnancies will also inflict additional pecuniary harm on the States. See Steinberg Decl., ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

defined the weight to be given the competing interests, a court of equity is not justified in ignoring that pronouncement under the guise of exercising equitable discretion.” *Youngstown Sheet*, 343 U.S. at 609-10.

Here, given the States’ clear interest in securing the health and well-being of women residents and limiting their costs for contraceptive services, the balance of the equities weighs in their favor. Defendants will not be substantially prejudiced by a preliminary injunction. If the Final Rules were issued in violation of applicable law, they will have suffered no harm. If Defendants ultimately prevail, then a preliminary injunction will have merely delayed their preferred regulatory outcome.

5. Public Interest

“If a plaintiff proves both a likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interests favors preliminary relief.” *Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 143 (3d Cir. 2017) (internal quotation marks omitted). So it proves here. A preliminary injunction is unquestionably in the public interest because it maintains the status quo pending the outcome of this litigation. The Final Rules permit any entity to opt out of coverage after 30 to 60 days’ notice to plan members. This litigation will not conclude in that short span. A preliminary injunction will maintain the status quo: those eligible for exemptions or accommodations prior to October 6, 2017 will maintain their status; those with injunctions preventing enforcement of the Contraceptive Mandate will maintain their injunctions;²⁷ those alleging RFRA violations may pursue “Judicial Relief;” and those with coverage will maintain their coverage as well.

²⁷ For example, Defendant-Intervenor has secured a permanent injunction, preventing enforcement of the Contraceptive Mandate against it. See *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611, Dkt. 82 (D. Colo. May 29, 2018). Nothing in this Court’s ruling will disturb that order.

D. Remedy

Before concluding, an additional word is required on the scope of the preliminary injunction to be issued. When the IFRs were initially before this Court, they were enjoined generally, without any specific geographic or temporal limitation. *See Pennsylvania*, 281 F. Supp.3d at 585.

Since then, however, much has been made about the propriety (or impropriety) of so-called nation-wide injunctions. *See, e.g., Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring); Zayn Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. 2095 (2017); Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev. 417 (2017). In light of this increased focus on the proper exercise of district courts' remedial powers, it is prudent to explain in some detail why a nation-wide injunction is appropriate here.

First, it is well established that a district court sitting in equity has the *authority* to enter a nation-wide injunction. *See Lemon v. Krentler-Arnold Hinge Last Co.*, 284 U.S. 448, 451 (1932) (holding district court's order "binding upon the respondent, not simply within the District of Massachusetts, but throughout the United States"); *Texas*, 809 F.3d at 188 ("[T]he Constitution vests the District Court with 'the judicial power of the United States.' That power is not limited to the district wherein the court sits but extends across the country.") (quoting U.S. Const. art. III, § 1); *McLendon v. Cont'l Can Co.*, 908 F.2d 1171, 1182 (3d Cir. 1990) (holding "[f]ull relief required a nationwide injunction"). The issue, then, is whether a nation-wide injunction is appropriate here, given the facts of this specific case.

"In shaping equity decrees, the trial court is vested with broad discretionary power." *Lemon v. Kurtzman*, 411 U.S. 192, 200 (1973) (plurality opinion). That is because crafting

equitable remedies is an inexact science; instead, “equitable remedies are a special blend of what is necessary, what is fair, and what is workable.” *Id.*; see also *Trump v. Int’l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (“Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents.”). As Justice Douglas succinctly put it seventy-five years ago: “[t]he essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it.” *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944).

The Supreme Court articulated the relevant standard for determining the proper scope of a preliminary injunction in *Califano v. Yamasaki*, 442 U.S. 682 (1979), stating that “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.” *Id.* at 702 (emphasis added). Subsequent Supreme Court and lower court decisions have treated the “no more burdensome than necessary” rubric as the “general rule” for determining whether an injunction is overbroad. *Madsen v. Women’s Health Center, Inc.*, 512 U.S. 753, 765 (1994); see also *Trump*, 137 S. Ct. at 2090 (Thomas, J., concurring in part and dissenting in part); see also *McLendon*, 908 F.2d at 1182 (“In granting injunctive relief, the court’s remedy should be no broader than necessary to provide full relief to the aggrieved plaintiff.”).²⁸

The *Califano* standard requires district courts to balance the competing principles of providing complete relief to meritorious plaintiffs against a defendant’s right to be free from overly burdensome injunctions. The complete relief requirement reflects the “well-settled principle that the nature and scope of the remedy are to be determined by the violation.”

²⁸ In *Califano*, the Court indicated that the “no more burdensome than necessary” standard is a general rule of injunctions, regardless of whether a nation-wide class-action is certified. See 442 U.S. at 702.

Milliken v. Bradley, 433 U.S. 267, 281-82 (1977). Where a violation has been found, “the remedy does not ‘exceed’ the violation if the remedy is tailored to cure the ‘condition that offends [the law.]’” *Id.* at 282 (quoting *Milliken v. Bradley*, 418 U.S. 717, 738 (1974)).

The complete relief principle explains why, in APA cases, “when a reviewing court determines that agency regulations are unlawful, the *ordinary result* is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Nat’l Min. Ass’n v. U.S. Army Corps of Eng’rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (internal quotation marks omitted and emphasis added). Where “agency action . . . consist[s] of a rule of broad applicability” that violates the strictures of the APA, *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 913 (Blackmun, J., dissenting),²⁹ a remedy “tailored to cure the condition that offends [the law]” may be correspondingly broad, *Milliken*, 433 U.S. at 282 (internal quotation marks omitted). Thus, when an individual challenges agency action and prevails, “the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual.” *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting).³⁰ Put differently, the national character of an APA violation “ordinar[ily]” demands a national remedy. *Nat’l Min. Ass’n*, 145 F.3d at 1409.

At the same time, the Supreme Court has warned that injunctions should be “no more burdensome to the defendants than necessary.” *Califano*, 442 U.S. at 702. Over fifty years ago, Justice Fortas cautioned:

[A]rming each of the federal district judges in this Nation with power to enjoin enforcement of regulations and actions under the federal law designed to protect the people of this Nation. . . is a general hunting license; and I respectfully submit, a license for mischief because it authorizes aggression

²⁹ In *Nat’l Min. Ass’n*, the D.C. Circuit explained that, while Justice Blackmun’s observations came in a dissent, they “apparently express[ed] the view of all nine Justices on this question.” 145 F.3d at 1409.

³⁰ Indeed, at least one scholar has argued that the language of the APA—providing that a reviewing court “shall . . . hold unlawful and set aside” agency action that is arbitrary or capricious, 5 U.S.C. § 706—requires courts to vacate all unlawful agency actions. See Brian S. Prestes, *Remanding Without Vacating Agency Action*, 32 Seton Hall L. Rev. 108, 110 (2001).

which is richly rewarded by delay in the subjection of private interests to programs which Congress believes to be required in the public interest.

Toilet Goods Ass’n v. Gardner, 387 U.S. 167, 183 (1967) (Fortas, J., dissenting). More recently, the Supreme Court has warned that overbroad injunctions “have detrimental effect[s] by foreclosing adjudication by a number of different courts and judges,” which “often will be preferable in order to gain the benefit of adjudication by different courts in different factual contexts.” *Califano*, 442 U.S. at 701-02; *California*, 911 F.3d at 583 (raising same concern). In addition, courts worry that overly broad injunctions invite “forum shopping, which hinders the equitable administration of laws.” *California*, 911 F.3d at 583 (citing *Bray, Multiple Chancellors*, 131 Harv. L. Rev. at 458-59).

The concerns about overbroad injunctions carry into APA cases. Courts have, at times, resisted granting nation-wide relief, even where “agency action . . . consist[s] of a rule of broad applicability.” *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting); *see, e.g., California*, 911 F.3d at 584 (finding an APA violation, but concluding “the scope of the preliminary injunction is overbroad”); *Baeder v. Heckler*, 768 F.2d 547, 553 (3d Cir. 1985) (holding regulation invalid, but determining district court did not have “the authority to issue an injunction aimed at controlling [Agency’s] behavior in every . . . case in the country”). Thus, while an APA violation may “ordinar[ily]” result in a nation-wide remedy, the potential dangers of an overbroad injunction must still be weighed when crafting a remedy for an APA violation.

The upshot is that striking the appropriate balance between providing complete relief to meritorious plaintiffs, on the one hand, and protecting defendants from overly burdensome injunctions, on the other, is necessarily a difficult line-drawing exercise, even in APA cases.

To see why, recall the injury the States stand to suffer from enforcement of the Final Rules: both Pennsylvania and New Jersey complain that, because enforcement of the Final Rules

will result in “numerous insureds—and their female dependents—[losing] the medical coverage for contraceptive care required by the Affordable Care Act,” the States will suffer “significant, direct and proprietary harm” in the form of increased use of state-funded contraceptive services as well as increased costs associated with unintended pregnancies. Affording complete relief to the States would require the Court to enjoin enforcement of the Final Rules as to all entities that “offer[] and arrange[]” health insurance to insureds residing in Pennsylvania or New Jersey.³¹

But drafting—much less enforcing—a preliminary injunction that runs only to those entities is nigh impossible. Neither the Court nor the parties can readily ascertain what those entities are or whether they intend to take advantage of the exemption, given that providing notice to the Agencies is only optional under the Final Rules. At the same time, the Court cannot, consistent with Rule 65 of the Federal Rules of Civil Procedure simply and broadly enjoin “all entities that offer and arrange health insurance to insureds residing in Pennsylvania or New Jersey.” That is because “[e]very order granting an injunction . . . must . . . state its terms specifically and describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained.” Fed. R. Civ. P. 65 (internal punctuation omitted).

Given the challenges associated with crafting a “perfect” injunction, district courts tend to rely on geographic proxies when tailoring a remedy. For example, the Ninth Circuit—hearing an appeal from a district court decision that also enjoined the enforcement of the IFRs nationwide—held that “an injunction that applies only to the plaintiff states would provide complete relief to them.” *California*, 911 F.3d at 584; *see also California v. Health & Human Servs.*, ---

³¹ Even that may not provide complete relief because a non-resident that lost contraceptive coverage may try to take advantage of the States’ programs. *Cf. Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2304 (2016) (explaining that, following the enactment of a Texas regulation that would force the closure of abortion clinics in west Texas, “the Court of Appeals said that women in El Paso wishing to have an abortion could use abortion providers in nearby New Mexico”).

F. Supp. ---, No. 17-cv-5783, ECF No. 234 (N.D. Cal. 2019) (enjoining enforcement of Final Rules within plaintiff States only). Defendants similarly argue that, if the Final Rules are to be enjoined, then the injunction should be limited to Pennsylvania and New Jersey.

The problem with the Ninth Circuit’s approach, however, is that it simply does not afford the meritorious plaintiffs—the States—complete relief. Hundreds of thousands of the States’ citizens travel across state lines—to New York, Ohio, Delaware, Maryland, West Virginia and even further afield—to work for out-of-state entities. *See* Amici Curiae Brief of Massachusetts, *et al.* in Support of Plaintiffs’ Motion for a Preliminary Injunction, at 13-14 (2019) (noting that “548,040 New Jersey residents, or 14% of the workforce, and 299,970 Pennsylvania residents, or 5.4% of the workforce” travel to jobs in other states) (citing U.S. Census Bureau, *Out-of-State and Long Commutes: 2011, American Community Survey Reports*, at 10 (Feb. 2013), *available at* <https://www2.census.gov/library/publications/2013/acs/acs-20.pdf>). Furthermore, with their many universities and educational institutes, the States take in tens of thousands of out-of-state students each year. *Id.* at 14 (noting that Pennsylvania takes in 32,000 out-of-state students alone) (citing Nat’l Ctr. for Education Statistics, *Residence and Migration of All First-Time Degree/Certificate-Seeking Undergraduates* (2017), *available at* https://nces.ed.gov/programs/digest/d17/tables/dt17_309.20.asp?current=ye).

An injunction limited to Pennsylvania and New Jersey would, by its terms, not reach Pennsylvania and New Jersey citizens who work for out-of-state employers. Despite residing in the States, those out-of-state workers could lose contraceptive coverage if the out-of-state employers took advantage of the exemptions included in the Final Rules, resulting in proprietary harm to the States. Nor would an injunction limited to the States cover out-of-state students attending school in Pennsylvania and New Jersey, who may not be considered “residents” of the

States. Such students, by remaining on their parents' out-of-state employer-based health plans or other health insurance through their State of "residency," could lose contraceptive coverage but still turn to in-state publicly-funded clinics for contraceptive coverage. Put differently, "an injunction that applies only to the plaintiff states" *would not* "provide complete relief to them" because it *would not* "prevent the economic harm extensively detailed in the record." *California*, 911 F.3d at 584.

Injunctions that are intermediate in geographic scope—that is, applicable beyond the States but not nation-wide—encounter the same problems in ensuring "complete relief to the plaintiffs." *Madsen*, 512 U.S. at 765. An injunction limited to the Third Circuit, for example, would fail to account for the thousands of Pennsylvania and New Jersey citizens that commute to neighboring or nearby states outside the Third Circuit for work. Similarly, an injunction covering the surrounding states would not account for the fact that the States draw out-of-state students from across the nation.

At the same time, the Court recognizes that, on the record before it, a nation-wide injunction may prove "broader than necessary to provide full relief" to the States. *McLendon*, 908 F.2d at 1182. The States concede, for example, that there is no evidence that any citizen of the States physically commutes to New Mexico, so an injunction that covers the Land of Enchantment appears "broader than unnecessary." Nor have the States presented evidence of a New Mexican that currently attends a Pennsylvania or New Jersey institute of higher learning, who may lose her contraceptive coverage through her out-of-state insurance. The same can be said for a host of other states.

Ultimately, crafting a remedy that provides "complete relief to the plaintiffs," while being "no more burdensome to the defendant than necessary" would require empirical data—the

working conditions of each and every citizen of the States—that is simply not ascertainable.³² In the absence of such information, the Court must exercise “discretion and judgment,” *Trump*, 137 S. Ct. at 2087, in balancing the competing risks and uncertainties associated with either a potentially under- or over-inclusive remedy, bearing in mind the maxim that “[w]e should not allow the infeasible perfect to oust the feasible good.” *Resorts Int’l Hotel Casino v. NLRB*, 996 F.2d 1553, 1558 (3d Cir. 1993) (internal quotation marks and alternations omitted).

On balance, the Court finds that, in this case, potential over-inclusiveness is the more prudent route. For one, anything short of a nation-wide injunction would likely fail to provide the States “complete relief.” *Cf. Texas*, 809 F.3d at 188 (“[T]here is a substantial likelihood that a geographically-limited injunction would be ineffective because DAPA beneficiaries would be free to move among states,” which would leave Texas open to potential injury); *see also* Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. at 2146-47 (“If one agrees with the district court that Texas suffers some injury from having deferred action beneficiaries within its territorial boundaries, the only way to afford *complete* relief to Texas and prevent any deferred action beneficiaries from making their way to Texas is by enjoining the grant of deferred action nationwide.”). While a nation-wide injunction may prove overbroad, there is no more geographically limited injunction that protects the States from potential harm.

Second, it is far from clear how burdensome a nation-wide injunction would be on Defendants, given that when “agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Nat’l Min. Ass’n*, 145 F.3d at 1409.

³² This is neither an explicit or implicit critique of the parties. Rather, it is the frank observation that crafting a perfect remedy would require information that would be insurmountable to gather and maintain.

Third, one of the risks associated with a nation-wide injunction—namely, “foreclosing adjudication by a number of different courts,” *Califano*, 442 U.S. at 701-02—is not necessarily present here, as the parallel litigation in the Ninth Circuit evidences. *See also* Spencer E. Amdur & David Hausman, *Nationwide Injunctions and Nationwide Harm*, 131 Harv. L. Rev. F. 49, 53 n.27 (2017) (noting that “in practice, nationwide injunctions do not always foreclose percolation,” and giving several recent examples).

Fundamentally, given the harm to the States should the Final Rules be enforced—numerous citizens losing contraceptive coverage, resulting in “significant, direct and proprietary harm” to the States in the form of increased use of state-funded contraceptive services, as well as increased costs associated with unintended pregnancies—a nation-wide injunction is required to ensure complete relief to the States.

An appropriate order follows.

January 14, 2019

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF
PENNSYLVANIA AND STATE OF NEW
JERSEY,

Plaintiffs,

v.

DONALD J. TRUMP, ALEX M. AZAR II,
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
STEVEN T. MNUCHIN, UNITED STATES
DEPARTMENT OF THE TREASURY,
RENE ALEXANDER ACOSTA, THE
UNITED STATES DEPARTMENT OF
LABOR, AND THE UNITED STATES OF
AMERICA,

Defendants,

LITTLE SISTERS OF THE POOR
SAINTS PETER AND PAUL HOME,

Defendant-Intervenor.

CIVIL ACTION

NO. 17-4540

ORDER

AND NOW, this 14th day of January, 2019, upon consideration of the Plaintiffs' Second Motion for a Preliminary Injunction (ECF No. 90), Defendants' and Defendant-Intervenor's Responses thereto (ECF Nos. 107 & 108), the Plaintiffs' Reply in Support thereof (ECF No. 118), the Administrative Record (ECF Nos. 23, 47 & 126), Briefs of the Amici Curiae (ECF Nos. 110, 112, 113, 115, 117 & 127), and following a Hearing on Plaintiffs' Motion on January 10, 2019, **IT IS HEREBY ORDERED** that the Motion is **GRANTED**.

It is **FURTHER ORDERED** that Defendants Alex M. Azar II, as Secretary of the United States Department of Health and Human Service; the United States Department of Health

and Human Services; Steven T. Mnuchin, as Secretary of the United States Department of Treasury; the United States Department of Treasury; Rene Alexander Acosta, as Secretary of the United States Department of Labor; and the United States Department of Labor;¹ and their officers, agents, servants, employees, attorneys, designees, and subordinates, as well as any person acting in concert or participation with them, are hereby **ENJOINED** from enforcing the following Final Rules across the Nation, pending further order of this Court:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); and
2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018).

The Court has considered the issue of security pursuant to Rule 65(c) of the Federal Rules of Civil Procedure and determines that Defendants will not suffer any financial loss that warrants the need for the Plaintiffs to post security.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

¹ In light of the constitutional concerns associated with enjoining the President of the United States for a claim under the Administrative Procedure Act, this injunction does not apply to the President. *See Franklin v. Massachusetts*, 505 U.S. 788, 801 (1992).

CERTIFICATE OF SERVICE

I hereby certify that on February 15, 2019, I electronically filed the foregoing appendix with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Lowell V. Sturgill Jr.
Lowell V. Sturgill Jr.

Nos. 17-3752, 18-1253, 19-1129, and 19-1189

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY,

Plaintiffs-Appellees,

v.

PRESIDENT, UNITED STATES OF AMERICA; SECRETARY,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY,
U.S. DEPARTMENT OF THE TREASURY; U.S. DEPARTMENT OF THE
TREASURY; SECRETARY, U.S. DEPARTMENT OF LABOR; and
U.S. DEPARTMENT OF LABOR,

Defendants-Appellants,

and

LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,

Intervenor-Defendant-Appellant.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

**JOINT APPENDIX
Vol. 2 (pp. 126-803)**

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TABLE OF CONTENTS

Volume 1

Notice of Appeal of the Federal Defendants (Case No. 18-1253) (dkt. no. 68)	1
Notice of Appeal of Defendant-Intervenor the Little Sisters of the Poor (Case No. 17-3752) (dkt. no. 61).....	4
Opinion (interim rules) (dkt. no. 59).....	7
Order (enjoining interim rules) (dkt. no. 60).....	51
Notice of Appeal of the Federal Defendants (Case No. 19-1189) (dkt. no. 139)	53
Notice of Appeal of Defendant-Intervenor the Little Sisters of the Poor (Case No. 19-1129) (dkt. no. 138).....	56
Opinion (final rules) (dkt. no. 136)	59
Order (enjoining final rules) (dkt. no. 135)	124

Volume 2

Docket Sheet	126
Complaint (dkt. no. 1).....	165
Amended Complaint (dkt. no. 89).....	198
Declaration of Kathryn Kost (dkt. no. 90-13).....	234
Declaration of Cynthia H. Chuang (dkt. no. 90-14)	267
Declaration of Carol S. Weisman (dkt. no. 90-15).....	277
Declaration of Samantha F. Butts (dkt. no 90-17).....	288

Declaration of Seth A. Mendelsohn (dkt. no 90-18)	297
Declaration of Leesa Allen (dkt. no 90-19)	301
Declaration of Dayle Steinberg (dkt. no 90-20)	307
Declaration of Sarah Adelman (dkt. no. 90-21).....	314
Declaration of Philip Gennace (dkt. no. 90-22)	319
Declaration of Elizabeth Coulter (dkt. no. 90-23)	324
Supplemental Declaration of Kathryn Kost (dkt. no. 118-3).....	331
Declaration of Mother Superior Marie Vincente (dkt. no. 19-2)	334
Spreadsheet from Administrative Record (Litigating Entities) (dkt. no. 90-24)	350
Spreadsheet from Administrative Record (Accommodation) (dkt. no. 90-25)	357
Spreadsheet from Administrative Record (Litigating Entities) (Bates nos. 00805059-00805065).....	384
Transcript of Preliminary-Injunction Hearing (interim rules) (dkt. no. 69)	391
Declaration and Excerpts from Exhibit to Declaration of Sharita Gruberg (ex. 20 at preliminary-injunction hearing)	645
Transcript of Preliminary-Injunction Hearing (final rules) (dkt. no. ____)	673

Volume 3

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017)*	804
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017)*	848
Comments on Interim Final Rules (dkt. no. 90-26)	873
Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018)	882
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018)	937
Executive Order No. 13,798 (May 4, 2017) (dkt. no. 90-11)	977
Health Resources & Services Administration, Women’s Preventive Services Guidelines (2016) (dkt. no. 90-10)	979
Health Resources & Services Administration, Women’s Preventive Services Guidelines (2011) (dkt. no. 90-9)	984
Excerpts from Institute of Medicine, <i>Clinical Preventive Services for Women: Closing the Gaps</i> (2011) (dkt. no. 90-8)	987
Ashley H. Snyder et al., <i>The Impact of the Affordable Care Act on Contraceptive Use and Costs Among Privately Insured Women</i> (2018) (dkt. no. 90-16)	1036

* “Public inspection” copies of the interim final rules were attached to the complaint. For ease of reference and citation, we have included in the appendix the interim rules as published in the Federal Register.

This case was appealed to

03rd Circuit: [17-3679](#), [17-3752](#), [18-1253](#), [19-1129](#), [19-1189](#)

US District Court Civil Docket

**U.S. District - Pennsylvania Eastern
(Philadelphia)**

2:17cv4540

Commonwealth of Pennsylvania v. Trump et al

This case was retrieved from the court on Tuesday, January 29, 2019

Date Filed: 10/11/2017

**Assigned To: Honorable WENDY
BEETLESTONE**

Referred To:

**Nature of
suit: Other Civil Rights (440)**

**Cause: Federal Question: Other Civil
Rights**

Lead Docket: None

Other USCA, 17-03679

Docket: USCA, 17-03752

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USCA, 19-01129

USCA, 19-01189

Jurisdiction: Federal Question

Class Code: OPEN

Closed:

Statute: 28:1331

Jury Demand: None

Demand Amount: \$0

NOS Description: Other Civil Rights

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Date	#	Proceeding Text	Source
10/11/2017	1	COMPLAINT against RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT (Filing fee \$ 400 receipt number 167178.), filed by COMMONWEALTH OF PENNSYLVANIA.(Attachments: # 1 Civil Cover Sheet, # 2 Designation Form, # 3 Case Management Track Form, # 4 Exhibit A, # 5 Exhibit B, # 6 Exhibit C)(ahf) (Entered: 10/12/2017)	
10/11/2017		Summons Issued as to RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT, U.S. Attorney and U.S. Attorney General. Eight Forwarded To: Counsel and One Given to AUSA on 10/12/2017.(ahf) (Entered: 10/12/2017)	
10/20/2017	2	Acceptance of Service by U.S. Attorney Re: accepted summons and complaint on behalf of the United States Attorney (only). (aeg) (Entered: 10/23/2017)	
10/23/2017	3	NOTICE of Appearance by MICHAEL J. FISCHER on behalf of COMMONWEALTH OF PENNSYLVANIA (FISCHER, MICHAEL) (Entered: 10/23/2017)	
10/23/2017	4	NOTICE of Appearance by NICOLE J. BOLAND on behalf of COMMONWEALTH OF PENNSYLVANIA (BOLAND, NICOLE) (Entered: 10/23/2017)	
10/25/2017	5	Praecipe to Re-Issue Summons by COMMONWEALTH OF PENNSYLVANIA. (BOLAND, NICOLE) (Entered: 10/25/2017)	
10/25/2017		Alias Summons Issued as to RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. 8 Given To: Counsel on 10/25/2017. (ahf) (Entered: 10/25/2017)	

- 10/27/2017 6 NOTICE of Appearance by ELIZABETH L. KADE on behalf of RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT (KADE, ELIZABETH) (Entered: 10/27/2017)
- 11/01/2017 7 NOTICE of Appearance by SCOTT WEBSTER REID on behalf of RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT with Certificate of Service(REID, SCOTT) (Entered: 11/01/2017)
- 11/02/2017 8 Consent MOTION for Leave to File Excess Pages in Support of Motion for a Preliminary Injunction filed by COMMONWEALTH OF PENNSYLVANIA.Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Memorandum Proposed Memorandum of Law)(FISCHER, MICHAEL) (Entered: 11/02/2017)
- 11/02/2017 9 MOTION for Preliminary Injunction filed by COMMONWEALTH OF PENNSYLVANIA.Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E, # 7 Exhibit F, # 8 Exhibit G, # 9 Exhibit H, # 10 Exhibit I, # 11 Exhibit J, # 12 Exhibit K, # 13 Exhibit L, # 14 Exhibit M, # 15 Exhibit N, # 16 Exhibit O)(FISCHER, MICHAEL) (Entered: 11/02/2017)
- 11/03/2017 10 PAPERLESS ORDER GRANTING 8 MOTION FOR LEAVE TO FILE EXCESS PAGES BY HONORABLE WENDY BEETLESTONE ON 11/03/2017.11/03/2017 ENTERED AND COPIES MAILED, E-MAILED AND FAXED.(amw,) (Entered: 11/03/2017)
- 11/07/2017 11 ORDER THAT DEFENDANTS' BRIEF IN RESPONSE TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION IS DUE NO LATER THAN 11/16/2017. PLAINTIFF'S REPLY BRIEF IN FURTHER SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION IS DUE NO LATER THAN 11/27/2017. A HEARING ON PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION SHALL COMMENCE ON 12/14/2017, AT 8:30 AM, IN COURTROOM 3B. FURTHER INFORMATION OUTLINED HEREIN. SIGNED BY HONORABLE WENDY BEETLESTONE ON 11/7/2017. 11/7/2017 ENTERED AND COPIES E-MAILED.(amas) (Entered: 11/07/2017)
- 11/14/2017 12 MOTION for Leave to File Excess Pages and for Leave to File Reply in Support of Their Motion to Dismiss filed by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT.Certificate of Service. (Attachments: # 1 Text of Proposed Order) (KADE, ELIZABETH) (Entered: 11/14/2017)
- 11/15/2017 13 RESPONSE to Motion re 12 MOTION for Leave to File Excess Pages and for Leave to File Reply in Support of Their Motion to Dismiss filed by COMMONWEALTH OF PENNSYLVANIA. (Attachments: # 1 Text of Proposed Order)(FISCHER, MICHAEL) (Entered: 11/15/2017)
- 11/16/2017 14 ORDER THAT DEFENDANTS MAY FILE A MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION OF UP TO 55 PAGES. DEFENDANTS MAY ALSO FILE A SEPARATE MOTION TO DISMISS. DEFENDANTS REQUEST FOR LEAVE TO FILE A REPLY TO ANY AMICUS CURIAE BRIEFS IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION IS DENIED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 11/15/17.11/16/17 ENTERED AND COPIES E-MAILED.(ti,) (Entered: 11/16/2017)
- 11/16/2017 15 RESPONSE in Opposition re 9 MOTION for Preliminary Injunction filed by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C)(KADE, ELIZABETH) (Entered: 11/16/2017)

- 11/16/2017 16 MOTION to Dismiss filed by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. Certificate of Service. (Attachments: # 1 Memorandum, # 2 Text of Proposed Order, # 3 Exhibit A, # 4 Exhibit B)(KADE, ELIZABETH) (Entered: 11/16/2017)
- 11/20/2017 17 ORDER THAT DEFENDANTS' LETTER REQUEST TO FILE THE GOVERNMENTS' PRELIMINARY PARTIAL ADMINISTRATIVE RECORD BY CD RATHER THAN HARD COPIES WHICH IS IN EXCESS OF 500,000 PAGES IS GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 11/17/17. 11/20/17 ENTERED & E-MAILED.(fdc) (Entered: 11/20/2017)
- 11/21/2017 18 Preliminary Partial Administrative Record by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. (Attachments: # 1 Appendix Index to the Preliminary Partial Administrative Record)(KADE, ELIZABETH) (Entered: 11/21/2017)
- 11/22/2017 19 EMERGENCY MOTION TO INTERVENE FILED BY LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME, MEMORANDUM, DECLARATION, CERTIFICATE OF SERVICE.(Attachments: # 1 Memorandum, # 2 Declaration, # 3 Certificate of Service, # 4 Text of Proposed Order)(fdc) (Entered: 11/22/2017)
- 11/22/2017 20 Proposed Answer of Proposed Defendant-Intervenor LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME.(fdc) (Entered: 11/22/2017)
- 11/22/2017 21 MOTION for Pro Hac Vice of Lori Windham (Filing fee \$ 40 receipt number 0313-12472728.) filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. Certificate of Service.(CENTRELLA, NICHOLAS) (Entered: 11/22/2017)
- 11/22/2017 22 MOTION for Pro Hac Vice Admission for Mark Rienzi (Filing fee \$ 40 receipt number 0313-12472808.) filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. Certificate of Service.(CENTRELLA, NICHOLAS) (Entered: 11/22/2017)
- 11/22/2017 23 Administrative Record. (nd) (Additional attachment(s) added on 11/22/2017: # 2 II. A. Studies and Articles Part 1, # 3 II. A. Studies and Articles Part 2, # 4 II. A. Studies and Articles Part 3, # 5 II. A. Studies and Articles Part 4, # 6 II. B. Regulatory Analysis Part 1, # 7 II. B. Regulatory Analysis Part 2, # 8 II. B. Regulatory Analysis Part 3, # 9 II. B. Regulatory Analysis Part 4, # 10 II. B. Regulatory Analysis Part 5) (nd,). (Additional attachment(s) added on 11/22/2017: # 11 III Congressional Correspondence) (nd,). (Additional attachment(s) added on 11/22/2017: # 12 IV. Public Comments Part 1) (nd,). (Additional attachment(s) added on 11/22/2017: # 13 IV Public Comments Part 2) (nd,). (Additional attachment(s) added on 11/22/2017: # 14 IV. Public Comments Part 3, # 15 IV. Public Comments Part 4, # 16 IV. Public Comments Part 5, # 17 IV. Public Comments Part 6, # 18 IV. Public Comments Part 7) (nd,). (Additional attachment(s) added on 11/22/2017: # 19 HHS-OS-2011-0023-0001 - 2814_Part1, # 20 HHS-OS-2011-0023-0001 - 2814_Part2, # 21 HHS-OS-2011-0023-0001 - 2814_Part3, # 22 HHS-OS-2011-0023-0001 - 2814_Part4, # 23 HHS-OS-2011-0023-0001 - 2814_Part5, # 24 HHS-OS-2011-0023-0001 - 2814_Part6, # 25 HHS-OS-2011-0023-2814 Dft0003 - Dft84603_Part1, # 26 HHS-OS-2011-0023-2814 Dft0003 - Dft84603_Part2, # 27 HHS-OS-2011-0023-2814 Dft0003 - Dft84603_Part3, # 28 HHS-OS-2011-0023-2814 Dft0003 - Dft84603_Part4) (nd,). (Additional attachment(s) added on 11/22/2017:

29 HHS-OS-2011-0023-2815 - 3899_Part1, # 30 HHS-OS-2011-0023-2815 - 3899_Part2, # 31 HHS-OS-2011-0023-2815 - 3899_Part3, # 32 HHS-OS-2011-0023-3900 - 4999_Part1, # 33 HHS-OS-2011-0023-3900 - 4999_Part2, # 34 HHS-OS-2011-0023-5000 - 5999_Part1, # 35 HHS-OS-2011-0023-5000 - 5999_Part2) (nd,). (Additional attachment(s) added on 11/22/2017: # 36 HHS-OS-2011-0023-7816 - 8999_Part1, # 37 HHS-OS-2011-0023-7816 - 8999_Part2, # 38 HHS-OS-2011-0023-7816 - 8999_Part3, # 39 HHS-OS-2011-0023-7816 - 8999_Part4, # 40 HHS-OS-2011-0023-7816 - 8999_Part5, # 41 HHS-OS-2011-0023-7816 - 8999_Part6, # 42 HHS-OS-2011-0023-7816 - 8999_Part7, # 43 HHS-OS-2011-0023-7816 - 8999_Part8, # 44 HHS-OS-2011-0023-7816 - 8999_Part9, # 45 HHS-OS-2011-0023-7816 - 8999_Part10, # 46 HHS-OS-2011-0023-7816 - 8999_Part11, # 47 HHS-OS-2011-0023-7816 - 8999_Part12, # 48 HHS-OS-2011-0023-7816 - 8999_Part13, # 49 HHS-OS-2011-0023-7816 - 8999_Part14, # 50 HHS-OS-2011-0023-7816 - 8999_Part15, # 51 HHS-OS-2011-0023-7816 - 8999_Part16, # 52 HHS-OS-2011-0023-7816 - 8999_Part17, # 53 HHS-OS-2011-0023-7816 - 8999_Part18, # 54 HHS-OS-2011-0023-7816 - 8999_Part19, # 55 HHS-OS-2011-0023-7816 - 8999_Part20, # 56 HHS-OS-2011-0023-7816 - 8999_Part21, # 57 HHS-OS-2011-0023-7816 - 8999_Part22, # 58 HHS-OS-2011-0023-7816 - 8999_Part23, # 59 HHS-OS-2011-0023-7816 - 8999_Part24, # 60 HHS-OS-2011-0023-7816 - 8999_Part25, # 61 HHS-OS-2011-0023-7816 - 8999_Part26) (nd,). (Additional attachment(s) added on 11/22/2017: # 62 HHS-OS-2011-0023-9000 - 9999, # 63 HHS-OS-2011-0023-10000 - 10999, # 64 HHS-OS-2011-0023-11000 - 11999, # 65 HHS-OS-2011-0023-12000 - 12816, # 66 HHS-OS-2011-0023-12817 - 13999) (nd,). (Additional attachment(s) added on 11/22/2017: # 67 HHS-OS-2011-0023-14000 - 14999_Part1, # 68 HHS-OS-2011-0023-14000 - 14999_Part2) (nd,). (Additional attachment(s) added on 11/22/2017: # 69 HHS-OS-2011-0023-15000 - 15999, # 70 HHS-OS-2011-0023-16000 - 16999, # 71 HHS-OS-2011-0023-17000 - 17817) (nd,). (Additional attachment(s) added on 11/22/2017: # 72 HHS-OS-2011-0023-17818 - 18999_Part1, # 73 HHS-OS-2011-0023-17818 - 18999_Part2, # 74 HHS-OS-2011-0023-19000 - 19999_Part1, # 75 HHS-OS-2011-0023-19000 - 19999_Part2, # 76 HHS-OS-2011-0023-20000 - 20999, # 77 HHS-OS-2011-0023-21000 - 21999, # 78 HHS-OS-2011-0023-22000 - 22818) (nd,). (Additional attachment(s) added on 11/24/2017: # 79 HHS-OS-2011-0023-22819 - 27819_Part1, # 80 HHS-OS-2011-0023-22819 - 27819_Part2, # 81 HHS-OS-2011-0023-22819 - 27819_Part3, # 82 HHS-OS-2011-0023-22819

- 11/22/2017 24 ORDER THAT THE APPLICATION OF LORI H. WINDHAM, ESQ. TO PRACTICE IN THIS COURT PURSUANT TO LRCP 83.5.2(B) IS GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 11/22/17. 11/22/17 ENTERED AND COPIES MAILED, E-MAILED.(fdc) (Entered: 11/22/2017)
- 11/22/2017 25 ORDER THAT THE APPLICATION OF MARK L. RIENZI, ESQ. TO PRACTICE IN THIS COURT PURSUANT TO LRCP 83.5.2(B) IS GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 11/22/17. 11/22/17 ENTERED AND COPIES MAILED, E-MAILED.(fdc) (Entered: 11/22/2017)
- 11/27/2017 26 MOTION to File Amicus Brief filed by AMERICAN CENTER FOR LAW AND JUSTICE.Brief. (Attachments: # 1 Brief of Amicus Curiae American Center for Law & Justice in Support of Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction, # 2 Text of Proposed Order, # 3 Disclosure Statement Form)(MANION, FRANCIS) (Entered: 11/27/2017)
- 11/27/2017 27 MOTION to File Amicus Brief filed by GIRLS INC., IF/WHEN/HOW: LAWYERING FOR REPRODUCTIVE JUSTICE, SERVICE EMPLOYEES INTERNATIONAL UNION, THE AMERICAN ASSOCIATION OF UNIVERSITY WOMEN, THE AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES (AFL-CIO), THE AMERICAN FEDERATION OF TEACHERS, THE COLORADO WOMENS BAR ASSOCIATION, THE NATIONAL ASSOCIATION OF SOCIAL WORKERS, THE NATIONAL ASSOCIATION OF

WOMEN LAWYERS, THE WOMENS BAR ASSOCIATION OF MASSACHUSETTS, CALIFORNIA WOMEN LAWYERS, LAWYERS CLUB OF SAN DIEGO, THE WOMEN LAWYERS ASSOCIATION OF LOS ANGELES, THE WOMEN'S BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA .Brief, Certificate of Service. (Attachments: # 1 Brief, # 2 Exhibit A: Amicus Brief, # 3 Text of Proposed Order, # 4 Certificate of Service)(LEVITT, JAMIE) Modified on 11/28/2017 (nd,). (Entered: 11/27/2017)

- 11/27/2017 28 NOTICE of Appearance by JANIE F. SCHULMAN on behalf of GIRLS INC., IF/WHEN/HOW: LAWYERING FOR REPRODUCTIVE JUSTICE, SERVICE EMPLOYEES INTERNATIONAL UNION, THE AMERICAN ASSOCIATION OF UNIVERSITY WOMEN, THE AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES (AFL-CIO), THE AMERICAN FEDERATION OF TEACHERS, THE COLORADO WOMENS BAR ASSOCIATION, THE NATIONAL ASSOCIATION OF SOCIAL WORKERS, THE NATIONAL ASSOCIATION OF WOMEN LAWYERS, THE WOMENS BAR ASSOCIATION OF MASSACHUSETTS, CALIFORNIA WOMEN LAWYERS, LAWYERS CLUB OF SAN DIEGO, THE WOMEN LAWYERS ASSOCIATION OF LOS ANGELES, THE WOMEN'S BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA with Certificate of Service(SCHULMAN, JANIE) Modified on 11/28/2017 (nd,). (Entered: 11/27/2017)
- 11/27/2017 29 NOTICE of Appearance by RHIANNON N. BATCHELDER on behalf of GIRLS INC., IF/WHEN/HOW: LAWYERING FOR REPRODUCTIVE JUSTICE, SERVICE EMPLOYEES INTERNATIONAL UNION, THE AMERICAN ASSOCIATION OF UNIVERSITY WOMEN, THE AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES (AFL-CIO), THE AMERICAN FEDERATION OF TEACHERS, THE COLORADO WOMENS BAR ASSOCIATION, THE NATIONAL ASSOCIATION OF SOCIAL WORKERS, THE NATIONAL ASSOCIATION OF WOMEN LAWYERS, THE WOMENS BAR ASSOCIATION OF MASSACHUSETTS, CALIFORNIA WOMEN LAWYERS, LAWYERS CLUB OF SAN DIEGO, THE WOMEN LAWYERS ASSOCIATION OF LOS ANGELES, THE WOMEN'S BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA with Certificate of Service(BATCHELDER, RHIANNON) Modified on 11/28/2017 (nd,). (Entered: 11/27/2017)
- 11/27/2017 30 REPLY to Response to Motion re 9 MOTION for Preliminary Injunction filed by COMMONWEALTH OF PENNSYLVANIA. (FISCHER, MICHAEL) (Entered: 11/27/2017)
- 11/28/2017 31 NOTICE of Appearance by JONATHAN B. MILLER on behalf of COMMONWEALTH OF MASSACHUSETTS (MILLER, JONATHAN) (Entered: 11/28/2017)
- 11/28/2017 32 MOTION to File Amicus Brief on behalf of Amici States Massachusetts, California, Connecticut, Delaware, District of Columbia, Hawaii, Illinois, Iowa, Maine, Maryland, Minnesota, New Mexico, New York, North Carolina, Oregon, Rhode Island, Vermont, Virginia, Washington filed by COMMONWEALTH OF MASSACHUSETTS. Brief. (Attachments: # 1 Brief, # 2 Text of Proposed Order)(MILLER, JONATHAN) (Entered: 11/28/2017)
- 11/28/2017 33 ORDER THAT THE MOTIONS FOR LEAVE TO FILE AMICUS BRIEFS [ECF NOS. 26, 27, AND 32] ARE GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 11/28/17. 11/28/17 ENTERED AND COPIES MAILED, E-MAILED.(fdc) (Entered: 11/28/2017)
- 11/28/2017 34 Brief of Amicus Curiae, AMERICAN CENTER FOR LAW AND JUSTICE, in Support of Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction. (fdc) (Entered: 11/28/2017)
- 11/28/2017 35 Brief of Amicus Curiae filed by CALIFORNIA WOMEN LAWYERS, GIRLS INC., IF/WHEN/HOW: LAWYERING FOR REPRODUCTIVE JUSTICE, LAWYERS CLUB OF SAN DIEGO, SERVICE EMPLOYEES INTERNATIONAL UNION, THE AMERICAN ASSOCIATION OF UNIVERSITY WOMEN, THE AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES (AFL-CIO), THE AMERICAN FEDERATION OF TEACHERS, THE COLORADO

WOMENS BAR ASSOCIATION, THE NATIONAL ASSOCIATION OF SOCIAL WORKERS, THE NATIONAL ASSOCIATION OF WOMEN LAWYERS, THE WOMEN LAWYERS ASSOCIATION OF LOS ANGELES, THE WOMEN'S BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA, THE WOMENS BAR ASSOCIATION OF MASSACHUSETTS in Support of Plaintiff's Motion 9 for a Preliminary Injunction. (fdc) (Entered: 11/28/2017)

- 11/28/2017 36 Amicus Curiae Brief of COMMONWEALTH OF MASSACHUSETTS, COMMONWEALTH OF VIRGINIA, DISTRICT OF COLUMBIA, STATE OF CALIFORNIA, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF IOWA, STATE OF MAINE, STATE OF MARYLAND, STATE OF MINNESOTA, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OREGON, STATE OF RHODE ISLAND, STATE OF VERMONT, STATE OF WASHINGTON in Support of 9 Motion for Preliminary Injunction, Certificate of Service. (fdc) (Entered: 11/28/2017)
- 11/30/2017 37 RESPONSE in Opposition re 16 MOTION to Dismiss filed by COMMONWEALTH OF PENNSYLVANIA. (Attachments: # 1 Text of Proposed Order)(FISCHER, MICHAEL) (Entered: 11/30/2017)
- 12/06/2017 38 RESPONSE in Opposition re 19 MOTION to Intervene by Little Sisters of the Poor filed by COMMONWEALTH OF PENNSYLVANIA. (Attachments: # 1 Exhibit Press Release from Little Sisters' Counsel Becket Fund for Religious Liberty, # 2 Text of Proposed Order)(GOLDMAN, JONATHAN) (Entered: 12/06/2017)
- 12/07/2017 39 REPLY to Response to Motion re 16 MOTION to Dismiss filed by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. (KADE, ELIZABETH) (Entered: 12/07/2017)
- 12/07/2017 40 REPLY to Response to Motion re 19 MOTION to Intervene filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. (RIENZI, MARK) (Entered: 12/07/2017)
- 12/08/2017 41 MEMORANDUM AND OPINION. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/8/17. 12/8/17 ENTERED & E-MAILED.(fdc) (VACATED PURSUANT TO JUDGE BEETLESTONE'S ORDER OF 5/10/18 77) Modified 5/10/18 (fdc). (Entered: 12/08/2017)
- 12/08/2017 42 MEMORANDUM AND ORDER THAT THE LITTLE SISTERS' MOTION TO INTERVENE IS DENIED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/8/17. 12/8/17 ENTERED & E-MAILED.(fdc) (VACATED PURSUANT TO JUDGE BEETLESTONE'S ORDER OF 5/10/18 77) Modified 5/10/18 (fdc). (Entered: 12/08/2017)
- 12/08/2017 43 NOTICE OF APPEAL as to 42 Order (Memorandum and/or Opinion) by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. Filing fee \$ 505, receipt number 0313-12506386. Copies to Judge, Clerk USCA, Appeals Clerk and (RIENZI, MARK) (Entered: 12/08/2017)
- 12/11/2017 44 NOTICE of Appearance by JUSTIN MICHAEL SANDBERG on behalf of RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT (SANDBERG, JUSTIN) (Entered: 12/11/2017)
- 12/11/2017 45 NOTICE of Appearance by ETHAN PRICE DAVIS on behalf of RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT (DAVIS, ETHAN) (Entered: 12/11/2017)
- 12/11/2017 46

NOTICE of Appearance by REBECCA M. KOPPLIN on behalf of RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT with Certificate of Service(KOPPLIN, REBECCA) (Entered: 12/11/2017)

- 12/11/2017 47 Praecipe to file Additional Attachments to Administrative Record ECF 23 by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. (Attachments: # 1 Certification, # 2 Index)(KADE, ELIZABETH) Modified on 12/12/2017 (lvj,). Modified on 12/14/2017 (nd,). (Entered: 12/11/2017)
- 12/11/2017 48 MOTION in Limine TO LIMIT EVIDENCE AT PI HEARING filed by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT.Brief. (Attachments: # 1 Text of Proposed Order)(KADE, ELIZABETH) (Entered: 12/11/2017)
- 12/12/2017 49 NOTICE of Appearance by CHRISTOPHER HEALY on behalf of RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT (HEALY, CHRISTOPHER) (Entered: 12/12/2017)
- 12/13/2017 50 RESPONSE in Opposition re 48 MOTION in Limine TO LIMIT EVIDENCE AT PI HEARING filed by COMMONWEALTH OF PENNSYLVANIA. (Attachments: # 1 Exhibit A, # 2 Text of Proposed Order)(FISCHER, MICHAEL) (Entered: 12/13/2017)
- 12/13/2017 51 NOTICE of Appearance by JOEL L. MCELVAIN on behalf of RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT (MCELVAIN, JOEL) (Entered: 12/13/2017)
- 12/13/2017 52 NOTICE of Appearance by LAUREN E. SULCOVE on behalf of COMMONWEALTH OF PENNSYLVANIA (SULCOVE, LAUREN) (Entered: 12/13/2017)
- 12/13/2017 53 NOTICE of Appearance by NIKOLE BROCK on behalf of COMMONWEALTH OF PENNSYLVANIA (BROCK, NIKOLE) (Entered: 12/13/2017)
- 12/13/2017 54 RESPONSE in Support re 48 MOTION in Limine TO LIMIT EVIDENCE AT PI HEARING filed by DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. (HEALY, CHRISTOPHER) (Entered: 12/13/2017)
- 12/13/2017 55 Minute Entry for proceedings held before HONORABLE WENDY BEETLESTONE. A Conference Call was held on 12/12/17. (fdc) (Entered: 12/13/2017)
- 12/13/2017 56 ORDER THAT DEFENDANT'S 48 MOTION IN LIMINE IS DENIED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/13/17.12/13/17 ENTERED & E-MAILED.(fdc) (Entered: 12/13/2017)
- 12/14/2017 57 NOTICE of Docketing Record on Appeal from USCA re 43 Notice of Appeal (Credit Card Payment) filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. USCA Case Number 17-3679 (dmc,) (Entered: 12/14/2017)
- 12/15/2017 58

Minute Entry for proceedings held before HONORABLE WENDY BEETLESTONE. Preliminary Injunction Hearing held on 12/14/17. Court Reporter: S. White. (fdc) (Entered: 12/15/2017)

- 12/15/2017 59 MEMORANDUM AND OPINION. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/15/17. 12/15/17 ENTERED & E-MAILED.(fdc) (Entered: 12/15/2017)
- 12/15/2017 60 MEMORANDUM AND ORDER THAT THE COMMONWEALTH OF PENNSYLVANIA'S MOTION FOR A PRELIMINARY INJUNCTION 9 IS GRANTED. IT IS FURTHER ORDERED THAT DEFENDANTS ERIC D. HARGAN, AS ACTING SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (SUBSTITUTED PURSUANT TO RULE 25(D) OF THE FRCP); THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, AS SECRETARY OF THE U.S. DEPARTMENT OF TREASURY; THE U.S. DEPARTMENT OF TREASURY, RENE ALEXANDER ACOSTA, AS SECRETARY OF THE U.S. DEPARTMENT OF LABOR; AND THE U.S. DEPARTMENT OF LABOR; AND THEIR OFFICERS, AGENTS, SERVANTS, EMPLOYEES, ATTORNEYS, DESIGNEES, AND SUBORDINATES, AS WELL AS ANY PERSON ACTING IN CONCERT OR PARTICIPATION WITH THEM, ARE HEREBY ENJOINED FROM ENFORCING THE FOLLOWING INTERIM FINAL RULES PENDING FURTHER ORDER OF THIS COURT: 1. RELIGIOUS EXEMPTIONS AND ACCOMODATIONS FOR COVERAGE OF CERTAIN PREVENTIVE SERVICES UNDER THE AFFORDABLE CARE ACT DESCRIBED AT 82 FED. REG. 47792; AND 2. MORAL EXEMPTIONS AND ACCOMODATIONS FOR COVERAGE OF CERTAIN PREVENTIVE SERVICES UNDER THE AFFORDABLE CARE ACT DESCRIBED AT 82 FED. REG. 47838. THE COURT HAS CONSIDERED THE ISSUE OF SECURITY PURSUANT TO RULE 65(C) OF THE FRCP AND DETERMINES THAT DEFENDANTS WILL NOT SUFFER ANY FINANCIAL LOSS THAT WARRANTS THE NEED FOR THE PLAINTIFF TO POST SECURITY. AFTER CONSIDERING THE FACTS AND CIRCUMSTANCES OF THIS CASE, THE COURT FINDS THAT SECURITY IS UNNECESSARY AND EXERCISES ITS DISCRETION NOT TO REQUIRE THE POSTING OF SECURITY IN THIS SITUATION. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/15/17. 12/15/17 ENTERED & E-MAILED.(fdc) (Entered: 12/15/2017)
- 12/15/2017 61 NOTICE OF APPEAL as to 60 Order (Memorandum and/or Opinion), 59 Memorandum and/or Opinion by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. Filing fee \$ 505, receipt number 0313-12521339. Copies to Judge, Clerk USCA, and Appeals Clerk. Certificate of Service. (RIENZI, MARK) Modified on 12/15/2017 (tjd). (Entered: 12/15/2017)
- 12/21/2017 62 NOTICE of Docketing Record on Appeal from USCA re 61 Notice of Appeal (Credit Card Payment), filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. USCA Case Number 17-3752 (dmc,) (Entered: 12/21/2017)
- 01/04/2018 63 NOTICE by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME [TRANSCRIPT ORDER FORM]. (FILED IN ERROR; ATTORNEY MUST RE-FILE ORIGINAL HARD COPY WITH CLERK'S OFFICE). (RIENZI, MARK) Modified on 1/9/2018 (fb). (Entered: 01/04/2018)
- 01/09/2018 64 NOTICE OF CONFERENCE: PRETRIAL CONFERENCE SET FOR 2/15/2018 04:30 PM IN JUDGE'S CHAMBERS 3809 BEFORE HONORABLE WENDY BEETLESTONE. (Attachments: # 1 Electronic Discovery Order, # 2 Joint Report of Rule 26(f) Meeting and Proposed Discovery Plan)(amw,) (Entered: 01/09/2018)
- 01/11/2018 65 Copy of TPO Form re 61 Notice of Appeal (Credit Card Payment), : (fdc,) (Entered: 01/11/2018)
- 01/22/2018 66 NOTICE of Withdrawal of Appearance by ELIZABETH L. KADE on behalf of All Defendants (KADE, ELIZABETH) (Entered: 01/22/2018)
- 02/05/2018 67

NOTICE by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME of Transcript Order for 12/14/2017 proceedings (RIENZI, MARK) (Entered: 02/05/2018)

- 02/06/2018 68 NOTICE OF APPEAL as to 60 Order (Memorandum and/or Opinion),,,,,, 59 Memorandum and/or Opinion by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. Filing fee \$ 505. Copies to Judge, Clerk USCA, Appeals Clerk and (SANDBERG, JUSTIN) (Entered: 02/06/2018)
- 02/06/2018 69 TRANSCRIPT of Preliminary Injunction Hearing held on 12/14/17, before Judge Beetlestone. Court Reporter/Transcriber Suzanne R. White, RPR, FCRR, CM. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER.. Redaction Request due 2/27/2018. Redacted Transcript Deadline set for 3/9/2018. Release of Transcript Restriction set for 5/7/2018. (fdc) (Entered: 02/07/2018)
- 02/06/2018 70 Notice of Filing of Official Transcript with Certificate of Service re 69 Transcript - PDF,, 2/7/18 Entered and Copies Emailed and Mailed. (fdc) (Entered: 02/07/2018)
- 02/07/2018 71 NOTICE - AT THE REQUEST OF COUNSEL FOR BOTH PARTIES IN CORRESPONDENCE DATED FEBRUARY 7, 2018 AND UPON REPRESENTATION THAT DEFENDANTS INTEND TO FILE SHORTLY A MOTION TO STAY DISTRICT COURT PROCEEDINGS IN THIS CASE, PENDING RESOLUTION OF THEIR APPEAL OF THE PRELIMINARY INJUNCTION IN THE THIRD CIRCUIT COURT OF APPEALS, THE RULE 16 CONFERENCE ON FEBRUARY 15, 2018 IS HEREBY CANCELLED AND THE JOINT RULE 26 (F) REPORT DEADLINE IS VACATED.(amw,) (Entered: 02/07/2018)
- 02/08/2018 72 MOTION to Stay filed by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT.Brief. (Attachments: # 1 Text of Proposed Order)(SANDBERG, JUSTIN) (Entered: 02/08/2018)
- 02/09/2018 73 ORDER THAT DEFENDANTS' 72 MOTION TO STAY IS GRANTED. THIS CIVIL ACTION SHALL BE MARKED STAYED PENDING DEFENDANT'S APPEAL OF THIS COURT'S ORDER ON PENNSYLVANIA'S MOTION FOR PRELIMINARY INJUNCTION (ECF NO. 59 & 60) TO THE THIRD CIRCUIT COURT OF APPEALS. IT IS FURTHER ORDERED THAT THE CLERK OF COURT SHALL MARK THIS ACTION CLOSED FOR STATISTICAL PURPOSES AND PLACE THE MATTER IN THE CIVIL SUSPENSE FILE. SIGNED BY HONORABLE WENDY BEETLESTONE ON 2/8/18.2/9/18 ENTERED & E-MAILED.(fdc) (Entered: 02/09/2018)
- 02/15/2018 74 NOTICE of Docketing Record on Appeal from USCA re 68 Notice of Appeal, filed by DONALD J. TRUMP, RENE ALEXANDER ACOSTA, UNITED STATES DEPARTMENT OF LABOR, STEVEN T. MNUCHIN, DONALD J. WRIGHT, UNITED STATES DEPARTMENT OF THE TREASURY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. USCA Case Number 18-1253 (dmc,) (Entered: 02/15/2018)
- 03/12/2018 75 Request to File Supplemented Administrative Record by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. (Attachments: # 1 Exhibit, # 2 Exhibit) (SANDBERG, JUSTIN) (Additional attachment(s) added on 3/28/2018: # 3 Rulemaking Notices and Guidance., # 4 attachment, # 5 attachment, # 6

attachment, # 7 attachment, # 8 attachment, # 9 attachment, # 10 attachment, # 11 attachment, # 12 attachment, # 13 attachment, # 14 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 15 attachment, # 16 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 17 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 18 attachment, # 19 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 20 attachment, # 21 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 22 attachment, # 23 attachment, # 24 attachment, # 25 attachment, # 26 attachment, # 27 attachment, # 28 attachment, # 29 attachment, # 30 attachment, # 31 attachment, # 32 attachment, # 33 attachment, # 34 attachment, # 35 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 36 attachment, # 37 attachment, # 38 attachment, # 39 attachment, # 40 attachment, # 41 attachment, # 42 attachment, # 43 attachment, # 44 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 45 attachment, # 46 attachment, # 47 attachment, # 48 attachment, # 49 attachment, # 50 attachment, # 51 attachment, # 52 attachment, # 53 attachment, # 54 attachment, # 55 attachment, # 56 attachment, # 57 attachment, # 58 attachment, # 59 attachment, # 60 attachment, # 61 attachment, # 62 attachment, # 63 attachment, # 64 attachment, # 65 attachment, # 66 attachment, # 67 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 68 attachment, # 69 attachment, # 70 attachment, # 71 attachment, # 72 attachment, # 73 attachment, # 74 attachment, # 75 attachment, # 76 attachment, # 77 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 78 attachment, # 79 attachment, # 80 attachment, # 81 attachment, # 82 attachment, # 83 attachment, # 84 attachment, # 85 attachment, # 86 attachment, # 87 attachment, # 88 attachment, # 89 attachment, # 90 attachment, # 91 attachment, # 92 attachment, # 93 attachment, # 94 attachment, # 95 attachment, # 96 attachment, # 97 attachment, # 98 attachment, # 99 attachment, # 100 attachment, # 101 attachment, # 102 attachment, # 103 attachment, # 104 attachment, # 105 attachment, # 106 attachment, # 107 attachment, # 108 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 109 attachment, # 110 attachment, # 111 attachment, # 112 attachment, # 113 attachment, # 114 attachment, # 115 attachment, # 116 attachment, # 117 attachment, # 118 attachment, # 119 attachment, # 120 attachment, # 121 attachment, # 122 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 123 attachment, # 124 attachment, # 125 attachment, # 126 attachment, # 127 attachment, # 128 attachment, # 129 attachment, # 130 attachment, # 131 attachment, # 132 attachment, # 133 attachment, # 134 attachment, # 135 attachment, # 136 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 137 attachment, # 138 attachment, # 139 attachment, # 140 attachment, # 141 attachment, # 142 attachment, # 143 attachment, # 144 attachment, # 145 attachment, # 146 attachment, # 147 attachment, # 148 attachment, # 149 attachment, # 150 attachment, # 151 attachment, # 152 attachment, # 153 attachment, # 154 attachment, # 155 attachment, # 156 attachment, # 157 attachment, # 158 attachment, # 159 attachment, # 160 attachment, # 161 attachment, # 162 attachment, # 163 attachment) (nd,). (Additional attachment(s) added on 3/28/2018: # 164 attachment, # 165 attachment, # 166 attachment, # 167 attachment, # 168 attachment, # 169 attachment, # 170

- 04/24/2018 76 MANDATE of USCA as to 43 Notice of Appeal (Credit Card Payment) filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. RE: ORDERED THAT THE ORDER OF THE DISTRICT COURT IS HEREBY REVERSED AND REMANDED. (fdc) (Entered: 04/24/2018)
- 05/10/2018 77 ORDER THAT THIS COURT'S MEMORANDUM AND ORDER (ECF NOS. 41 42) ARE VACATED, AND THE LITTLE SISTERS' MOTION TO INTERVENE (ECF

- NO. 19) IS GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 5/9/18. 5/10/18 ENTERED & E-MAILED.(fdc) (Entered: 05/10/2018)
- 07/02/2018 78 NOTICE of Withdrawal of Appearance by JOEL L. MCELVAIN on behalf of All Defendants (MCELVAIN, JOEL) (Entered: 07/02/2018)
- 07/11/2018 79 NOTICE of Withdrawal of Appearance by ETHAN PRICE DAVIS on behalf of All Defendants (Attachments: # 1 Certificate of Service)(DAVIS, ETHAN) (Entered: 07/11/2018)
- 11/26/2018 80 NOTICE of Appearance by AIMEE D. THOMSON on behalf of COMMONWEALTH OF PENNSYLVANIA (THOMSON, AIMEE) (Entered: 11/26/2018)
- 11/26/2018 81 MOTION Lift Stay of Proceedings filed by COMMONWEALTH OF PENNSYLVANIA.Certificate of Service. (Attachments: # 1 Text of Proposed Order)(THOMSON, AIMEE) (Entered: 11/26/2018)
- 12/07/2018 82 RESPONSE to Motion re 81 MOTION Lift Stay of Proceedings filed by RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT. (SANDBERG, JUSTIN) (Entered: 12/07/2018)
- 12/07/2018 83 NOTICE OF STATUS CONFERENCE: STATUS CONFERENCE SET FOR 12/13/2018 03:30 PM IN COURTROOM 3B BEFORE THE HONORABLE WENDY BEETLESTONE.(amw,) (Entered: 12/07/2018)
- 12/10/2018 84 MOTION Appear by Telephone filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME.Motion. (Attachments: # 1 Text of Proposed Order)(RIENZI, MARK) (Entered: 12/10/2018)
- 12/10/2018 85 RESPONSE in Opposition re 81 MOTION Lift Stay of Proceedings filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. (Attachments: # 1 Exhibit Order, # 2 Exhibit Motion)(RIENZI, MARK) (Entered: 12/10/2018)
- 12/12/2018 86 PAPERLESS ORDER DENYING 84 MOTION TO APPEAR BY TELEPHONE BY HONORABLE WENDY BEETLESTONE ON 12/12/2018.12/12/2018 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 12/12/2018)
- 12/14/2018 87 MEMORANDUM AND/OR OPINION. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/14/18. 12/14/18 ENTERED AND COPIES E-MAILED. (mbh,) (Entered: 12/14/2018)
- 12/14/2018 88 ORDER THAT PLAINTIFF'S MOTION TO LIFE STAY OF DISTRICT COURT PROCEEDINGS IS GRANTED AND THE CLERK SHALL TRANSFER THIS CASE TO THE COURT'S ACTIVE DOCKET. IT IS FURTHER ORDERED THAT PLAINTIFF SHALL SUPPLEMENT OR AMEND ITS COMPLAINT AND FILE A MOTION FOR PRELIMINARY INJUNCTION NO LATER THAN 12/17/18. A HEARING ON PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION SHALL COMMENCE ON JANUARY 10, 2019 at 9:00 AM. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/14/18. 12/14/18 ENTERED AND COPIES E-MAILED.(mbh,) . (Entered: 12/14/2018)
- 12/14/2018 89 AMENDED COMPLAINT for Declaratory and Injunctive Relief against RENE ALEXANDER ACOSTA, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, DONALD J. WRIGHT, ALEX M. AZAR, II, UNITED STATES OF AMERICA, filed by COMMONWEALTH OF PENNSYLVANIA, STATE OF NEW JERSEY. (Attachments: # 1 Ex.A, # 2 Ex.B)(fdc) (Entered: 12/17/2018)
- 12/14/2018 Three Summons Issued as to ALEX M. AZAR, II, UNITED STATES OF AMERICA, U.S. Attorney's Office. Forwarded To: Michael J. Fischer, PA Atty. General, U.S. Attorney's Office on 12/17/18. (fdc) (Entered: 12/17/2018)

- 12/14/2018 MOTION HEARING SET FOR 1/10/2019 09:00 AM IN COURTROOM BEFORE HONORABLE WENDY BEETLESTONE. (mbh,) (Entered: 12/18/2018)
- 12/17/2018 90 Second MOTION for Preliminary Injunction filed by COMMONWEALTH OF PENNSYLVANIA, STATE OF NEW JERSEY.. (Attachments: # 1 Text of Proposed Order, # 2 Exhibit Index, # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit C, # 6 Exhibit D, # 7 Exhibit E, # 8 Exhibit F, # 9 Exhibit G, # 10 Exhibit H, # 11 Exhibit I, # 12 Exhibit J, # 13 Exhibit K, # 14 Exhibit L, # 15 Exhibit M, # 16 Exhibit N, # 17 Exhibit O, # 18 Exhibit P, # 19 Exhibit Q, # 20 Exhibit R, # 21 Exhibit S, # 22 Exhibit T, # 23 Exhibit U, # 24 Exhibit V, # 25 Exhibit W, # 26 Exhibit X)(FISCHER, MICHAEL) (Entered: 12/17/2018)
- 12/17/2018 91 MOTION for Leave to File Excess Pages filed by COMMONWEALTH OF PENNSYLVANIA, STATE OF NEW JERSEY.Memorandum. (Attachments: # 1 Text of Proposed Order, # 2 Memorandum)(FISCHER, MICHAEL) (Entered: 12/17/2018)
- 12/18/2018 92 APPLICATION for Admission Pro Hac Vice of Elspeth L.F. Hans by STATE OF NEW JERSEY. (Filing fee \$ 40 receipt number 0313-13234262.). (Attachments: # 1 Affidavit, # 2 Certificate of Service, # 3 Text of Proposed Order)(KREFETZ, MARC) (Entered: 12/18/2018)
- 12/18/2018 93 PAPERLESS ORDER GRANTING 91 MOTION FOR LEAVE TO FILE EXCESS PAGES BY HONORABLE WENDY BEETLESTONE ON 12/18/2018.12/18/2018 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 12/18/2018)
- 12/19/2018 94 Minute Entry for proceedings held before HONORABLE WENDY BEETLESTONEin Courtroom 3B. A Status Conference was held on 12/13/18. Court Reporter: Suzanne White/ESR. (fdc) (Entered: 12/19/2018)
- 12/20/2018 95 ORDER THAT ATTORNEY ELSPETH L.F. HANS APPLICATION FOR PRO HAC VICE FOR STATE OF NEW JERSEY IS GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 12/20/2018. 12/21/2018 ENTERED AND COPIES MAILED AND E-MAILED. ECF APP MAILED.(sg,) (Entered: 12/21/2018)
- 12/26/2018 96 MOTION to Stay , MOTION for Extension of Time to File Answer filed by RENE ALEXANDER ACOSTA, ALEX M. AZAR, II, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, UNITED STATES OF AMERICA, DONALD J. WRIGHT.Certificate of Service.(SANDBERG, JUSTIN) (Entered: 12/26/2018)
- 12/26/2018 97 MOTION for Extension of Time to File Answer filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME.Brief. (Attachments: # 1 Brief, # 2 Text of Proposed Order)(RIENZI, MARK) (Entered: 12/26/2018)
- 12/27/2018 98 APPLICATION for Admission Pro Hac Vice of Glenn J Moramarco by STATE OF NEW JERSEY. (Filing fee \$ 40 receipt number 0313-13250752.). (KREFETZ, MARC) (Entered: 12/27/2018)
- 12/27/2018 99 RESPONSE in Opposition re 96 MOTION to Stay MOTION for Extension of Time to File Answer filed by COMMONWEALTH OF PENNSYLVANIA, STATE OF NEW JERSEY. (FISCHER, MICHAEL) (Entered: 12/27/2018)
- 12/27/2018 103 ORDER THAT DEFTS' MOTION FOR STAY OF PROCEEDINGS OR IN THE ALTERNATIVE FOR EXTENSION OF THE ANSWER DEADLINE (ECF #96) IS GRANTED IN PART & DENIED IN PART. DEFTS' MOTION FOR EXTENSION OF THE ANSWER DEADLINE IS GRANTED. IT IS ORDERED THAT DEFTS HAVE UNTIL 2/28/2019 TO ANSWER OR OTHERWISE RESPOND TO THE COMPLAINT. DEFTS' MOTION TO STAY IS DENIED. IT IS FURTHER ORDERED THAT INTERVENOR-DEFT'S MOTION TO EXTEND TIME TO RESPOND TO AMENDED COMPLAINT (ECF #97) IS GRANTED. INTERVENOR-DEFT HAS UNTIL 2/28/2019 TO ANSWER OR OTHERWISE RESPOND TO THE COMPLAINT, ETC. SIGNED BY HONORABLE WENDY

BEETLESTONE ON 12/27/18. 12/28/18 ENTERED AND COPIES E-MAILED.
(kw,) (Entered: 12/28/2018)

- 12/28/2018 100 REPLY to Response to Motion re 96 MOTION to Stay MOTION for Extension of Time to File Answer filed by RENE ALEXANDER ACOSTA, ALEX M. AZAR, II, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, UNITED STATES OF AMERICA, DONALD J. WRIGHT. (SANDBERG, JUSTIN) (Entered: 12/28/2018)
- 12/28/2018 101 CERTIFICATE of Counsel certifying motion as unopposed by MARK L. RIENZI on behalf of LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME(RIENZI, MARK) (Entered: 12/28/2018)
- 12/28/2018 102 CERTIFICATE of Counsel re 97 MOTION for Extension of Time to File Answer certifying motion as unopposed by MARK L. RIENZI on behalf of LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME(RIENZI, MARK) (FILED IN ERROR BY ATTY; DUPLICATE ENTRY) Modified on 1/2/2019 (md). (Entered: 12/28/2018)
- 12/31/2018 104 MOTION for Leave to File Excess Pages filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME.. (Attachments: # 1 Text of Proposed Order)(RIENZI, MARK) (Entered: 12/31/2018)
- 01/02/2019 105 PAPERLESS ORDER GRANTING 104 MOTION FOR LEAVE TO FILE EXCESS PAGES BY HONORABLE WENDY BEETLESTONE ON 01/02/2018.01/02/2018 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/02/2019)
- 01/03/2019 106 Acceptance of Service by U.S. Attorney Re: accepted summons and complaint on behalf of the United States Attorney (only). (fdc,) (Entered: 01/03/2019)
- 01/03/2019 107 MOTION for Leave to File Excess Pages filed by RENE ALEXANDER ACOSTA, ALEX M. AZAR, II, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, UNITED STATES OF AMERICA, DONALD J. WRIGHT.Certificate of Service. (Attachments: # 1 Exhibit, # 2 Text of Proposed Order)(SANDBERG, JUSTIN) (Entered: 01/03/2019)
- 01/03/2019 108 RESPONSE in Opposition re 90 Second MOTION for Preliminary Injunction filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. (Attachments: # 1 Exhibit A, # 2 Text of Proposed Order)(RIENZI, MARK) (Entered: 01/03/2019)
- 01/04/2019 109 PAPERLESS ORDER GRANTING 107 MOTION FOR LEAVE TO FILE EXCESS PAGES BY HONORABLE WENDY BEETLESTONE ON 01/04/2019.01/04/2019 ENTERED AND COPIES MAILED AND E-MAILED. (amw,) (Entered: 01/04/2019)
- 01/07/2019 110 Consent MOTION to File Amicus Brief and to Appear Amici Curiae filed by PHYSICIANS FOR REPRODUCTIVE HEALTH, AMERICAN ACADEMY OF NURSING, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, AMERICAN NURSES ASSOCIATION, Certificate of Service. (Attachments: # 1 Memorandum in Support of Motion for Leave, # 2 Exhibit A, Brief Amici Curiae, # 3 Text of Proposed Order)(MATHEWSON, LISA) Modified on 1/8/2019 (md). (Entered: 01/07/2019)
- 01/07/2019 111 MOTION for Pro Hac Vice of Leah R. Bruno filed by NATIONAL ASSOCIATION FOR FEMALE EXECUTIVES, U.S. WOMEN'S CHAMBER OF COMMERCE.Certificate of Service. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service)(FELDMAN, JEFFREY) (Filing Fee Paid) Modified 1/8/19 (fdc). (Entered: 01/07/2019)
- 01/07/2019 112

Consent MOTION to File Amicus Brief and to Appear as Amici Curiae filed by NATIONAL ASSOCIATION FOR FEMALE EXECUTIVES, U.S. WOMEN'S CHAMBER OF COMMERCE.Certificate of Service. (Attachments: # 1 Memorandum in Support of Motion for Leave, # 2 Exhibit A to Memorandum (Brief of Amici Curiae), # 3 Text of Proposed Order) (FELDMAN, JEFFREY) (Entered: 01/07/2019)

01/07/2019 113 Consent MOTION to File Amicus Brief filed by COMMONWEALTH OF MASSACHUSETTS, COMMONWEALTH OF VIRGINIA, DISTRICT OF COLUMBIA, STATE OF CALIFORNIA, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF IOWA, STATE OF MAINE, STATE OF MARYLAND, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OREGON, STATE OF RHODE ISLAND, STATE OF VERMONT, STATE OF WASHINGTON.Brief. (Attachments: # 1 Brief Amici Curiae Brief of Massachusetts et al., # 2 Text of Proposed Order)(MILLER, JONATHAN) (Entered: 01/07/2019)

01/07/2019 114 Request to Manually File Supplemented Admin. Record by RENE ALEXANDER ACOSTA, ALEX M. AZAR, II, STEVEN T. MNUCHIN, DONALD J. TRUMP, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, UNITED STATES OF AMERICA, DONALD J. WRIGHT. (Attachments: # 1 Exhibit, # 2 Exhibit)(SANDBERG, JUSTIN) (Entered: 01/07/2019)

01/07/2019 115 MOTION to File Amicus Brief on behalf of Amici Curiae the National Women's Law Center, the National Latina Institute for Reproductive Health, SisterLove, Inc., and the National Asian Pacific American Women's Forum in support of Plaintiffs' Motion for a Preliminary Injunction filed by COMMONWEALTH OF PENNSYLVANIA, STATE OF NEW JERSEY.Brief, Certificate of Service. (Attachments: # 1 Brief, # 2 Text of Proposed Order, # 3 Corporate Disclosure Statement)(KAPLAN, MICHAEL) (Entered: 01/07/2019)

01/07/2019 116 NOTICE of Appearance by MICHAEL A. KAPLAN on behalf of COMMONWEALTH OF PENNSYLVANIA, STATE OF NEW JERSEY with Certificate of Service (Attachments: # 1 Certificate of Service)(KAPLAN, MICHAEL) (Entered: 01/07/2019)

01/07/2019 117 Consent MOTION to File Amicus Brief filed by CALIFORNIA WOMEN LAWYERS, GIRLS INC., IF/WHEN/HOW: LAWYERING FOR REPRODUCTIVE JUSTICE, LAWYERS CLUB OF SAN DIEGO, SERVICE EMPLOYEES INTERNATIONAL UNION, THE AMERICAN ASSOCIATION OF UNIVERSITY WOMEN, THE AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES (AFL-CIO), THE AMERICAN FEDERATION OF TEACHERS, THE COLORADO WOMENS BAR ASSOCIATION, THE NATIONAL ASSOCIATION OF SOCIAL WORKERS, THE NATIONAL ASSOCIATION OF WOMEN LAWYERS, THE WOMEN'S BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA, THE WOMENS BAR ASSOCIATION OF MASSACHUSETTS.Memorandum, Proposed Brief, Certificate of Service. (Attachments: # 1 Memorandum, # 2 Brief [Proposed] Brief of Amici Curiae, # 3 Text of Proposed Order)(LEVITT, JAMIE) (Entered: 01/07/2019)

01/07/2019 118 MOTION for Leave to File Excess Pages filed by COMMONWEALTH OF PENNSYLVANIA, STATE OF NEW JERSEY.. (Attachments: # 1 Text of Proposed Order, # 2 Memorandum, # 3 Exhibit)(FISCHER, MICHAEL) (Entered: 01/07/2019)

01/07/2019 126 Supplemental Administrative Record. (Attachments: # 1 Exhibit, # 2 Exhibit, # 3 Exhibit, # 4 Exhibit, # 5 Exhibit, # 6 Exhibit, # 7 Exhibit, # 8 Exhibit, # 9 Exhibit, # 10 Exhibit)(fdc,) (Additional attachment(s) added on 1/9/2019: # 11 Exhibit, # 12 Exhibit, # 13 Exhibit, # 14 Exhibit, # 15 Exhibit, # 16 Exhibit, # 17 Exhibit, # 18 Exhibit, # 19 Exhibit, # 20 Exhibit, # 21 Exhibit, # 22 Exhibit, # 23 Exhibit, # 24 Exhibit, # 25

Exhibit, # 26 Exhibit, # 27 Exhibit, # 28 Exhibit, # 29 Exhibit, # 30 Exhibit, # 31 Exhibit, # 32 Exhibit, # 33 Exhibit, # 34 Exhibit, # 35 Exhibit, # 36 Exhibit, # 37 Exhibit, # 38 Exhibit, # 39 Exhibit, # 40 Exhibit, # 41 Exhibit, # 42 Exhibit, # 43 Exhibit, # 44 Exhibit, # 45 Exhibit, # 46 Exhibit, # 47 Exhibit, # 48 Exhibit, # 49 Exhibit, # 50 Exhibit, # 51 Exhibit, # 52 Exhibit, # 53 Exhibit, # 54 Exhibit, # 55 Exhibit, # 56 Exhibit, # 57 Exhibit, # 58 Exhibit, # 59 Exhibit, # 60 Exhibit, # 61 Exhibit, # 62 Exhibit, # 63 Exhibit, # 64 Exhibit, # 65 Exhibit, # 66 Exhibit, # 67 Exhibit, # 68 Exhibit, # 69 Exhibit, # 70 Exhibit, # 71 Exhibit, # 72 Exhibit, # 73 Exhibit, # 74 Exhibit, # 75 Exhibit, # 76 Exhibit, # 77 Exhibit, # 78 Exhibit, # 79 Exhibit, # 80 Exhibit, # 81 Exhibit, # 82 Exhibit, # 83 Exhibit, # 84 Exhibit, # 85 Exhibit, # 86 Exhibit, # 87 Exhibit, # 88 Exhibit) (fdc,). (Additional attachment(s) added on 1/9/2019: # 89 Exhibit, # 90 Exhibit, # 91 Exhibit, # 92 Exhibit) (fdc,). (Additional attachment(s) added on 1/10/2019: # 93 Exhibit, # 94 Exhibit) (fdc,). (Additional attachment(s) added on 1/10/2019: # 95 Exhibit, # 96 Exhibit, # 97 Exhibit, # 98 Exhibit, # 99 Exhibit, # 100 Exhibit, # 101 Exhibit, # 102 Exhibit, # 103 Exhibit, # 104 Exhibit) (fdc,). (Additional attachment(s) added on 1/10/2019: # 105 Exhibit, # 106 Exhibit, # 107 Exhibit, # 108 Exhibit, # 109 Exhibit, # 110 Exhibit, # 111 Exhibit) (fdc,). (Additional attachment(s) added on 1/10/2019: # 112 Exhibit, # 113 Exhibit, # 114 Exhibit, # 115 Exhibit, # 116 Exhibit, # 117 Exhibit, # 118 Exhibit, # 119 Exhibit, # 120 Exhibit, # 121 Exhibit, # 122 Exhibit, # 123 Exhibit, # 124 Exhibit, # 125 Exhibit, # 126 Exhibit, # 127 Exhibit, # 128 Exhibit, # 129 Exhibit, # 130 Exhibit, # 131 Exhibit, # 132 Exhibit, # 133 Exhibit, # 134 Exhibit, # 135 Exhibit, # 136 Exhibit, # 137 Exhibit, # 138 Exhibit, # 139 Exhibit, # 140 Exhibit, # 141 Exhibit, # 142 Exhibit, # 143 Exhibit, # 144 Exhibit, # 145 Exhibit, # 146 Exhibit, # 147 Exhibit, # 148 Exhibit, # 149 Exhibit, # 150 Exhibit, # 151 Exhibit, # 152 Exhibit, # 153 Exhibit, # 154 Exhibit, # 155 Exhibit, # 156 Exhibit, # 157 Exhibit, # 158 Exhibit, # 159 Exhibit, # 160 Exhibit, # 161 Exhibit, # 162 Exhibit, # 163 Exhibit, # 164 Exhibit, # 165 Exhibit, # 166 Exhibit, # 167 Exhibit, # 168 Exhibit) (fdc,). (Additional attachment(s) added on 1/15/2019: # 169 Exhibit, # 170 Exhibit, # 171 Exhibit, # 172 Exhibit, # 173 Exhibit, # 174 Exhibit, # 175 Exhibit, # 176 Exhibit, # 177 Exhibit, # 178 Exhibit, # 179 Exhibit, # 180 Exhibit, # 181 Exhibit, # 182 Exhibit, # 183 Exhibit, # 184 Exhibit, # 185 Exhibit, # 186 Exhibit, # 187 Exhibit, # 188 Exhibit, # 189 Exhibit, # 190 Exhibit, # 191 Exhibit, # 192 Exhibit, # 193 Exhibit, # 194 Exhibit, # 195 Exhibit, # 196 Exhibit, # 197 Exhibit, # 198 Exhibit, # 199 Exhibit, # 200 Exhibit, # 201 Exhibit, # 202 Exhibit, # 203 Exhibit, # 204 Exhibit, # 205 Exhibit, # 206 Exhibit, # 207 Exhibit, # 208 Exhibit, # 209 Exhibit, # 210 Exhibit, # 211 Exhibit, # 212 Exhibit, # 213 Exhibit, # 214 Exhibit, # 215 Exhibit, # 216 Exhibit, # 217 Exhibit, # 218 Exhibit, # 219 Exhibit, # 220 Exhibit, # 221 Exhibit, # 222 Exhibit, # 223 Exhibit, # 224 Exhibit, # 225 Exhibit, # 226 Exhibit, # 227 Exhibit) (fdc,). (Additional attachment(s) added on 1/16/2019: # 228 Exhibit, # 229 Exhibit, # 230 Exhibit, # 231 Exhibit, # 232 Exhibit, # 233 Exhibit, # 234 Exhibit, # 235 Exhibit, # 236 Exhibit, # 237 Exhibit, # 238 Exhibit, # 239 Exhibit, # 240 Exhibit, # 241 Exhibit, # 242 E

01/08/2019 119 ORDER THAT THE CONSENT 117 MOTION FOR LEAVE TO APPEAR AS AMICI CURIAE AND TO FILE A BRIEF AMICI CURIAE IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION BY AMERICAN NURSES ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, AMERICAN ACADEMY OF NURSING, AMERICAN ACADEMY OF PEDIATRICS, AND PHYSICIANS FOR REPRODUCTIVE HEALTH IS GRANTED. THE BRIEF AMICI CURIAE ATTACHED AS EXHIBIT A TO THE MEMORANDUM IN SUPPORT OF THE MOTION IS HEREBY ACCEPTED FOR FILING. SIGNED BY HONORABLE WENDY BEETLESTONE ON 1/7/19.1/8/19 ENTERED & E-MAILED.(fdc) (Entered: 01/08/2019)

01/08/2019 120

- PAPERLESS ORDER GRANTING 110 MOTION TO FILE AMICUS BRIEF BY HONORABLE WENDY BEETLESTONE ON 01/08/2019.01/08/2019 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/08/2019)
- 01/08/2019 121 PAPERLESS ORDER GRANTING 112 MOTION TO FILE AMICUS BRIEF BY HONORABLE WENDY BEETLESTONE ON 01/08/2019.01/08/2019 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/08/2019)
- 01/08/2019 122 PAPERLESS ORDER GRANTING 113 MOTION TO FILE AMICUS BRIEF BY HONORABLE WENDY BEETLESTONE ON 01/08/2019.01/08/2019 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/08/2019)
- 01/08/2019 123 PAPERLESS ORDER GRANTING 115 MOTION TO FILE AMICUS BRIEF BY HONORABLE WENDY BEETLESTONE ON 01/08/2019.01/08/2019 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/08/2019)
- 01/08/2019 124 PAPERLESS ORDER granting 118 MOTION FOR LEAVE TO FILE EXCESS PAGES BY HONORABLE WENDY BEETLESTONE ON 01/08/2019.01/08/2019 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/08/2019)
- 01/08/2019 125 ORDER THAT THE APPLICATION OF LEAH R. BRUNO, ESQ. TO PRACTICE IN THIS COURT PURSUANT TO LRCP 83.5.2(b) IS GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 1/8/19.1/8/19 ENTERED AND COPIES MAILED & E-MAILED. ECF APPLICATION MAILED TO BRUNO. (fdc) (Entered: 01/08/2019)
- 01/09/2019 127 Consent MOTION to File Amicus Brief (Corrected Version of ECF No. 117) filed by CALIFORNIA WOMEN LAWYERS, GIRLS INC., IF/WHEN/HOW: LAWYERING FOR REPRODUCTIVE JUSTICE, LAWYERS CLUB OF SAN DIEGO, SERVICE EMPLOYEES INTERNATIONAL UNION, THE AMERICAN ASSOCIATION OF UNIVERSITY WOMEN, THE AMERICAN FEDERATION OF STATE, COUNTY, AND MUNICIPAL EMPLOYEES (AFL-CIO), THE AMERICAN FEDERATION OF TEACHERS, THE COLORADO WOMENS BAR ASSOCIATION, THE NATIONAL ASSOCIATION OF SOCIAL WORKERS, THE NATIONAL ASSOCIATION OF WOMEN LAWYERS, THE WOMEN'S BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA, THE WOMENS BAR ASSOCIATION OF MASSACHUSETTS.Memorandum, Amicus Brief, Certificate of Service. (Attachments: # 1 Memorandum (Corrected Memorandum in Support of Motion for Leave to Appear as Amici Curiae and to File an Amicus Brief), # 2 Brief (Corrected Brief of Amici Curiae), # 3 Text of Proposed Order)(LEVITT, JAMIE) (Entered: 01/09/2019)
- 01/09/2019 128 PAPERLESS ORDER granting 127 MOTION TO FILE AMICUS BRIEF BY HONORABLE WENDY BEETLESTONE ON 01/09/2019.01/09/2019 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/09/2019)
- 01/10/2019 129 ORDER THAT THE APPLICATION OF GLENN J. MORAMARCO, ESQ. TO PRACTICE IN THIS COURT PURSUANT TO LRCP 83.5.2(B) IS GRANTED. SIGNED BY HONORABLE WENDY BEETLESTONE ON 1/10/19. 1/10/19 ENTERED AND COPIES MAILED AND E-MAILED.(fdc) (Entered: 01/10/2019)
- 01/10/2019 130 Entry of Appearance by GLENN J. MORAMARCO on behalf of STATE OF NEW JERSEY. (fdc) (Entered: 01/10/2019)
- 01/10/2019 131 Minute Entry for proceedings held before HONORABLE WENDY BEETLESTONE. Preliminary Injunction Hearing held on 1/10/19. Court Reporter: K. Feldman/ESR. (fdc) (Entered: 01/10/2019)
- 01/10/2019 132 Consent MOTION to Amend/Correct 108 Response in Opposition to Motion Exhibit A filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME.. (Attachments: # 1 Errata Exhibit A, # 2 Text of Proposed Order) (RIENZI, MARK) (Entered: 01/10/2019)
- 01/14/2019 133 NOTICE by COMMONWEALTH OF PENNSYLVANIA of decision in California, et al. v. HHS, et al. (No. 17-5783) (N.D.Cal.) (Attachments: # 1 Exhibit

Memorandum and Order (No. 17-5783) (N.D.Cal. Jan. 13, 2019))
(THOMSON, AIMEE) (Entered: 01/14/2019)

- 01/14/2019 134 NOTICE of Withdrawal of Appearance by LAUREN E. SULCOVE on behalf of COMMONWEALTH OF PENNSYLVANIA(SULCOVE, LAUREN) (Entered: 01/14/2019)
- 01/14/2019 135 ORDER THAT PLAINTIFFS' SECOND MOTION FOR A PRELIMINARY INJUNCTION (ECF NO. 90) IS GRANTED AS OUTLINED HEREIN. SIGNED BY HONORABLE WENDY BEETLESTONE ON 01/14/2019. 01/14/2019 ENTERED AND COPIES MAILED AND E-MAILED.(nd,) (Entered: 01/14/2019)
- 01/14/2019 136 MEMORANDUM AND/OR OPINION. SIGNED BY HONORABLE WENDY BEETLESTONE ON 01/14/2019. 01/14/2019 ENTERED AND COPIES MAILED AND E-MAILED.(nd,) (Entered: 01/14/2019)
- 01/14/2019 137 PAPERLESS ORDER GRANTING 132 MOTION TO AMEND/CORRECT BY HONORABLE WENDY BEETLESTONE ON 01/14/2019.01/14/2019 ENTERED AND COPIES E-MAILED.(amw,) (Entered: 01/14/2019)
- 01/14/2019 138 NOTICE OF APPEAL as to 135 Order (Memorandum and/or Opinion), 136 Memorandum and/or Opinion by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. . (No ifp or filing fee paid) Copies to Judge, Clerk USCA, Appeals Clerk (RIENZI, MARK) Modified on 1/16/2019 (lvj,). (Entered: 01/14/2019)
- 01/22/2019 USCA Appeal Fees received \$ 505 receipt number 191199 re 138 Notice of Appeal, filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME (fdc,) (Entered: 01/22/2019)
- 01/23/2019 139 NOTICE OF APPEAL as to 135 Order (Memorandum and/or Opinion), 136 Memorandum and/or Opinion by RENE ALEXANDER ACOSTA, ALEX M. AZAR, II, STEVEN T. MNUCHIN, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES DEPARTMENT OF LABOR, UNITED STATES DEPARTMENT OF THE TREASURY, Copies to Judge, Clerk USCA, Appeals Clerk and (SANDBERG, JUSTIN) Modified on 1/23/2019 (lvj,). Modified on 1/24/2019 (nd,). (Entered: 01/23/2019)
- 01/23/2019 140 NOTICE of Docketing Record on Appeal from USCA re 138 Notice of Appeal, filed by LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME. USCA Case Number 19-1129 (dmc,) (Entered: 01/23/2019)
- 01/24/2019 141 NOTICE of Docketing Record on Appeal from USCA re 139 Notice of Appeal, filed by RENE ALEXANDER ACOSTA, UNITED STATES DEPARTMENT OF LABOR, STEVEN T. MNUCHIN, ALEX M. AZAR, II, UNITED STATES DEPARTMENT OF THE TREASURY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. USCA Case Number 19-1189 (dmc,) (Entered: 01/24/2019)

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*** THIS DATA IS FOR INFORMATIONAL PURPOSES ONLY ***

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

DONALD J. TRUMP, *in his official capacity as President of the United States*; DONALD J. WRIGHT, *in his official capacity as Acting Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; and UNITED STATES DEPARTMENT OF LABOR,

Defendants.

CIVIL ACTION NO: _____

COMPLAINT

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

The Commonwealth of Pennsylvania, by and through Attorney General Josh Shapiro, hereby files this Complaint against Defendants Donald J. Trump, in his official capacity as President of the United States; Donald J. Wright, in his official capacity as Acting Secretary of Health and Human Services; the United States Department of Health and Human Services; Steven T. Mnuchin, in his official capacity as Secretary of the Treasury; the United States Department of the Treasury; Rene Alexander Acosta, in his official capacity as Secretary of Labor; and the United States Department of Labor (collectively, the “Defendants”) and, in support thereof, states the following:

PRELIMINARY STATEMENT

1. This lawsuit challenges the Defendants’ illegal and unjustified attempt to deny millions of women in Pennsylvania and across this country access to necessary preventive health care through their employer-sponsored insurance plans. As set forth more fully below, Defendants’ actions violate, among other provisions of law, the Administrative Procedure Act, the Affordable Care Act, the guarantee of equal protection enshrined in the Due Process Clause of the Fifth Amendment to the United States Constitution, Title VII of the Civil Rights Act, the Pregnancy Discrimination Act, and the Establishment Clause of the First Amendment. If Defendants are not blocked from implementing their unlawful rules, direct harm will result to the Commonwealth of Pennsylvania and the medical and economic health of its residents. Because these rules will cause irreparable harm and were issued in violation of law, the Commonwealth of Pennsylvania seeks declaratory and injunctive relief holding the new rules unlawful and preventing their further implementation.

INTRODUCTION

2. The Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 *et seq.* (2010) (the “Affordable Care Act” or “ACA”), together with its implementing regulations, requires employer-sponsored health plans to cover all FDA-approved methods of contraception without imposing cost-sharing requirements on the insured.

3. Because of this requirement (the “Contraceptive Mandate”) over 55 million women have access to birth control without paying out-of-pocket costs, including 2.5 million Pennsylvanians. *See Women’s Preventive Services Initiative, Recommendations for Preventive Services for Women: Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration* 84 (2016) (“WPSI Report”). American women and their

families covered by private insurance have saved an estimated 70% on contraceptive costs as a result. WPSI Report at 84.

4. Contraception is medicine, and its use has been shown to reduce the rates of unintended pregnancies and abortions. *See* Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps* 105 (2011) (the “Report”), attached hereto as Exhibit C.

5. But Doctors prescribe contraception to their patients for any number of reasons, some not having to do with birth control at all. For example, doctors frequently prescribe contraception for treatment of various menstrual disorders, acne, abnormal growth of bodily hair, and pelvic pain. According to a 2011 report, more than 1.5 million women rely on oral “birth control” pills for medical reasons unrelated to preventing pregnancy, and 58% of *all* users of birth control pills – *more than half* – use them, at least in part, for purposes other than pregnancy prevention. *See* Guttmacher Institute, *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills* (2011), available at https://www.guttmacher.org/sites/default/files/report_pdf/beyond-birth-control.pdf.

6. For these and other reasons, “access to contraception improves the social and economic status of women.” Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8725, 8728 (Feb. 15, 2012) (citations omitted).

7. As a result of the Affordable Care Act, millions of American women enjoy a greater degree of control over their own medical health and have the ability to more fully participate in the workforce.

8. Defendants, however, threaten to deny many of these women the contraceptive health coverage on which they have come to rely by, in effect, making the Contraceptive Mandate optional.

9. They have issued regulations, targeted solely at women, that create broad exemptions from the ACA's Contraceptive Mandate, and they have done so in violation of the Administrative Procedure Act, 5 U.S.C. §§ 553, 701-706 ("APA").

10. These regulations allow *individual employers* to decide whether women who are insured under their company's health insurance – specifically the company's female employees and the employees' female family members – may have access to contraception without out-of-pocket charges.

11. Defendants have issued two separate rules that dramatically expand the ability of employers to opt out of their obligation under the ACA to ensure that women covered by employer-sponsored health insurance plans have access to contraception without copays or deductibles. *See* "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" (filed Oct. 6, 2017) (the "Moral Exemption") and "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" (filed Oct. 6, 2017) (the "Religious Exemption") (collectively, the "Exemption Rules"), which are attached hereto, respectively, as Exhibits A and B.

12. Because the Exemption Rules were styled as "Interim Final Rules" or "IFRs" under the APA, they went into effect *immediately*.

13. The Exemption Rules were issued in direct violation of the substantive and procedural requirements of the APA.

14. Specifically, the Defendants failed to engage in notice-and-comment rulemaking, as required by the APA, and failed to offer an adequate justification for not doing so.

15. In addition, the Exemption Rules themselves violate the requirements of the Affordable Care Act.

16. They are also arbitrary and capricious, and their promulgation constitutes an abuse of discretion.

17. Furthermore, the Exemption Rules apply only to one category of health services: *contraception*. And contraception is used only by women.

18. By singling out women for such negative, differential treatment, the Defendants have violated the equal protection guarantee of the Due Process Clause of the Fifth Amendment to the Constitution of the United States.

19. The Commonwealth will suffer direct, proprietary harm as a result of the Exemption Rules. Where employers refuse to allow their health insurance plans to cover access to contraception, the Commonwealth will be forced to bear additional health care costs, in part, due to an increase in unintended pregnancies. Unintended pregnancies already cost the Commonwealth over \$248 million per year and will surely cost more if contraception access and use decline. *See* Guttmacher Institute, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care* National and State Estimates for 2010 at 13 (Feb. 2015).

20. In addition, the Commonwealth possesses strong interests in protecting the medical and economic health of its residents, minimizing unintended pregnancies and abortions, and ensuring that all of its residents – both men and women – are free and able to fully

participate in the workforce, maximize their social and economic status, and contribute to Pennsylvania's economy without facing discrimination on the basis of sex.

21. These interests are enshrined in the Pennsylvania Constitution, which declares, "Equality of rights under the law shall not be denied or abridged in the Commonwealth of Pennsylvania because of the sex of the individual." PA. CONST. art. I, § 28.

22. Defendants' actions directly undermine these vital state interests.

23. Because the Defendants have engaged in illegal conduct that will harm the Commonwealth and its citizens in these and other ways, this Court should hold that the Exemption Rules are unlawful and set them aside. The Commonwealth also seeks a preliminary injunction to maintain the status quo throughout all future proceedings in this matter.

JURISDICTION AND VENUE

24. This action arises under the Administrative Procedure Act, 5 U.S.C. §§ 553, 701-706, and the United States Constitution. This Court has subject matter jurisdiction under 28 U.S.C. § 1331.

25. In addition, this Court has the authority to issue the declaratory relief sought pursuant to 28 U.S.C. § 2201.

26. Venue is proper in this Court because Plaintiff the Commonwealth of Pennsylvania resides in this district and because a substantial part of the events giving rise to this action occurred in this judicial district. *See* 28 U.S.C. §§ 1391(e)(1)(B) & (C).

THE PARTIES

27. Plaintiff, the Commonwealth of Pennsylvania, is a sovereign state of the United States of America. This action is brought on behalf of the Commonwealth by Attorney General Josh Shapiro, the "chief law officer of the Commonwealth." PA. CONST. art. IV, § 4.1.

28. In filing this action, the Attorney General seeks to protect the citizens and agencies of the Commonwealth from harm caused by Defendants' illegal conduct, prevent further harm, and seek redress for the injuries caused to the Commonwealth by Defendants' actions. Those injuries include harm to the Commonwealth's sovereign, quasi-sovereign, and proprietary interests.

29. Defendant Donald J. Trump is the President of the United States of America and is sued in his official capacity. His principal address is 1600 Pennsylvania Avenue NW, Washington, D.C. 20201.

30. Defendant Donald J. Wright is the Acting Secretary of the United States Department of Health and Human Services and is sued in his official capacity. His principal address is 200 Independence Avenue, SW, Washington, D.C. 20201

31. Defendant the United States Department of Health and Humans Services is an executive agency of the United States of America. Its principal address is 200 Independence Avenue, SW, Washington, D.C. 20201

32. Defendant Steven T. Mnuchin is the Secretary of the United States Department of the Treasury and is sued in his official capacity. His principal address is 1500 Pennsylvania Avenue, NW, Washington, D.C. 20220.

33. Defendant the United States Department of the Treasury is an executive agency of the United States of America. Its principal address is 1500 Pennsylvania Avenue, NW, Washington, D.C. 20220.

34. Defendant Rene Alexander Acosta is the Secretary of the United States Department of Labor and is sued in his official capacity. His principal address is 200 Constitution Avenue, NW, Washington DC 20210.

35. Defendant the United States Department of Labor is an executive agency of the United States of America. Its principal address is 200 Constitution Avenue, NW, Washington DC 20210.

36. Defendants the Department of Health and Humans Services, the Department of the Treasury, and the Department of Labor (collectively the “Departments”) are each responsible for implementing various provisions of the ACA. The Departments jointly issued the Exemption Rules, which gave rise to this action.

37. Defendants Wright, Mnuchin, and Acosta are each responsible for carrying out the duties of their respective agencies under the Constitution of the United States of America and relevant statutes, including the Affordable Care Act.

38. Defendant Trump is responsible for faithfully enforcing the laws of the United States of America pursuant to and in accordance with the Constitution of the United States of America.

BACKGROUND

Congress Passes the Affordable Care Act and Women’s Health Amendment

39. Access to preventive health services, including contraception, is essential for women to exercise control over their own health care and fully participate as members of society.

40. Access to contraception, in particular, allows women greater control over their reproductive health choices so they can better pursue educational, career, and personal goals.

41. Indeed, the expansion of preventive health services for women was a specific goal of the health care reform efforts that led to the passage of the Affordable Care Act.

42. Recognizing this need to expand women’s access to preventive health services and reduce gender disparities in out-of-pocket costs, the U.S. Senate passed the “Women’s

Health Amendment” during debate over the ACA. *See* S. Amdt. 2791, 111th Congress (2009-2010).

43. This Amendment was included in the final version of the ACA, which was signed into law on March 23, 2010. *See* ACA § 1001; Public Health Service Act (as amended by the ACA) § 2713, 42 U.S.C. § 300gg–13(a)(4).

44. During Senate debate on the Women’s Health Amendment, lead sponsor Senator Barbara Mikulski set forth that Amendment’s key feature: it “leaves the decision of which preventive services a patient will use between the doctor and the patient.” 155 Cong. Rec. S11988 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). Senator Mikulski explained that this is essential because the “decision about what is medically appropriate and medically necessary is between a woman and her doctor.” *Id.*

45. Another sponsor of the Amendment, Senator Al Franken, stressed that insurance coverage for contraceptive care allows “women and families to make informed decisions about when and how they become parents.” He described access to contraception as “a fundamental right of every adult American” that also “reduce[s] the number of unintended pregnancies.” 155 Cong. Rec. S12052 (Dec. 1, 2009) (statement of Sen. Al Franken) (“It is also a top priority for me that health reform includes another crucial women’s health service, which is access to affordable family planning services. These services enable women and families to make informed decisions about when and how they become parents. Access to contraception is fundamental, a fundamental right of every adult American, and when we fulfill this right, we are able to accomplish a goal we all share—all of us on both sides of the aisle to reduce the number of unintended pregnancies.”).

46. The Women’s Health Amendment *mandated* that group health plans and health insurance issuers offering group or individual health insurance coverage cover preventive health services and screenings for women – and do so with no cost-sharing responsibilities. *See* 42 U.S.C.A. § 300gg-13(a)(3). Some employer-sponsored plans that were in existence prior to passage, were exempt from this requirement and most of the other requirements imposed by the ACA. *See* 29 C.F.R. § 2590.715-1251 (2010).

47. The specific services insurers were required to cover without charge were to be determined by guidelines issued by the Health Resources and Services Administration (the “HRSA”), an agency of Defendant the United States Department of Health and Human Services (“HHS”). *Id.*

The Institute of Medicine Report on Clinical Preventive Services for Women

48. Following passage of the Affordable Care Act, the HRSA complied with its legal responsibility to determine coverage guidelines by commissioning the Institute of Medicine (the “Institute”), a widely respected organization of medical professionals, to issue recommendations identifying what specific preventive women’s health services should be covered under the ACA’s mandate.

49. The Institute, in turn, convened a committee of sixteen members, including specialists in disease prevention, women’s health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. *See* Report.

50. After conducting an extensive study, that committee issued a comprehensive report, which identified several evidence-based preventive health services, unique to women, that it recommended be included as part of the HRSA’s comprehensive guidelines under the ACA. *See* Report.

51. As set forth in their Report, the Institute found that contraceptives are a preventive service that should be covered under the ACA's mandate. *See* Report at 109-10. In making this finding, the Institute cited evidence that "contraception and contraceptive counseling" are "effective at reducing unintended pregnancies" and observed that "[n]umerous health professional associations recommend" that such family planning services be included as part of mandated preventive care for women. *See id.* at 109.

52. Relying, in part, on recommendations from the American Academy of Pediatrics, the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, and the Association of Women's Health, Obstetric and Neonatal Nurses, the Institute recommended that all employer sponsored health plans cover the "the *full range* of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." Report at 109-10 (emphasis added).

53. The Institute based its recommendation on several important factors, including the prevalence of unintended pregnancy in the United States. As stated in their Report, in 2001, an estimated "49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception." Report at 102 (internal citations omitted).

54. The Institute found that these unintended pregnancies disproportionately impact the most vulnerable: Although one in every 20 American women has an unintended pregnancy each year, unintended pregnancy is "more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group." *Id.*

55. And unintended pregnancies are more likely to result in abortions: “In 2001, 42 percent of [] unintended pregnancies [in the United States] ended in abortion.” *Id.*

56. Moreover, women carrying babies to term are less likely to follow best health practices where those pregnancies are *unintended*. According to the Institute Committee on Unintended Pregnancy, “women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy.” Report at 103.

57. Women facing unintended pregnancies are also more likely to be “depressed during pregnancy, and to experience domestic violence during pregnancy.” *Id.*

58. The Institute also found “significantly increased odds of preterm birth and low birth weight among unintended pregnancies ending in live births compared with pregnancies that were intended.” *Id.*

59. While all pregnancies carry inherent health risks, some women have serious medical conditions for which pregnancy is strictly contraindicated. The Institute specifically found that “women with serious medical conditions such as pulmonary hypertension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and ... Marfan Syndrome,” are advised against becoming pregnant. Report at 103. For these women, contraception can be necessary, lifesaving medical care.

60. Use of contraceptives also promotes medically recommended “spacing” between pregnancies. The Institute found that such pregnancy spacing is important because of the “increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)” and that “[s]hort interpregnancy intervals in particular

have been associated with low birth weight, prematurity, and small for gestational age births.” Report at 103.

61. The Institute also found that contraceptives are effective in preventing unintended pregnancies. As stated in the Report, “greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally.” Report at 105.

62. The Committee specifically highlighted a study showing that, as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, their rates of unintended pregnancy and abortion declined. *Id.*

63. The Committee reported other studies that showed increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a “decline in teen pregnancies” and, conversely, that “periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use.” Report at 105.

64. The Institute also found that contraception, as a method of preventing unintended pregnancy, is highly cost-effective, citing, *inter alia*, savings in medical costs alone. It reported that “the direct medical cost of unintended pregnancy in the United States was estimated to be nearly \$5 billion in 2002, with the cost savings due to contraceptive use estimated to be \$19.3 billion.” Report at 107.

65. In addition to preventing unintended pregnancies, the Institute recognized that contraceptives have other significant health benefits unrelated to preventing unintended pregnancy. The Institute stated in its Report that these “non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain.” Report at 104. Long-term use of oral contraceptives has also been shown to “reduce a woman’s

risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases.” *Id.*

66. Indeed, a leading research and policy organization committed to advancing sexual and reproductive health and rights in the United States and globally, found in a 2011 report that more than 1.5 million women rely on oral contraceptive “birth control” pills for medical reasons *unrelated to preventing pregnancy* and that that 58% of *all* users of birth control pills – more than half – use them, at least in part, for purposes other than pregnancy prevention. *See* Guttmacher Report.

67. As of 2008, there were still “approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years)” who were “estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant.” Report at 103.

68. Importantly, the Institute noted that *cost* is a meaningful barrier to contraceptive access, stating that “[d]espite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years” and citing to a Kaiser Permanente study that found “when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods.” Report at 109.

**The Health Resources and Services Administration
Adopts the IOM Report and Promulgates Guidelines**

69. The HRSA agreed with and adopted the Institute’s recommendation that contraceptive services be covered under the Women’s Health Amendment to the Affordable Care Act.

70. In August 2011, pursuant to its responsibility under the ACA, the HRSA promulgated the Women’s Preventive Service Guidelines (the “Guidelines”). *See* HRSA, Women’s Preventive Service Guidelines (2011), available at <https://www.hrsa.gov/womens-guidelines/index.html#2>.

71. These Guidelines required that, as part of their group health plans, employers must cover “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity,” without any cost-sharing or payment by the insureds. *Id.*

72. As recently as December 2016, HRSA updated the Guidelines, following yet another review of evidence-based facts, determining that full coverage for contraceptive care and services must continue to be required. *See* <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

The Departments Grant Limited Exemptions and Accommodations to Religious Objectors

73. The Affordable Care Act does not contain a “conscience clause” that would allow employers to opt out of providing those preventive services required by the statute.

74. Nevertheless, in 2011, the Departments undertook regulatory action to accommodate religious objectors.

75. The Departments issued regulations in 2011 that exempt “churches, their integrated auxiliaries, and conventions or associations of churches” from the ACA’s requirement that employers cover contraceptive services, without cost-sharing requirements, under employee group health care plans – provided these conscientious objectors satisfied certain criteria (the “Original Religious Exemption”). *See* Group Health Plans and Health Insurance Issuers Relating

to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46621 (Aug. 3, 2011).

76. To qualify, the purpose of the organization had to be “[t]he inculcation of religious values,” the organization had to primarily employ and serve, “persons who share the religious tenets of the organization,” and the organization had to be a certified non-profit. 76 Fed. Reg. 46621.

77. Following the issuance of the HRSA guidelines, several Senators proposed amending the Affordable Care Act to allow health plans to refuse to provide coverage for certain services if doing so was “contrary to the religious beliefs or moral convictions of the sponsor, issuer, or other entity offering the plan.” S. Amdt. 1520, 112th Congress (2011-2012).

78. The proposed amendment was necessary, as its signors specifically acknowledged, because the ACA “does *not* allow purchasers, plan sponsors, and other stakeholders with religious or moral objections to specific items or services to decline providing or obtaining coverage of such items or services, or allow health care providers with such objections to decline to provide them.” *Id.* (emphasis added).

79. That proposed amendment was rejected; it did not become law. 158 Cong. Rec. S1172-S1172 (Mar. 1, 2012).

80. The following year, the Departments issued regulations to accommodate *additional* religious nonprofit organizations that had not been exempted from the ACA’s Contraceptive Mandate under the Departments’ 2011 regulations but still wanted to avoid the ACA’s mandate of having to provide contraceptive services to their employees (the “Religious Non-Profit Accommodation”). *See* 80 FR 41318-01.

81. Under the Religious Non-Profit Accommodation, an objecting employer could notify its health insurance provider of religious objections and the insurer – not the objecting employer – would then have to provide the necessary and required contraceptive services directly to women covered under the employer’s plan. *See* 80 FR 41318-01. In this way, women whose employers refused to pay for the legally mandated contraceptive coverage under the Religious Non-Profit Accommodation still had access to contraceptive care.

82. This was different from those women who were insured under coverage from “churches, their integrated auxiliaries, and conventions or associations of churches” that were wholly exempt from the ACA’s Contraceptive Mandate under the Original Religious Exemption.

83. At that time, the Defendant Departments declined to create any broader exceptions to the Contraceptive Mandate. Instead, they struck a balance by adhering to the evidence-based approach to women’s preventive health needs intended by Congress and allowing only the Original Religious Exemption and the Religious Non-Profit Accommodation, two reasonable exceptions under which religious organizations and nonprofit employers with religious objections, could opt out of the ACA’s Contraceptive Mandate.

84. Indeed, throughout this process, the government continued to focus on the evidence-based medical conclusion that guaranteeing women’s access to contraceptives is an essential healthcare component to allowing women to participate as full members of society.

85. For example, even while trying to accommodate the views of religious objectors, the Defendant Departments firmly articulated their evidence-based conclusion that barriers to contraceptive access “place[] women in the workforce at a disadvantage compared to their male co-workers” and observed that, “by reducing the number of unintended and potentially unhealthy pregnancies, [contraceptive coverage] furthers the goal of eliminating this disparity by allowing

women to achieve equal status as healthy and productive members of the job force.” 77 Fed. Reg. 8725, 8728 (Feb. 15, 2012) (footnote omitted).

Litigation Challenging the ACA’s Contraceptive Mandate

86. Following enactment of the ACA and the relevant implementing regulations, several employers filed lawsuits to challenge the scope of the Contraceptive Mandate, the Original Religious Exemption and the Religious Non-Profit Accommodation.

87. In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Supreme Court concluded that applying the ACA’s Contraceptive Mandate to closely held corporations that objected on the basis of sincerely held religious beliefs violated the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb–1.

88. That statute provides that the government may not “substantially burden a person’s exercise of religion” unless it did so “in furtherance of a compelling governmental interest” and adopted “the least restrictive means of furthering that compelling governmental interest.” *Id.*

89. As a result of the ruling in *Hobby Lobby*, the Defendant Departments began allowing such employers to take advantage of the Religious Non-Profit Accommodation process previously available only to nonprofit employers.

90. Two years later, in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), the Supreme Court considered several consolidated challenges to the accommodation process itself. Following oral argument, the Court sought clarification from the parties as to whether a modified accommodation process that did not require the employer to formally notify its insurance company of its objection – but would still ensure that the employer’s employees received

contraceptive coverage – would accommodate both the government’s interests and the objections of certain religious employers.

91. After receiving clarification from the parties, the Supreme Court remanded to provide them with “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans ‘receive full and equal health coverage, including contraceptive coverage.’” *Id.* at 1560 (citation omitted).

92. On January 9, 2017, however, the Department of Labor announced that “no feasible approach has been identified ... that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” FAQs about Affordable Care Act Implementation Part 36 (Jan. 9, 2017).

President Trump’s Executive Order “Promoting Free Speech and Religious Liberty”

93. On May 4, 2017, President Donald Trump issued an Executive Order entitled “Promoting Free Speech and Religious Liberty.” President Donald Trump, “Presidential Executive Order Promoting Free Speech and Religious Liberty,” (May 4, 2017).

94. Among other provisions, this Executive Order directed the Defendant Departments to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of Title 42, United States Code.” *Id.* § 3.

95. This Executive Order did not specifically mention the Contraceptive Mandate. Rather, the President directed the Defendant Departments to consider issuing amended

regulations to address conscience-based objections to services provided under the *Women's Health Amendment* to the Affordable Care Act *only*.

96. The President did not, for example, direct the Departments to consider regulations addressing objections to any other preventive services.

97. President Trump's Executive Order did not identify any deficiencies with the existing regulations that addressed conscience-based objections (the Original Religious Exemption and the Religious Non-Profit Accommodation) or provide any guidance whatsoever as to the amended regulations that the President had directed the Departments to consider issuing.

98. The Executive Order stated only that any amended regulations issued must be "consistent with applicable law." *Id.* § 6(b).

**The Departments Issue New Exemption Rules
Without Engaging in Required Notice-and-Comment Rulemaking**

99. In May and June 2017, several news organizations obtained and published an otherwise unreleased draft regulation entitled "Coverage of Certain Preventive Services under the Affordable Care Act." *See, e.g.*, Vox.com, "Leaked regulation: Trump plans to roll back Obamacare birth control mandate" (May 31, 2017), available at <https://www.vox.com/policy-and-politics/2017/5/31/15716778/trump-birth-control-regulation>. This draft regulation was dated May 23, 2017.

100. Last Friday on October 6, 2017, the Defendant Departments simultaneously issued both the Religious Exemption Rule and the Moral Exemption Rule.

101. These new Exemption Rules significantly expanded exemptions to the Contraceptive Mandate – they are the proverbial exceptions that swallowed the rule.

102. Though more than four months had passed since the draft regulation had leaked, the Departments issued the Exemption Rules without any advance public notice and without inviting or providing opportunity for comment.

The Religious Exemption Rule

103. The Religious Exemption Rule significantly expands the scope of the existing Original Religious Exemption for certain religious employers.

104. Specifically, it allows *all* employers – including large, publicly traded corporations – to opt out of providing no-cost contraceptive coverage to their employees on the basis of “sincerely held religious beliefs.” Religious Exemption at 74.

105. In the context of publicly traded corporations, the Religious Exemption Rule suggests that, if owners of a majority of a company’s shares possess a religious objection to contraceptive coverage, the company can simply refuse to provide such coverage.

106. The Religious Exemption Rule states that “in a country as large as America comprised of a supermajority of religious persons ... the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.” Religious Exemption at 68-69.

107. In other words, the rule is speculative, on its face, concerned with the possibility that a “religious publicly traded company *might* have objections to contraceptive coverage...” Religious Exemption at 69 (emphasis added).

108. The Religious Exemption Rule is not based on any identifiable injury to any group of people.

The Moral Exemption Rule

109. The Moral Exemption Rule creates a brand new exemption allowing employers to refuse to provide their employees with contraceptive coverage solely “based on sincerely held moral convictions.” IFR 2017-21852.

110. This exemption applies to nonprofit entities *and* for-profit entities whose shares are not publicly traded. Unlike the Religious Exemption Rule, the Moral Exemption Rule does not allow publicly traded companies to opt out of the Mandate.

111. Taken together, however, the Exemption Rules eliminate the accommodation process entirely because objecting entities “do not need to file notices or certifications of their exemption.” *See* Moral Exemption 48-49; Religious Exemption 61.

112. Employees of companies that object under either Exemption Rule will lose access to the contraceptive coverage required under the ACA’s Contraceptive Mandate.

The Defendant Departments’ Purported Justification for the New Exemption Rules

113. The Departments justify the Exemption Rules on the basis that *some other federal statutes* contain express provisions creating exemptions for individuals or organizations that object to certain conduct on religious or moral grounds. *See* Religious Exemption at 5 & n.1.

114. But the Affordable Care Act is *not* one of them – the ACA contains no exemption whatsoever for individuals or organizations that object to provisions of the law based on religious or moral grounds.

115. In fact, the Senate expressly rejected adding such an exemption to the ACA. *See supra* ¶¶ 74-76.

116. Despite Congress’s specific choice *not to include* such a provision in the ACA, the Defendant Departments claim that “Congress has *consistently* sought to protect religious

beliefs in the context of health care and human services, including health insurance, even as it has sought to promote access to health services.” Religious Exemption at 5 (emphasis added).

117. The Departments further suggest that the Religious Exemption was necessary to comply with the Religious Freedom Restoration Act, *id.* at 32 – but state that, “even if exemptions are not required” under that Act, they will “exercise their discretion to address the substantial burden identified in *Hobby Lobby* by expanding the exemptions from the [Contraceptive] Mandate instead of revising accommodations previously offered,” *id.* at 53.

118. The Defendant Departments did not rely on the Religious Freedom Restoration Act in issuing the Moral Exemption; instead they claimed that the ACA granted them broad discretion to create exemptions from the Contraceptive Mandate. *See* IFR 2017-21852 at 9 (“The Departments have consistently interpreted section 2713(a)(4)’s of the PHS Act grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women’s preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA’s Guidelines.”).

119. The Exemption Rules did *not* say, however, that HRSA had determined that contraception was no longer preventive medical care; nor did they assert any valid medical reasons for exempting certain employers from the mandate.

120. Because both of the Exemption Rules were issued as Interim Final Rules (IFRs), they did not go through the ordinary notice-and-comment process—they became effective immediately.

121. The Departments argued that it was necessary to take this extraordinary step of issuing the Exemption Rules as IFRs because several lawsuits challenging varying aspects of the

Contraceptive Mandate were ongoing and allowing the rules to go into effect immediately would “help settle or resolve cases, and ... ensure, moving forward, that [the Departments’] regulations are consistent with any approach [they] have taken in resolving certain litigation matters.”

Religious Exemption at 81.

122. Among the supposed burdens imposed by the ongoing litigation, the Departments identified the fact that “Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days” and that “several courts have issued orders setting more pressing deadlines.” Religious Exemption at 80.

123. The Departments further asserted that they had been unable to comply with court orders directing them to set forth their position in specific lawsuits “because this interim final rule [the Religious Exemption] was not yet on public display.” Religious Exemption at 81.

124. The Departments do not explain why this litigation precluded them from following the notice-and-comment requirements of the APA, nor do they explain why their own inability to articulate their position in individual cases justifies imposing sweeping rules with immediate effect.

125. The Exemption Rules undermine the balance struck under the prior regulatory scheme and run counter to the Affordable Care Act’s mandate that evidence-based preventive services be provided.

126. As a result of these abuses, which replace evidence-based science and medical reasoning with political calculation, millions of women will be penalized and denied needed contraceptive care against the advice of science, public health and medical professionals.

Specific Harm to the Commonwealth of Pennsylvania Caused by the New Exemption Rules

127. The States are generally preempted from regulating self-insured plans. Such plans are, instead, governed by the Employee Retirement Income Security Act of 1974 (“ERISA”) (Pub. L. 93–406, 88 Stat. 829, enacted September 2, 1974, codified in part at 29 U.S.C. ch. 18), a federal law that establishes minimum standards for pension plans in private industry and provides for extensive rules on the federal income tax effects of transactions associated with employee benefit plans.

128. As of 2010, approximately 80% of “large employers” (with over 1000 employees), and 50% of “mid-sized employers” (with 200-1000 employees), offered self-insured plans. *See* Rand Corp., “Employer Self-Insurance Decisions,” at 17-18 (Mar. 2011) (prepared for United States Department of Labor and HHS).

129. As a result of the Defendants’ new Exemption Rules, it is estimated that many employers will claim newly expanded exemptions and will bar their own employees from receiving medical coverage that is otherwise required under the Contraceptive Mandate.

130. Upon information and belief, many of these newly-created Contraceptive Mandate-exempted employers are expected to be Pennsylvania companies.

131. This will result in numerous insureds – and their female dependents – losing medical coverage for contraceptive care under the Affordable Care Act.

132. Many of those losing this legally-mandated coverage will be Pennsylvania policy holders; all of the women affected will face an increased risk of medical harm or an increased economic burden if they choose to self-fund contraception

133. This broad loss of formerly-mandated contraceptive care will result in significant, direct and proprietary harm to the Commonwealth, which will bear increased costs as a result of the Exemption Rules.

134. Some women who lose their employer-sponsored health coverage for contraceptive care will seek coverage through Pennsylvania's subsidized family planning program, which provides preventive screenings and contraceptives for low-income women who are not eligible for Medicaid. This additional financial burden will be borne by the Commonwealth.

135. Other women will forgo contraceptive health services altogether, because the loss of their employer-sponsored coverage will make their formerly-mandated care unaffordable or inaccessible. But this will not help Pennsylvania's coffers.

136. Rather, as a result of the affected women no longer receiving coverage, Pennsylvania will see an increase in unintended pregnancies and other negative health outcomes which, in addition to other personal, social and societal burdens, will impose direct costs on the Commonwealth.

137. Indeed, to date – before the Defendants issued their new Exemption Rules – the Contraceptive Mandate has resulted in extraordinary savings for women that are also enjoyed by the Commonwealth of Pennsylvania.

138. A recent study conducted by the University of Pennsylvania found, for example, that the ACA's Contraceptive Mandate "is saving the average [contraceptive] pill user \$255 per year" and "the average woman receiving an IUD is saving \$248." *See* University of Pennsylvania School of Medicine, "Affordable Care Act results in dramatic drop in out-of-pocket prices for

prescription contraceptives,” Press Release (July 7, 2015), https://www.eurekalert.org/pub_releases/2015-07/uops-aca070615.php.

139. Spread over an estimated 6.88 million privately insured oral contraceptive users in the United States, the University of Pennsylvania study estimates that, as a result of the ACA’s Contraceptive Mandate, “consumer annual contribution to spending on the pill could be reduced by almost \$1.5 billion annually.” *Id.* It is believed that the Commonwealth has enjoyed increased tax revenue as a result of its female citizens enjoying increased savings borne from the contraceptive mandate.

140. In addition to the direct, proprietary harm set forth above, the new Exemption Rules impermissibly encroach on the Commonwealth’s sovereign interest in protecting the health, safety, and well-being of its residents, and in ensuring that they enjoy equal access to federal programs. As such, in addition to proprietary standing, the Commonwealth has *parens patriae* standing to vindicate these interests.

CAUSES OF ACTION

COUNT I

Violation of Equal Protection of the Law

141. The Commonwealth incorporates by reference the foregoing paragraphs of this Complaint as if set forth at length.

142. Under the Due Process Clause of the Fifth Amendment to the U.S. Constitution, the federal government may not deny any person equal protection of the law. US CONST. amend. V.

143. Discrimination on the basis of sex violates this constitutional guarantee.

144. The new Exemption Rules apply to one category of preventive medical care only – *contraception*.

145. And contraception is used solely by women.

146. Because the Exemption Rules allow employers to refuse previously-mandated preventive medical services for women only, they violate the Constitution’s guarantee of equal protection under the law.

COUNT II

Violation of Title VII of the Civil Rights Act and the Pregnancy Discrimination Act

147. The Commonwealth incorporates by reference the foregoing paragraphs of this Complaint as if set forth at length.

148. The Exemption Rules violate Title VII of the Civil Rights Act of 1964, as amended by the Pregnancy Discrimination Act, which prohibits discrimination based on sex. *See* 42 U.S.C. § 2000e et seq. (Title VII).

149. The Pregnancy Discrimination Act prohibits discrimination “on the basis of pregnancy, childbirth, or related medical conditions.” *See* 42 U.S.C.A. § 2000e. That protects employees from discrimination based on their need for contraception.

150. Classifying employees on the basis of their childbearing capacity, regardless of whether they are, in fact, pregnant, is prohibited sex discrimination under Title VII.

151. Male and female employees have different health care needs, and only women can get pregnant, bear children, or use contraception.

152. The Exemption Rules violate Title VII because they discriminate against women on the basis of their capacity to get pregnant.

COUNT III

Violation of the Establishment Clause

153. The Commonwealth incorporates by reference the foregoing paragraphs of this Complaint as if set forth at length.

154. The IFRs violate the Establishment Clause of the First Amendment to the U.S. Constitution.

155. The Departments have used their rulemaking authority for the primary purpose, and with the actual effect, of advancing and endorsing religious interests.

156. The Departments have acted to promote employers' religious beliefs over the self-determination of women who do not share those beliefs, and over the ACA's mandate that preventive care be provided.

157. Through the IFRs, the government has endorsed employers' religious beliefs, over science, to the detriment and discrimination of women. The expanded exemptions grant employers executive authority over whether employees receive contraceptive coverage, whether needed to prevent unintended pregnancy, and/or to treat a medical condition, with no accommodation process.

158. The IFRs elevate employers' religious beliefs over the constitutional rights, and statutory guarantees, of women, in violation of the Establishment Clause to the United State Constitution.

COUNT IV

Failure to Engage in Notice and Comment Rulemaking

159. The Commonwealth incorporates by reference the foregoing paragraphs of this Complaint as if set forth at length.

160. Under the APA, a court shall “hold unlawful” and “set aside” any “agency action, findings, and conclusions found to be ... without observance of procedure required by law.”

5 U.S.C. § 706(2)(D).

161. In issuing substantive rules, federal agencies are required to follow the notice and comment process set forth in the APA unless the agency “for good cause” finds that notice and public procedure are “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(3)(B). Any such findings must be incorporated into the rules along with “a brief statement of reasons therefor.” *Id.*

162. Specifically, before issuing any rule, the agency must publish a “[g]eneral notice of proposed rule making” in the *Federal Register*. 5 U.S.C. § 553(b).

163. That notice must describe “either the terms or substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. § 553(b)(3).

164. The agency must further provide “interested persons” an “opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.” 5 U.S.C. § 553(b)(c).

165. Here, in issuing the Exemption Rules, the Defendant Departments failed to follow these basic legal requirements of the APA.

166. Furthermore, the justifications offered by the Departments for their failure to engage in notice and comment rulemaking do not remotely satisfy the “good cause” standard required under section 553(b)(3)(B) of the APA; they are legally insufficient, contradictory, and inconsistent with the factual record.

167. Because the Departments failed to follow the procedural requirements of the APA, both Rules should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2)(D).

COUNT V

Violation of the Substantive Requirements of the Administrative Procedure Act

168. The Commonwealth incorporates by reference the foregoing paragraphs of this Complaint as if set forth at length.

169. Under the APA, a court shall “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

170. Both the Moral Exemption Rule and the Religious Exemption Rule are inconsistent with the Affordable Care Act’s requirement that group health plans and insurers provide women with preventive care as provided for in guidelines issued by the HRSA, without any cost-sharing requirements.

171. The Rules also violate the civil rights protections in the ACA prohibiting discrimination on the basis of sex and other protected categories in most health care programs and activities. These protections added to existing federal anti-discrimination provisions, including Title VII of the Civil Rights Act of 1964, which prohibits discrimination in the provision of employer sponsored health care plans. See 42 U.S.C.A. § 18116.

172. They are also in derogation of the provisions of the ACA that prohibit the promulgation of any regulation that “[c]reates any unreasonable barrier to the ability of individuals to obtain appropriate medical care,” “[i]mpedes timely access to health care services,” or “[l]imits the availability of health care treatment for the full duration of a patient’s medical needs.” 42 U.S.C. § 1811.

173. In addition, neither Rule is required by the Religious Freedom Restoration Act or any other relevant statute.

174. Indeed, when it passed the Affordable Care Act, Congress elected *not* to include a “conscientious objector” or other exemption for individuals or organizations who object to any portion of the ACA on religious or moral grounds.

175. The Departments further abused their discretion and acted in a manner that was arbitrary and capricious in issuing the Rules.

176. Both Rules should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

WHEREFORE, the Commonwealth of Pennsylvania requests that this Court enter judgment in its favor and grant the following relief:

- a. Declare the Moral Exemption Rule and the Religious Exemption Rule unlawful;
- b. Vacate the Moral Exemption Rule and the Religious Exemption Rule;
- c. Preliminarily and Permanently enjoin the application of the Moral Exemption Rule and the Religious Exemption Rule;
- d. Award Plaintiff reasonable costs, including attorneys' fees; and
- e. Grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

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**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA and
STATE OF NEW JERSEY,

Plaintiffs,

v.

No. 2:17-cv-04540-WB

DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA,

Defendants.

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

The Commonwealth of Pennsylvania, by and through Attorney General Josh Shapiro, and the State of New Jersey, by and through Attorney General Gurbir S. Grewal, hereby file this Amended Complaint against Defendants Donald J. Trump, in his official capacity as President of the United States; Alex M. Azar II, in his official capacity as Secretary of Health and Human Services; the United States Department of Health and Human Services (HHS); Steven T. Mnuchin, in his official capacity as Secretary of the Treasury; the United States Department of the Treasury; Rene Alexander Acosta, in his official capacity as Secretary of Labor; the United

States Department of Labor; and the United States of America (collectively, “Defendants”) and, in support thereof, state the following:

1. This lawsuit challenges Defendants’ illegal and unjustified attempts to deny millions of women in Pennsylvania, New Jersey, and across the country access to necessary preventive healthcare. As set forth more fully below, Defendants’ actions violate, among other provisions of law, the Administrative Procedure Act, the Affordable Care Act, the guarantee of equal protection enshrined in the Due Process Clause of the Fifth Amendment to the United States Constitution, Title VII of the Civil Rights Act, the Pregnancy Discrimination Act, and the Establishment Clause of the First Amendment. If Defendants are not blocked from implementing their unlawful rules, direct harm will result to the Commonwealth of Pennsylvania, the State of New Jersey, and the medical and economic health of their residents. Because these rules will cause irreparable harm and were issued in violation of law, the Commonwealth of Pennsylvania and the State of New Jersey seek declaratory and injunctive relief holding the rules unlawful and preventing their implementation.

INTRODUCTION

2. The Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18001 et seq. (2010), together with its implementing regulations, requires certain health plans to cover all FDA-approved methods of contraception without imposing cost-sharing requirements on the insured. This requirement is known as the Contraceptive Care Mandate.

3. Because of the Contraceptive Care Mandate, over 55 million women have access to birth control without paying out-of-pocket costs, including 2.5 million women in Pennsylvania and 1.7 million in New Jersey. *See Women’s Preventive Services Initiative, Recommendations for Preventive Services for Women: Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration* 84 (2016) (the “WPSI Report”); HHS,

The Affordable Care Act is improving access to preventive services for millions of Americans (2015).¹ American women and their families covered by private insurance have saved an estimated 70 percent on contraceptive costs as a result. WPSI Report at 84.

4. Contraception approved by the U.S. Food and Drug Administration is medicine, and its use has been shown to reduce the rates of unintended pregnancies and abortions. *See* Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps* 105 (2011) (the “IOM Report”) (ECF No. 9-4).

5. Doctors prescribe contraception to their patients for many reasons, some not having to do with birth control at all. For example, doctors frequently prescribe contraception for treatment of various menstrual disorders, acne, abnormal growth of bodily hair, and pelvic pain. According to a 2011 report, more than 1.5 million women rely on oral “birth control” pills for medical reasons unrelated to preventing pregnancy, and 58 percent of all users of birth control pills—more than half—use them, at least in part, for purposes other than pregnancy prevention. *See* Rachel K. Jones, *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills*, Guttmacher Institute 3 (2011).²

6. For these and other reasons, “access to contraception improves the social and economic status of women.” *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8725, 8728 (Feb. 15, 2012) (citations omitted).

¹ <https://aspe.hhs.gov/sites/default/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf>.

² https://www.guttmacher.org/sites/default/files/report_pdf/beyond-birth-control.pdf.

7. As a result of the Affordable Care Act, millions of American women enjoy a greater degree of control over their own medical health and can more fully participate in the workforce.

8. Defendants, however, threaten to deny many of these women the contraceptive health coverage on which they have come to rely by making the Contraceptive Care Mandate effectively optional.

9. Defendants have issued regulations that create broad exemptions from the ACA's Contraceptive Care Mandate, and they have done so in violation of the Administrative Procedure Act (APA), the ACA, the U.S. Constitution, and federal law.

10. These regulations will allow individual employers, educational institutions, or other plan sponsors to decide whether women insured have access to contraception without out-of-pocket charges.

11. Defendants first issued these regulations as Interim Final Rules (IFRs). *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792 (Oct. 13, 2017) (the "Religious Exemption IFR"); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (the "Moral Exemption IFR") (together, "the IFRs") (ECF Nos. 9-2 & 9-3).

12. The IFRs went into effect immediately but were subsequently enjoined by this Court for violating the APA and the ACA (ECF Nos. 59 & 60).

13. After accepting public comment, Defendants subsequently issued rules that "finalize" the religious and moral exemptions created in the IFRs. *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*,

83 Fed. Reg. 57,536 (Nov. 15, 2018) (the “final Religious Exemption Rule”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (the “final Moral Exemption Rule”) (together, the “final Exemption Rules”). The final Exemption Rules are attached respectively as Exhibits A and B.

14. The final Exemption Rules are scheduled to go into effect on January 14, 2019.

15. The final Exemption Rules were issued in direct violation of the substantive and procedural requirements of the APA.

16. In issuing the IFRs, Defendants failed to engage in notice and comment rulemaking as required by the APA and failed to show good cause for not doing so.

17. Because the final Exemption Rules “finalize” the IFRs, Defendants’ subsequent acceptance of public comment does not cure the final rules of this procedural violation.

18. Defendants also failed to respond to significant comments and failed to provide adequate statements of the final rules’ bases and purposes, as required by the APA.

19. The final Exemption Rules are also arbitrary and capricious, and their promulgation constitutes an abuse of discretion.

20. In addition, the final Exemption Rules themselves violate the requirements of the Affordable Care Act.

21. Furthermore, the final Exemption Rules apply only to one category of health services: contraception. And the preventative health benefits of contraception apply only to women.

22. By singling out women for such negative, differential treatment, Defendants have violated the equal protection guarantee of the Due Process Clause of the Fifth Amendment to the Constitution of the United States.

23. Pennsylvania and New Jersey will suffer direct, proprietary harm as a result of the final Exemption Rules. When employers refuse to allow their health insurance plans to cover access to contraception, women will be forced to turn to state-funded programs that provide contraceptive services. Pennsylvania and New Jersey will also be forced to bear additional healthcare costs due to an increase in unintended pregnancies.

24. In addition, Pennsylvania and New Jersey possess strong interests in protecting the medical and economic health of their residents, minimizing unintended pregnancies and abortions, and ensuring that all of their residents—both men and women—are free and able to fully participate in the workforce, maximize their social and economic status, and contribute to their economies without facing discrimination on the basis of sex.

25. These interests are enshrined in the Pennsylvania Constitution, which declares, “Equality of rights under the law shall not be denied or abridged in the Commonwealth of Pennsylvania because of the sex of the individual.” PA. CONST. art. I, § 28.

26. Likewise, Article I, Paragraph 1 of the New Jersey Constitution guarantees equal protection rights to New Jersey residents, and New Jersey’s Law Against Discrimination, N.J.S.A. 10:5-12, makes it unlawful to subject people to differential treatment based on sex.

27. Defendants’ actions directly undermine these vital state interests.

28. Because Defendants have engaged in illegal conduct that will harm Pennsylvania, New Jersey, and their citizens in these and other ways, this Court should hold that the final Exemption Rules, like the IFRs, are unlawful and set them aside. Pennsylvania and New Jersey

also seek a preliminary injunction to maintain the status quo throughout all future proceedings in this matter.

JURISDICTION AND VENUE

29. This action arises under the Administrative Procedure Act, 5 U.S.C. §§ 553, 701–06, and the United States Constitution. This Court has subject matter jurisdiction under 28 U.S.C. § 1331.

30. In addition, this Court has the authority to issue the declaratory relief sought pursuant to 28 U.S.C. § 2201.

31. Venue is proper in this Court because Plaintiff the Commonwealth of Pennsylvania resides in this district and because a substantial part of the events giving rise to this action occurred in this district. *See* 28 U.S.C. § 1391(e)(1).

THE PARTIES

32. Plaintiff, the Commonwealth of Pennsylvania, is a sovereign state of the United States of America. This action is brought on behalf of the Commonwealth by Attorney General Josh Shapiro, the “chief law officer of the Commonwealth.” Pa. Const. art. IV, § 4.1.

33. Plaintiff, the State of New Jersey, is a sovereign state of the United States of America. This action is being brought on behalf of the State by Attorney General Gurbir S. Grewal, the State’s chief legal officer. *See* N.J. Stat. Ann. § 52:17A-4(e), (g).

34. In filing this action, the Attorneys General seek to protect the citizens and agencies of Pennsylvania and New Jersey from harm caused by Defendants’ illegal conduct, prevent further harm, and seek redress for the injuries caused to Pennsylvania and New Jersey by Defendants’ actions. Those injuries include harm to Pennsylvania’s and New Jersey’s sovereign, quasi-sovereign, and proprietary interests.

35. Defendant Donald J. Trump is the President of the United States of America and is sued in his official capacity. His principal address is 1600 Pennsylvania Avenue NW, Washington, D.C. 20201.

36. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services and is sued in his official capacity. His principal address is 200 Independence Avenue, SW, Washington, D.C. 20201

37. Defendant the United States Department of Health and Humans Services is an executive agency of the United States of America. Its principal address is 200 Independence Avenue, SW, Washington, D.C. 20201

38. Defendant Steven T. Mnuchin is the Secretary of the United States Department of the Treasury and is sued in his official capacity. His principal address is 1500 Pennsylvania Avenue, NW, Washington, D.C. 20220.

39. Defendant the United States Department of the Treasury is an executive agency of the United States of America. Its principal address is 1500 Pennsylvania Avenue, NW, Washington, D.C. 20220.

40. Defendant Rene Alexander Acosta is the Secretary of the United States Department of Labor and is sued in his official capacity. His principal address is 200 Constitution Avenue, NW, Washington DC 20210.

41. Defendant the United States Department of Labor is an executive agency of the United States of America. Its principal address is 200 Constitution Avenue, NW, Washington DC 20210.

42. Defendants the Department of Health and Humans Services, the Department of the Treasury, and the Department of Labor (together, the “Departments”) are each responsible

for implementing various provisions of the ACA. The Departments jointly issued the IFRs and the final Exemption Rules, which gave rise to this action.

43. Defendant the United States of America encompasses the government agencies and departments responsible for the implementation of the Affordable Care Act under the Constitution of the United States.

44. Defendants Azar, Mnuchin, and Acosta are each responsible for carrying out the duties of their respective agencies under the Constitution of the United States of America and relevant statutes, including the Affordable Care Act.

45. Defendant Trump is responsible for faithfully enforcing the laws of the United States of America pursuant to and in accordance with the Constitution of the United States.

BACKGROUND

Congress Passes the Affordable Care Act and Women's Health Amendment

46. Access to preventive health services, including contraception, is essential for women to exercise control over their own healthcare and fully participate as members of society.

47. Access to contraception, in particular, allows women greater control over their reproductive health choices so they can better pursue educational, career, and personal goals.

48. Indeed, the expansion of preventive health services for women was a specific goal of the healthcare reform efforts that led to the passage of the Affordable Care Act.

49. Recognizing this need to expand women's access to preventive health services and reduce gender disparities in out-of-pocket costs, the U.S. Senate passed the "Women's Health Amendment" during debate over the ACA. *See* S. Amdt. 2791, 111th Congress (2009–2010).

50. This Amendment was included in the final version of the ACA, which was signed into law on March 23, 2010. *See* ACA § 1001; Public Health Service Act (as amended by the ACA) § 2713, 42 U.S.C. § 300gg-13(a)(4).

51. The Women’s Health Amendment mandated that group health plans and health insurance issuers offering group or individual health insurance cover preventive health services and screenings for women—and do so with no cost-sharing responsibilities. 42 U.S.C. § 300gg-13(a)(4). Some employer-sponsored plans that were in existence prior to passage were exempt from this requirement and most of the other requirements imposed by the ACA. *See* 29 C.F.R. § 2590.715-1251 (2010).

52. During Senate debate on the Women’s Health Amendment, lead sponsor Senator Barbara Mikulski explained that the amendment “leaves the decision of which preventive services a patient will use between the doctor and the patient.” 155 Cong. Rec. S11988 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). She further emphasized that the “decision about what is medically appropriate and medically necessary is between a woman and her doctor.” *Id.*

53. Senator Benjamin Cardin, who co-sponsored the Amendment, explained that it “extends the preventive services covered by the bill to those *evidence-based* services for women that are recommended by the Health Resources and Services Administration.” 155 Cong. Rec. S12058–59 (Dec. 1, 2009) (statement of Sen. Benjamin Cardin) (emphasis added).

54. Congress did not dictate which specific preventive services were to be covered by the Amendment. Rather, they were to be determined by guidelines issued by experts at the Health Resources and Services Administration (HRSA), an agency of Defendant the United States Department of Health and Human Services (HHS). *Id.*

The Institute of Medicine Report on Clinical Preventive Services for Women

55. Following passage of the Affordable Care Act, HRSA complied with its legal responsibility to determine coverage guidelines by commissioning the then-named Institute of Medicine (IOM³) to issue recommendations identifying what specific preventive women's health services should be covered under the ACA's mandate. A private, nonprofit, and non-governmental institution, IOM is an "independent, evidence-based scientific advisor" operating under the 1863 congressional charter of the National Academy of Sciences. Nat'l Acad. Med., *About the National Academy of Medicine*.⁴

56. IOM, in turn, convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. *See* IOM Report.

57. After conducting an extensive study, that committee issued a comprehensive report, which identified several evidence-based preventive health services, unique to women, that it recommended be included as part of the HRSA's comprehensive guidelines under the ACA. *See* IOM Report.

58. As set forth in its Report, IOM found that contraceptives are a preventive service that should be covered under the ACA's mandate. *See* IOM Report at 109–10. In making this finding, IOM cited evidence that "contraception and contraceptive counseling" are "effective at reducing unintended pregnancies" and observed that "[n]umerous health professional

³ IOM was renamed the National Academy of Medicine in 2015. Press Release, National Academies of Sciences, Engineering, and Medicine, Institute of Medicine to Become National Academy of Medicine (Apr. 28, 2015), <http://www.nationalacademies.org/hmd/Global/News%20Announcements/IOM-to-become-NAM-Press-Release.aspx>. Because the Report was issued in the name of IOM, this Complaint refers to IOM throughout.

⁴ <https://nam.edu/about-the-nam/>.

associations recommend” that such family planning services be included as part of mandated preventive care for women. *See* IOM Report at 109.

59. Relying, in part, on recommendations from the American Academy of Pediatrics, the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, and the Association of Women’s Health, Obstetric and Neonatal Nurses, IOM recommended that all employer sponsored health plans cover the “the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.” IOM Report at 109–10.

60. IOM based its recommendation on several important factors, including the prevalence of unintended pregnancy in the United States. As stated in its Report, in 2001, an estimated “49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception.” IOM Report at 102 (internal citations omitted).

61. IOM found that these unintended pregnancies disproportionately impact the most vulnerable: Although one in every 20 American women has an unintended pregnancy each year, unintended pregnancy is “more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group.” *Id.*

62. Unintended pregnancies are more likely to result in abortions: “In 2001, 42 percent of ... unintended pregnancies [in the United States] ended in abortion.” *Id.*

63. Moreover, women carrying babies to term are less likely to follow best health practices where those pregnancies are unintended. According to the IOM Committee on Unintended Pregnancy, “women with unintended pregnancies are more likely than those with

intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy.” IOM Report at 103.

64. Women facing unintended pregnancies are also more likely to be “depressed during pregnancy, and to experience domestic violence during pregnancy.” *Id.*

65. IOM also found “significantly increased odds of preterm birth and low birth weight among unintended pregnancies ending in live births compared with pregnancies that were intended.” *Id.*

66. While all pregnancies carry inherent health risks, some women have serious medical conditions for which pregnancy is strictly contraindicated. IOM specifically found that “women with serious medical conditions such as pulmonary hypertension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and . . . Marfan Syndrome,” are advised against becoming pregnant. *Id.* For these women, contraception can be necessary, lifesaving medical care.

67. Use of contraceptives also promotes medically recommended “spacing” between pregnancies. IOM found that such pregnancy spacing is important because of the “increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)” and that “[s]hort interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small for gestational age births.” IOM Report at 103.

68. IOM also found that contraceptives are effective in preventing unintended pregnancies. As stated in the IOM Report, “greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally.” IOM Report at 105.

69. IOM specifically highlighted a study showing that, as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, their rates of unintended pregnancy and abortion declined. *Id.*

70. IOM reported other studies that showed increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a “decline in teen pregnancies” and, conversely, that “periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use.” IOM Report at 105.

71. IOM also found that contraception, as a method of preventing unintended pregnancy, is highly cost-effective, citing, among other things, savings in medical costs. It reported that “the direct medical cost of unintended pregnancy in the United States was estimated to be nearly \$5 billion in 2002, with the cost savings due to contraceptive use estimated to be \$19.3 billion.” IOM Report at 107.

72. In addition to preventing unintended pregnancies, IOM recognized that contraceptives have other significant health benefits unrelated to preventing unintended pregnancy. IOM stated in its Report that these “non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain.” IOM Report at 104. Long-term use of oral contraceptives has also been shown to “reduce a woman’s risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases.” *Id.*

73. Indeed, a leading research and policy organization committed to advancing sexual and reproductive health and rights in the United States and globally found in a 2011 report that more than 1.5 million women rely on oral contraceptive “birth control” pills for medical reasons unrelated to preventing pregnancy and that that 58 percent of all users of birth control pills—

more than half—use them, at least in part, for purposes other than pregnancy prevention. *See Jones, Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills*, at 3.

74. As of 2008, there were still “approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years)” who were “estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant.” IOM Report at 103.

75. Importantly, IOM noted that cost is a meaningful barrier to contraceptive access, stating that “[d]espite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years” and citing to a Kaiser Permanente study that found “when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods.” IOM Report at 109.

The Health Resources and Services Administration Adopts the IOM Report and Promulgates Guidelines

76. HRSA agreed with and adopted IOM’s recommendation that contraceptive services be covered under the Women’s Health Amendment to the Affordable Care Act.

77. In August 2011, pursuant to its responsibility under the ACA, HRSA promulgated the Women’s Preventive Service Guidelines (the “Guidelines”). *See HRSA, Women’s Preventive Services Guidelines* (2011).⁵

78. These Guidelines required that, as part of their group health plans, plan sponsors must cover “[a]ll Food and Drug Administration approved contraceptive methods, sterilization

⁵ <https://www.hrsa.gov/womens-guidelines/index.html#2>.

procedures, and patient education and counseling for all women with reproductive capacity,” without any cost-sharing or payment by the insureds. *Id.*

79. As recently as December 2016, HRSA updated the Guidelines, following yet another review of relevant evidence, and determined that contraceptive care and services should remain mandated preventive services. *See HRSA, Women’s Preventative Services Guidelines* (2016).⁶

The Departments Grant Limited Exemptions and Accommodations to Religious Objectors

80. The Affordable Care Act does not contain a “conscience clause” that would allow employers to opt out of providing those preventive services required by the statute.

81. Nevertheless, in 2011, the Departments undertook regulatory action to accommodate religious objectors.

82. The Departments first issued regulations in 2011 that exempted “churches, their integrated auxiliaries, and conventions or associations of churches” from the ACA’s requirement that employers cover contraceptive services, without cost-sharing requirements, under employee group healthcare plans—provided these conscientious objectors satisfied certain criteria.⁷

83. To qualify, the purpose of the organization had to be “[t]he inculcation of religious values”; the organization had to primarily employ and serve “persons who share the religious tenets of the organization”; and the organization had to operate as a non-profit. 76 Fed. Reg. at 46,623.

⁶ <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

⁷ *See Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 76 Fed. Reg. 46,621 (Aug. 3, 2011); *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8725 (Feb. 15, 2012).

84. In addition, several Senators proposed amending the Affordable Care Act to allow health plans to refuse to provide coverage for certain services if doing so was “contrary to the religious beliefs or moral convictions of the sponsor, issuer, or other entity offering the plan.” S. Amdt. 1520, 112th Congress (2011–2012).

85. The proposed amendment was necessary, its sponsors argued, because the ACA “does not allow purchasers, plan sponsors, and other stakeholders with religious or moral objections to specific items or services to decline providing or obtaining coverage of such items or services, or allow health care providers with such objections to decline to provide them.” *Id.*

86. That proposed amendment was rejected and did not become law. 158 Cong. Rec. S1172-S1172 (Mar. 1, 2012).

87. The following year, the Departments amended the original religious exemption. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 39,870 (July 2, 2013) (the “Second Religious Exemption”). To claim the Second Religious Exemption, an organization must simply operate as a non-profit and be a church, its integrated auxiliary, or a convention or association of churches. *Id.* at 39,874.

88. At the same time, the Departments established an “accommodation” for religious nonprofit organizations that did not qualify for the Second Religious Exemption but still wanted to avoid the ACA’s mandate of having to provide contraceptive services to their employees (the “Accommodation”). *Id.* at 39,874–82.

89. Under the Accommodation, an objecting employer could self-certify as an eligible organization. Once it self-certified, the health insurance issuer—not the objecting employer—would have to provide the necessary and required contraceptive services directly to women covered under the sponsor’s plan. *Id.* In this way, women whose employers refused to pay for the

legally mandated contraceptive coverage under the Accommodation still had access to contraceptive care.

90. At that time, the Defendant Departments declined to create any broader exceptions to the Contraceptive Care Mandate. Instead, they struck a balance by adhering to the evidence-based approach to women's preventive health needs intended by Congress and allowing only the Second Religious Exemption and the Accommodation, two reasonable exceptions under which religious organizations and nonprofit employers with religious objections, could opt out of the ACA's Contraceptive Care Mandate.

91. Indeed, throughout this process, the government continued to recognize that guaranteeing women's access to contraceptive services is an essential healthcare component to allowing women to participate as full members of society.

92. For example, even while trying to accommodate the views of religious objectors, the Defendant Departments firmly articulated that barriers to contraceptive access "place[] women in the workforce at a disadvantage compared to their male co-workers" and observed that, "by reducing the number of unintended and potentially unhealthy pregnancies, [contraceptive coverage] furthers the goal of eliminating this disparity by allowing women to achieve equal status as healthy and productive members of the job force." 77 Fed. Reg. at 8728 (footnote omitted).

Litigation Challenging the ACA's Contraceptive Care Mandate

93. Following passage of the ACA and promulgation of the relevant implementing regulations, several employers filed lawsuits to challenge the scope of the Contraceptive Care Mandate, the Second Religious Exemption, and the Accommodation.

94. In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Supreme Court concluded that applying the ACA's Contraceptive Care Mandate to closely held

corporations that objected on the basis of sincerely held religious beliefs but that were not eligible for the Accommodation violated the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb-1.

95. That statute provides that the government may not “substantially burden a person’s exercise of religion” unless it did so “in furtherance of a compelling governmental interest” and adopted “the least restrictive means of furthering that compelling governmental interest.” *Id.*

96. As a result of the ruling in *Hobby Lobby*, the Defendant Departments began allowing closely held for-profit entities to take advantage of the Accommodation process previously available only to nonprofit employers. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 80 Fed. Reg. 41,318 (July 14, 2015).

97. In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), the Supreme Court considered several consolidated challenges to the Accommodation itself. Following oral argument, the Court sought clarification from the parties as to whether a modified accommodation process that did not require the employer to formally notify its insurance company of its objection—but would still ensure that the employer’s employees received contraceptive coverage—would accommodate both the government’s interests and the objections of certain religious employers. *Id.* at 1559-60.

98. After receiving clarification from the parties, the Supreme Court remanded to provide them with “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans ‘receive full and equal health coverage, including contraceptive coverage.’” *Id.* at 1560 (citation omitted).

99. On January 9, 2017, the Department of Labor announced that “no feasible approach has been identified . . . that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” Dep’t of Labor, *FAQs about Affordable Care Act Implementation Part 36*, at 4 (Jan. 9, 2017).

100. As such, the Department reaffirmed that the Accommodation “does not substantially burden [objecting employers’] exercise of religion.” *Id.* at 4–5. Even if it did, the Department also reaffirmed that “the accommodation is the least restrictive means of furthering the government’s compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage.” *Id.*

President Trump’s Executive Order “Promoting Free Speech and Religious Liberty”

101. On May 4, 2017, President Donald Trump issued an Executive Order entitled “Promoting Free Speech and Religious Liberty.” Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017).

102. Among other provisions, this Executive Order directed the Defendant Departments to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of Title 42, United States Code.” *Id.* § 3.

103. This Executive Order did not specifically mention the Contraceptive Care Mandate. Rather, the President directed the Defendant Departments to consider issuing amended regulations to address conscience-based objections to services provided under the Women’s Health Amendment to the Affordable Care Act only.

104. The President did not, for example, direct the Departments to consider regulations addressing objections to similar requirements to provide other preventive services. *See* 42 U.S. Code § 300gg-13(a)(1)-(3).

105. President Trump’s Executive Order did not identify any deficiencies with the existing regulations that addressed conscience-based objections (the Second Religious Exemption and the Accommodation) or provide any guidance whatsoever as to the amended regulations that the President had directed the Departments to consider issuing.

106. The Executive Order did not direct the agencies to comply with *Zubik*’s command that any exemptions to the Contraceptive Care Mandate “ensur[e] that women covered by ... health plans ‘receive full and equal health coverage, including contraceptive coverage.’” 136 S. Ct. at 1560. It stated only that any amended regulations issued must be “consistent with applicable law.” *Id.* § 3.

The Departments Issue the IFRs Without Engaging in Required Notice-and-Comment Rulemaking

107. On October 6, 2017, the Defendant Departments issued the Moral Exemption and Religious Exemption IFRs without any advance public notice and without inviting or providing opportunity for comment.

108. The Religious Exemption IFR significantly expanded the scope of the existing religious exemption. Specifically, it allowed all employers—including non-profits, closely held for-profits companies, and publicly traded corporations—to opt out of providing no-cost contraceptive coverage to their employees on the basis of the employer’s “sincerely held religious beliefs.” 82 Fed. Reg. at 47,808–12. It also extended the exemption to institutions of higher education, insurance issuers, and individuals. *Id.*

109. The Religious Exemption IFR suggested that, if owners of a majority of a company's shares possess a religious objection to contraceptive coverage, the company can simply refuse to provide such coverage. The Religious Exemption IFR stated that "in a country as large as America comprised of a supermajority of religious persons . . . the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character." *Id.* at 47,810.

110. The Moral Exemption IFR created a brand new exemption allowing employers to refuse to provide their employees with contraceptive coverage solely "based on sincerely held moral convictions" of the employer. 82 Fed. Reg. at 47,844.

111. The Moral Exemption IFR could be claimed by nonprofit entities, for-profit entities whose shares are not publicly traded, institutions of higher education, health insurance issuers, and individuals. 82 Fed. Reg. at 47,850. Unlike the Religious Exemption IFR, the Moral Exemption IFR did not allow publicly traded companies to opt out of the Mandate.

112. In the IFRs, the Departments admitted that employees of companies that objected under either IFR would lose access to the contraceptive coverage required under the ACA's Contraceptive Care Mandate. *See* 82 Fed. Reg. at 47,818-22.

113. Both IFRs allowed objecting entities to utilize the Accommodation, but eliminated any requirement that they do so. 82 Fed. Reg. at 47,812-13; 82 Fed. Reg. at 47,854.

114. Under the IFRs, objecting entities did "not need to file notices or certifications of their exemption." 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850.

115. The Departments estimated that between 31,700 and 120,000 women would lose access to federally mandated contraceptive services when their employers claimed the Religious Exemption. 82 Fed. Reg. at 47,816-24.

This Court Enjoins the IFRs

116. On October 11, 2017, the Commonwealth filed its original Complaint in this matter, alleging that the IFRs were unlawfully issued in violation of the APA and other statutory and constitutional provisions (ECF No. 1).

117. The Commonwealth further alleged that many Pennsylvania women who were denied contraceptive coverage as a result of the IFRs would be forced to rely on government-funded programs, causing the Commonwealth irreparable harm.

118. The Commonwealth moved for a preliminary injunction of the IFRs (ECF Nos. 8 & 9).

119. On December 15, 2017, this Court granted the Commonwealth's motion and enjoined the federal defendants (with the exception of the President) from enforcing the IFRs (ECF Nos. 59 & 60).

120. This Court found that Defendants had issued the IFRs without notice and comment in violation of the APA, and further found that the exemptions themselves were arbitrary, capricious, and contrary to the requirements of the ACA.

121. On December 21, 2017, the U.S. District Court for the Northern District of California also entered a preliminary injunction against the IFRs. *California v. Health & Human Servs.*, 281 F. Supp. 3d 806 (N.D. Cal. 2017). This decision was recently affirmed. *California v. Azar*, No. 18-15155, Dkt. No. 136-1 (9th Cir. Dec. 13, 2018),

The Departments Issue the Final Exemption Rules

122. On November 15, 2018, the Departments issued the final Religious and Moral Exemption Rules. They are scheduled to go into effect on January 14, 2019. 83 Fed. Reg. at 57,536; 83 Fed. Reg. at 57,592.

123. The final Exemption Rules “finalize, with changes based on public comments,” the broad exemptions originally created in the IFRs. 83 Fed. Reg. at 57,536; 83 Fed. Reg. at 57,592.

124. Like the Religious Exemption IFR, the final Religious Exemption Rule will allow all employers—including non-profits, closely held for-profits companies, and publicly traded corporations—to opt out of providing no-cost contraceptive coverage to their employees on the basis of the employer’s “sincerely held religious beliefs.” 83 Fed. Reg. at 57,537. It will also extend the exemption to institutions of higher education, insurance issuers, and individuals. *Id.*

125. Like the Moral Exemption IFR, the final Moral Exemption Rule will allow entities to avoid complying with the Contraceptive Care Mandate on the basis of the employer’s “sincerely held moral convictions.” 83 Fed. Reg. at 57,616. The final Moral Exemption can be claimed by nonprofit entities, for-profit entities whose shares are not publicly traded, institutions of higher education, health insurance issuers, and individuals.

126. Unlike the IFRs, however, the final Religious Exemption Rule will allow any employer—even one that does not have a sincerely held religious objection to contraception—to avoid complying with the Contraceptive Care Mandate if it adopts a group health plan “established or maintained” by an objecting organization. 83 Fed. Reg. at 57,560, 57,563–64.

127. The final Exemption Rules will also allow any covered entity to claim the exemption if they have a sincerely held religious or moral objection to “establishing, maintaining, providing, offering, or arranging for ... a plan, issuer, or third party administrator that provides or arranges such coverage or payments [for some or all contraceptive services].” 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593.

128. As with the IFRs, the Departments admit that employees of companies that object under either final Exemption Rule would lose access to the contraceptive coverage required under the ACA's Contraceptive Care Mandate.

129. The Departments estimate that between 70,500 and 126,400 women will lose access to federally mandated contraceptive services when their employers claim the final Religious Exemption. 83 Fed. Reg. at 57,575–582.

130. To explain the more than doubled lower bound of impacted women, the Departments admit that the analysis they conducted in the IFR failed to properly account for the number of employees working for entities that had claimed the Accommodation. 83 Fed. Reg. at 57,576.

131. The final Exemption Rules undermine the balance struck under the prior regulatory scheme and run counter to the Affordable Care Act's mandate that evidence-based preventive services be provided.

132. As a result, millions of women potentially will be subjected to increased financial hardship and the loss of necessary contraceptive care.

Specific Harm to the Commonwealth of Pennsylvania and the State of New Jersey Caused by the final Exemption Rules

133. As a result of Defendants' final Exemption Rules, it is expected that many plan sponsors will claim the newly expanded exemptions and will deny their own employees and others medical coverage that is otherwise required under the Contraceptive Care Mandate.

134. As a result, numerous insureds—and their female dependents—will lose the medical coverage for contraceptive care required by the Affordable Care Act.

135. Upon information and belief, many of these employers operate in Pennsylvania and New Jersey.

136. During the course of litigation against the IFRs, Defendants revealed that they calculated their estimates of impacted women based on the assumption that many litigating and accommodated entities would use the religious and moral exemptions. A number of these entities are based in Pennsylvania and New Jersey: Bingaman and Son Lumber Inc., Kreamer, PA (number of employees unknown); Conestoga Wood Specialties Corporation, East Earl, PA (950 employees); Cummins Allison, Philadelphia, PA and Elmwood Park, NJ (number of employees unknown); DAS Companies, Inc., Palmyra, PA (number of employees unknown); Earth Sun Moon Trading Company, Inc., Grove City, PA (number of employees unknown); Geneva College, Beaver Falls, PA (1,850 students, 350 employees); Hobby Lobby (13,240 total employees, at least 25 stores in Pennsylvania and New Jersey); and Holy Ghost Preparatory School, Bensalem, PA (number of employees unknown).

137. Therefore, many of those losing legally-mandated coverage for contraceptive services will be Pennsylvania and New Jersey residents. All of the women affected will face an increased risk of medical harm or an increased economic burden if they choose to self-fund contraception

138. This broad loss of formerly-mandated contraceptive care will result in significant, direct and proprietary harm to Pennsylvania and New Jersey, which will bear increased costs as a result of the final Exemption Rules.

139. States are generally preempted from regulating self-insured plans. Such plans are, instead, governed by the Employee Retirement Income Security Act of 1974 (ERISA), Pub. L. 93–406, 88 Stat. 829 (codified in part at 29 U.S.C. ch. 18), a federal law that establishes minimum standards for pension plans in private industry and provides for extensive rules on the federal income tax effects of transactions associated with employee benefit plans.

140. As of 2010, approximately 80 percent of “large employers” (with over 1000 employees), and 50 percent of “mid-sized employers” (with 200-1000 employees), offered self-insured plans. *See* Rand Corp., Employer Self-Insurance Decisions, at 17-18 (Mar. 2011) (prepared for United States Department of Labor and HHS).

141. New Jersey law requires employers who offer fully-insured plans to provide coverage for expenses incurred in the purchase of prescription female contraceptives to the same extent as any other outpatient prescription drug covered under the policy. *E.g.*, N.J. Stat. Ann. §§ 17B:26-2.1y, 17B:27:46.1ee, 17B:27A-19.15 (West 2018).

142. Unlike the Women’s Health Amendment, New Jersey’s contraceptive mandate does not require insurers to offer women contraceptive services with zero out-of-pocket costs. In addition, New Jersey’s mandate only requires coverage for prescription female contraceptives, rather than all FDA-approved female contraceptive methods. As a result, female employees of objecting entities could lose coverage entirely for certain contraceptive methods and could be forced to pay significantly higher out-of-pocket costs for those methods that are covered.

143. These costs will impose an additional financial burden on women and will cause some women to forgo contraception entirely or to forgo their preferred method of contraception.

144. Approximately 3,434,000 New Jersey residents who have health insurance are covered by self-insured plans. Due to ERISA’s preemption provision, self-insured plans offered by private employers are exempt from New Jersey’s contraceptive mandate. As a result, New Jersey residents who are employed by organizations with self-insured plans that take advantage of the expanded exemption from the Contraceptive Care Mandate may lose all coverage for the medical costs associated with contraceptive care.

145. The complete loss of coverage (or partial loss of coverage and increased copays and deductibles for employees in non-ERISA plans) will be particularly problematic for women seeking to access long-acting reversible contraceptives, which are among the safest and most effective contraceptive methods available, but have very high initial costs, often in the range of \$400 to \$1,000 per person.

146. Some women who lose their contraceptive benefits because of the expanded exemptions granted will turn to state-funded programs for their contraceptives, which will force Pennsylvania and New Jersey to absorb additional financial costs presently borne by private-insurers.

147. In Pennsylvania, Medicaid (known as “Medical Assistance”) provides contraceptive services to women in Pennsylvania with incomes up to 138 percent of the federal poverty level. The Commonwealth’s Family Planning Services Program likewise provides contraceptive services to women with incomes up to 215 percent of the poverty level. The Commonwealth also funds Title X clinics, which have no income-based eligibility requirements. The additional financial burden from increased use of these programs will be borne by the Commonwealth.

148. New Jersey’s state- and federally-funded Medicaid and Children’s Health Insurance Programs (collectively, known as “NJ FamilyCare”) similarly provide contraceptive coverage to New Jersey women with incomes up to 138 percent of the federal poverty limit. In addition, New Jersey’s subsidized family planning clinics provide preventive screenings and contraceptives to all patients, regardless of income or insurance coverage, including financially vulnerable women who are not eligible for Medicaid. Increased use of these programs by women who lose coverage for contraceptive services under the final Exemption Rules will result in

additional costs to New Jersey, including the cost of providing services to low-income women who are eligible for free or reduced cost services, as well as the cost of expanding facilities to meet increased demand from all women, even those who due to their income level are required to pay fully or in part for the services they receive.

149. Other women will forgo contraceptive health services altogether, because the loss of their employer-sponsored coverage will make their formerly-mandated care unaffordable or inaccessible. As a result of the affected women no longer receiving coverage, Pennsylvania and New Jersey will see an increase in unintended pregnancies and other negative health outcomes which, in addition to other personal, social and societal burdens, are associated with significant additional costs to state-funded programs that protect the health of women and infants.

150. Nationally, a publicly funded birth in 2010 cost an average of \$12,770 for prenatal and postnatal care, labor and delivery, and for the first year of infant care. In 2010, according to one study, New Jersey spent an estimated \$186.1 million and Pennsylvania an estimated \$248.2 million on unintended pregnancies. *See* Sonfield & Kathryn Kost, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care National and State Estimates for 2010*, at 13.

151. Indeed, to date—before Defendants issued the IFRs and the final Exemption Rules—the Contraceptive Care Mandate had resulted in extraordinary savings for women.

152. A recent study conducted by the University of Pennsylvania found, for example, that the ACA’s Contraceptive Care Mandate “is saving the average [contraceptive] pill user \$255 per year” and “the average woman receiving an IUD is saving \$248.” *See* Press Release, University of Pennsylvania School of Medicine, *Affordable Care Act Results in Dramatic Drop*

in Out-of-Pocket Prices for Prescription Contraceptives, Penn Medicine Study Finds (July 7, 2015).⁸

153. Spread over an estimated 6.88 million privately insured oral contraceptive users in the United States, the University of Pennsylvania study estimates that, as a result of the ACA's Contraceptive Care Mandate, "consumer annual contribution to spending on the pill could be reduced by almost \$1.5 billion annually." *Id.*

154. In addition to the direct, proprietary harm set forth above, the final Exemption Rules impermissibly encroach on Pennsylvania's and New Jersey's quasi-sovereign interests in protecting the health, safety, and well-being of their residents, and in ensuring that they enjoy equal access to federal programs. As such, in addition to proprietary standing, Pennsylvania and New Jersey have *parens patriae* standing to vindicate these interests.

155. By failing to follow the procedures set forth in the APA, Defendants further harmed Pennsylvania and New Jersey by denying them the right to participate meaningfully in the rulemaking process.

CAUSES OF ACTION

COUNT I

Violation of Equal Protection of the Laws

156. Pennsylvania and New Jersey incorporate by reference the foregoing paragraphs of this Complaint as if set forth at length.

⁸ <https://www.pennmedicine.org/news/news-releases/2015/july/affordable-care-act-results-in>.

157. Under the Due Process Clause of the Fifth Amendment to the U.S. Constitution, the federal government may not deny any person equal protection of the laws. U.S. Const. amend. V.

158. Discrimination on the basis of sex violates this constitutional guarantee.

159. The final Exemption Rules apply to only one category of preventive medical care, contraception, which is used predominantly by women.

160. Because the final Exemption Rules are targeted at women and deny them needed preventive medical services, the Rules violate the Constitution's guarantee of equal protection under the laws.

COUNT II

Violation of Title VII of the Civil Rights Act and the Pregnancy Discrimination Act

161. Pennsylvania and New Jersey incorporate by reference the foregoing paragraphs of this Complaint as if set forth at length.

162. The Exemption Rules violate Title VII of the Civil Rights Act of 1964, as amended by the Pregnancy Discrimination Act, which prohibits discrimination based on sex. *See* 42 U.S.C. § 2000e et seq. (Title VII).

163. The Pregnancy Discrimination Act prohibits discrimination “on the basis of pregnancy, childbirth, or related medical conditions.” 42 U.S.C. § 2000e. It therefore prevents employees from discrimination based on need for contraception.

164. Classifying employees on the basis of their childbearing capacity, regardless of whether they are, in fact, pregnant, is prohibited sex discrimination under Title VII.

165. The Exemption Rules violate Title VII because they discriminate against women on the basis of their capacity to get pregnant.

COUNT III

Violation of the Procedural Requirements of the Administrative Procedure Act

166. Pennsylvania and New Jersey incorporate by reference the foregoing paragraphs of this Complaint as if set forth at length.

167. Under the APA, a court shall “hold unlawful” and “set aside” any “agency action, findings, and conclusions found to be . . . without observance of procedure required by law.” 5 U.S.C. § 706(2)(D).

168. In issuing substantive rules, federal agencies are required to follow the notice and comment process set forth in the APA unless the agency “for good cause” finds that notice and public procedure are “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(3)(B). Any such findings must be incorporated into the rules along with “a brief statement of reasons therefor.” *Id.*

169. Specifically, before issuing any rule, the agency must publish a “[g]eneral notice of proposed rule making” in the Federal Register. 5 U.S.C. § 553(b).

170. That notice must describe “either the terms or substance of the proposed rule or a description of the subjects and issues involved.” 5 U.S.C. § 553(b)(3).

171. The agency must further provide “interested persons” an “opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.” 5 U.S.C. § 553(c).

172. In issuing the IFRs, the Defendant Departments failed to follow these basic requirements.

173. Furthermore, the justifications offered by the Departments for their failure to engage in notice and comment rulemaking did not satisfy the “good cause” standard required under section 553(b)(3)(B) of the APA.

174. In issuing the final Exemption Rules, Defendants similarly did not follow the notice and comment procedures as set forth in the APA. Rather, Defendants accepted comments after the IFRs had already gone into effect, and purported to consider those comments in issuing the final Exemption Rules.

175. The final Exemption Rules “finalize” the IFRs, and adopt without change most of the language in the IFRs.

176. As a result, the final Exemption Rules are impermissibly tainted with the same procedural defects as the IFRs.

177. In addition, when an agency does accept comments, it must respond to all significant comments and provide a statement of the “basis and purpose” of each final rule. 5 U.S.C. § 553(c).

178. The responses to comments offered by Defendants in the final Exemption Rules are insufficient, and the statements of basis and purpose fail to satisfy APA requirements.

179. Because the Departments failed to follow the procedural requirements of the APA, the final Exemption Rules should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2)(D).

COUNT IV

Violation of the Substantive Requirements of the Administrative Procedure Act

180. Pennsylvania and New Jersey incorporate by reference the foregoing paragraphs of this Complaint as if set forth at length.

181. Under the APA, a court shall “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

182. Both the final Moral Exemption Rule and the final Religious Exemption Rule are inconsistent with the Affordable Care Act's requirement that group health plans and insurers provide women with preventive care as provided for in guidelines issued by HRSA, without any cost-sharing requirements.

183. The Rules also violate the civil rights protections in the ACA prohibiting discrimination on the basis of sex and other protected categories in most healthcare programs and activities. *See* 42 U.S.C. § 18116.

184. They also violate the provisions of the ACA that prohibit the promulgation of any regulation that “[c]reates any unreasonable barrier to the ability of individuals to obtain appropriate medical care,” “[i]mpedes timely access to health care services,” or “[l]imits the availability of health care treatment for the full duration of a patient’s medical needs.” 42 U.S.C. § 18114.

185. In addition, the Departments abused their discretion and acted in a manner that was arbitrary and capricious in issuing the final Exemption Rules. 5 U.S.C. § 706(2)(A).

186. Specifically, the Departments fail to provide an adequate rationale for concluding that the Accommodation violates the Religious Freedom Restoration Act. They also fail to provide adequate reasons for why the final Religious Exemption is required or permissible under the Religious Freedom Restoration Act.

187. Indeed, when it passed the Affordable Care Act, Congress elected not to include a “conscientious objector” or other exemption for individuals or organizations who object to any portion of the ACA on religious or moral grounds.

188. The Departments further rely on arbitrary and capricious explanations to justify their decision to issue the Final Exemptions Rules.

189. Because the final Exemption Rules are arbitrary, capricious, an abuse of discretion, and contrary to law, they should be held unlawful and set aside pursuant to 5 U.S.C. § 706(2)(A).

COUNT V

Violation of the Establishment Clause

190. Pennsylvania and New Jersey incorporate by reference the foregoing paragraphs of this Complaint as if set forth at length.

191. The final Exemption Rules violate the Establishment Clause of the First Amendment to the U.S. Constitution.

192. The Departments have used their rulemaking authority for the primary purpose, and with the actual effect, of advancing and endorsing religious interests.

193. The Departments have acted to promote employers' religious beliefs over the self-determination of women who may not share those beliefs and over the ACA's mandate that preventive care be provided.

194. As a result, the final Exemption Rules violate the Establishment Clause.

PRAYER FOR RELIEF

WHEREFORE, the Commonwealth of Pennsylvania and the State of New Jersey request that this Court enter judgment in their favor and grant the following relief:

- a. Declare the final Moral Exemption Rule and the final Religious Exemption Rule unlawful;
- b. Vacate the final Moral Exemption Rule and the final Religious Exemption Rule;
- c. Preliminarily and permanently enjoin the application of the final Moral Exemption Rule and the final Religious Exemption Rule;
- d. Award Plaintiffs reasonable costs, including attorneys' fees; and
- e. Grant such other and further relief as the Court deems just and proper.

December 14, 2018

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**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA et al.,

Plaintiffs,

v.

DONALD J. TRUMP et al.,

Defendants.

No. 2:17-cv-04540-WB

DECLARATION OF KATHRYN KOST

I, Kathryn Kost, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by Plaintiffs in the above-captioned matter and, in support thereof, state as follows:

1. I am the Acting Vice President for Domestic Research at the Guttmacher Institute. I have worked for the Guttmacher Institute in a full-time or consulting capacity for nearly 30 years since joining the Institute as a Senior Research Associate in 1989. I received my BA in sociology from Reed College and my PhD in sociology from Princeton University, where I specialized in demography at the Office of Population Research.

2. The Guttmacher Institute is a private, independent, nonprofit, nonpartisan corporation that advances sexual and reproductive health and rights through an interrelated program of research, policy analysis, and public education. The Institute's overarching goal is to ensure quality sexual and reproductive health for all people worldwide by conducting research according to the highest standards of methodological rigor and promoting evidence-based policies. It produces a wide range of resources on topics pertaining to sexual and reproductive health and publishes two peer-reviewed journals. The information and analysis it generates on

reproductive health and rights issues are widely used and cited by researchers, policymakers, the media and advocates across the ideological spectrum.

3. Over the course of more than 30 years, I have designed, executed, and analyzed numerous quantitative and qualitative research studies in the field of reproductive health care, including those on contraceptive use and failure, unintended pregnancy, maternal and child health, and the impact on public health and fisc associated with particular reproductive health care policies or trends. My peer-reviewed research has been published in dozens of articles, including first-authored work in *Demography*, *Perspectives on Sexual and Reproductive Health*, *Contraception*, *Studies in Family Planning* and other public health, medical and demographic journals. My education, training, responsibilities and publications are set forth in greater detail in my curriculum vitae, a true and correct copy of which is attached as Exhibit A. I submit this declaration as an expert on reproductive health care, family planning, and unintended pregnancy, and the impact on individuals, families, and the public health from access to contraception and related care, or interference with that care, in the United States.

4. I understand that this lawsuit involves a challenge to the federal government's Final Rules ("Final Rules") regarding the Affordable Care Act's ("ACA") contraceptive coverage mandate. In my expert opinion, the Final Rules would compromise women's ability to obtain contraceptive methods, services and counseling and, in particular, to consistently use the best methods for them, thus putting them at heightened risk of unintended pregnancy.

**Contraception Is Widely Used and the Majority of Women Rely on Numerous
Contraceptive Methods for Decades of Their Lives**

5. More than 99% of women aged 15–44 who have ever had sexual intercourse have used at least one contraceptive method; this is true across a variety of religious affiliations.¹ Some 61% of all women of reproductive age are currently using a contraceptive method.² Among women at risk of an unintended pregnancy (i.e., women aged 15–44 who have had sexual intercourse in the past three months, are not pregnant or trying to conceive, and are not sterile for noncontraceptive reasons), 90% are currently using a contraceptive method.³

6. A typical woman in the United States wishing to have two children will, on average, spend three decades—roughly 90% of her reproductive life—avoiding unintended pregnancy.⁴

7. Women and couples rely on a wide range of contraceptive methods: In 2014, 25% of female contraceptive users relied on oral contraceptives and 15% on condoms as their most effective method. That means that six in 10 contraceptive users relied on other methods: female or male sterilization; hormonal or copper intrauterine devices (IUDs); other hormonal methods including the injectable, the ring, the patch and the implant; and behavioral methods, such as withdrawal and fertility awareness methods.⁵

¹ Daniels K, Mosher WD and Jones J, Contraceptive methods women have ever used: United States, 1982–2010, *National Health Statistics Reports*, 2013, No. 62, <https://www.cdc.gov/nchs/products/nhsr.htm>.

² Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, <https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012>.

³ Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, <https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012>.

⁴ Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, <https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform>.

⁵ Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, <https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012>

8. Most women rely on multiple methods over the course of their reproductive lives, with 86% having used three or more methods by their early 40s.⁶ Sometimes, women and couples may try out different methods to find one that they can use consistently or that minimizes side effects. Other times, they may switch from method to method—such as from condoms to oral contraceptives to sterilization—as their relationships, life circumstances and family goals evolve.

9. Many people use two or more methods at once: 17% of female contraceptive users did so the last time they had sex.⁷ For example, they may use condoms to prevent STIs and an IUD for the most reliable prevention of pregnancy. Or they may use multiple methods simultaneously—for instance, condoms, withdrawal and oral contraceptives—to provide extra pregnancy protection.

**Women Need Access to the Full Range of Contraceptive Options to Most Effectively
Avoid Unintended Pregnancies**

10. Using any method of contraception greatly reduces a woman's risk of unintended pregnancy. Sexually active couples using no method of contraception have a roughly 85% chance of experiencing a pregnancy in a one-year period, while the risk for those using a contraceptive method ranges from 0.05% to 28%.^{8,9}

⁶ Daniels K, Mosher WD and Jones J, Contraceptive methods women have ever used: United States, 1982–2010, *National Health Statistics Reports*, 2013, No. 62, <https://www.cdc.gov/nchs/products/nhsr.htm>.

⁷ Kavanaugh ML and Jerman J, Concurrent multiple methods of contraception in the United States, poster presented at the North American Forum on Family Planning, Atlanta, Oct. 14–16, 2017.

⁸ Sundaram A et al., Contraceptive failure in the United States: estimates from the 2006-2010 National Survey of Family Growth, *Perspectives on Sexual and Reproductive Health*, 2017, 49(1):7–16, <https://www.guttmacher.org/journals/psrh/2017/02/contraceptive-failure-united-states-estimates-2006-2010-national-survey-family>.

⁹ Trussell J, Aiken A, “Contraceptive Efficacy” pp. 829–928. In Hatcher RA et al., eds., *Contraceptive Technology*, 21st ed., New York: Ayer Company Publishers, 2018.

11. All new contraceptive drugs and devices (just like other drugs and devices) must receive approval from the U.S. Food and Drug Administration (FDA) and must be shown to be safe and effective through rigorous scientific testing. Thus, the federal government itself provides the oversight to ensure that contraception is safe and effective in preventing pregnancy.

12. The government's effort to imply that there is doubt about whether contraception reduces the risk of unintended pregnancy is simply unfounded, as the data above illustrate. Though the Final Rules cite "conflicting evidence" for the effects of a contraceptive coverage requirement,¹⁰ in the previous interim final rules, the government made positive arguments that contraceptive access did not reduce the risk of unintended pregnancy. This argument is flawed. For example, in the interim final rules the government argued, "In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent, unintended pregnancy rates in the United States rose from 35.4 percent to 49 percent."¹¹

13. However, the government's assertion in the interim final rules that unintended pregnancy rates rose between 1972 and 2002 was incorrect and based on faulty calculations and an inappropriate comparison. First, the numbers cited (35.4% and 49%) are the *percentage* of all pregnancies that were unintended, not the unintended pregnancy *rate*, which is the appropriate indicator for assessing trends in unintended pregnancy because it is not affected by changes in the incidence of *intended* pregnancy. Second, the 1972 figure includes only *births* (not all

¹⁰ Department of the Treasury, Department of Labor and Department of Health and Human Services, Religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act, *Federal Register*, 83(221):57536–57590, <https://www.gpo.gov/fdsys/pkg/FR-2018-11-15/pdf/2018-24512.pdf>

¹¹ Department of the Treasury, Department of Labor and Department of Health and Human Services, Religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act, *Federal Register*, 82(197):47838–47862, <https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-21852.pdf>.

pregnancies), and then only those births that were to married women.¹² Births to unmarried women and all abortions are excluded; the proportion of both of these that were unintended were significantly higher, so excluding them results in an artificially low percentage. The 2002 figure, on the other hand, includes all pregnancies to all women. An appropriate comparison of rates based on pregnancies and on all women in the population shows a clear decline in the rate: In 1971, there were an estimated 2.041 million unintended pregnancies (including births and abortions, but excluding miscarriages),¹³ and 43.6 million women of reproductive age (15–44),¹⁴ for an unintended pregnancy rate (excluding miscarriages) of 47 per 1,000 women. By contrast, in 2011, the unintended pregnancy rate *including* miscarriages was 45 per 1,000.¹⁵ Even when including miscarriages in the later rate, it is lower than the earlier rate; because miscarriages typically represent about 14% of all pregnancies,¹⁶ excluding them from the 2011 figure for comparability would result in a rate of about 38 per 1,000, substantially lower than the 1971 rate.

14. Although using any method of contraception is more effective in preventing pregnancy than not using a method at all, having access to a *limited* set of methods is far different than being able to choose from among the full range of methods to find the *best* methods for a given point in a woman's life.

¹² Weller RH and Heuser RL, Wanted and unwanted childbearing in the United States: 1968, 1969, and 1972 National Natality Surveys, *Vital and Health Statistics*, 1978, No. 32.

¹³ Tietze C, Unintended pregnancies in the United States, 1970–1972, *Family Planning Perspectives*, 1979, 11(3):186–188.

¹⁴ National Center for Health Statistics, Centers for Disease Control and Prevention, Population by age groups, race, and sex for 1960–1997, no date, <https://www.cdc.gov/nchs/data/statab/pop6097.pdf>.

¹⁵ Finer LB and Zolna MR, Declines in unintended pregnancy in the United States, 2008–2011, *New England Journal of Medicine*, 2016, 374(9):843–852.

¹⁶ Finer LB and Henshaw SK, Disparities in rates of unintended pregnancy in the United States, 1994 and 2001, *Perspectives on Sexual and Reproductive Health*, 2006, 38(2):90–96, <https://www.guttmacher.org/journals/psrh/2006/disparities-rates-unintended-pregnancy-united-states-1994-and-2001>.

15. One important consideration for most women in choosing a contraceptive method is how well a method works for an individual woman to prevent pregnancy.¹⁷ IUDs and implants, for example, are effective for years after they are inserted by a health care provider, and do not require women using them to think about contraception on a day-to-day basis.¹⁸ By contrast, birth control pills must be taken every day, at approximately the same time. Nearly half of abortion patients who were users of birth control pills reported that they had forgotten to take their pills, and another quarter reported a lack of ready access to their pills (16% were away from their pills and 10% ran out).¹⁹ Methods of contraception designed to be used during intercourse, such as condoms or spermicide, must be available, accessible, remembered, and used properly each time intercourse occurs.

16. Beyond effectiveness, there are many other features that people say are important to them when choosing a contraceptive method.²⁰ These include concerns about and past experience with side effects, drug interactions or hormones; affordability and accessibility; how frequently they expect to have sex; their perceived risk of HIV and other STIs; the ability to use the method confidentially or without needing to involve their partner; and potential effects on sexual enjoyment and spontaneity. For example, methods such as male condoms, fertility awareness and withdrawal require the active and effective participation of male partners. By contrast, methods

¹⁷ Lessard LN et al., Contraceptive features preferred by women at high risk of unintended pregnancy, *Perspectives on Sexual and Reproductive Health*, 2012, 44(2):194–200.

¹⁸ Winner B et al., Effectiveness of long-acting reversible contraception, *New England Journal of Medicine*, 366(21):1998–2007.

¹⁹ Jones RK, Darroch JE and Henshaw SK, Contraceptive use among U.S. women having abortions in 2000–2001, *Perspectives on Sexual and Reproductive Health*, 2002, 34(6): 294–303, <https://www.guttmacher.org/journals/psrh/2002/11/contraceptive-use-among-us-women-having-abortions-2000-2001>.

²⁰ Lessard LN et al., Contraceptive features preferred by women at high risk of unintended pregnancy, *Perspectives on Sexual and Reproductive Health*, 2012, 44(2):194–200.

such as IUDs, implants, and oral contraceptives can be more reliably used by the woman alone in advance of intercourse.²¹

17. Being able to select the methods that best fulfill a woman's needs and priorities is an important way to ensure that she will be satisfied with her chosen methods. Women who are satisfied with their current contraceptive methods are more likely to use them consistently and correctly. For example, one study found that 30% of neutral or dissatisfied users had a temporal gap in use, compared with 12% of completely satisfied users.²² Similarly, 35% of satisfied oral contraceptive users had skipped at least one pill in the past three months, compared with 48% of dissatisfied users.²³

18. Consistent contraceptive in turn use helps women and couples prevent unwanted pregnancies and plan and space those they do want. The two-thirds of U.S. women (68%) at risk of unintended pregnancy who use contraceptives consistently and correctly throughout a year account for only 5% of all unintended pregnancies. In contrast, the 18% of women at risk who use contraceptives but do so inconsistently account for 41% of unintended pregnancies, and the 14% of women at risk who do not use contraceptives at all or have a gap in use of one month or longer account for 54% of unintended pregnancies.²⁴

²¹ Bailey MJ, More power to the pill: the impact of contraceptive freedom on women's life cycle labor supply, *Quarterly Journal of Economics*, 2006, 121(1): 289–320, <https://academic.oup.com/qje/article-abstract/121/1/289/1849021?redirectedFrom=fulltext>.

²² Guttmacher Institute, Improving contraceptive use in the United States, *In Brief*, New York: Guttmacher Institute, 2008, <https://www.guttmacher.org/report/improving-contraceptive-use-united-states>.

²³ Guttmacher Institute, Improving contraceptive use in the United States, *In Brief*, New York: Guttmacher Institute, 2008, <https://www.guttmacher.org/report/improving-contraceptive-use-united-states>.

²⁴ Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, <https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform>.

19. In summary, the ability to choose from among the full range of contraceptive methods encourages consistent and effective contraceptive use, thereby helping women to avoid unintended pregnancies and to time and space wanted pregnancies.

Access to Contraception Does Not Increase Adolescent Sexual Activity

20. Adolescent pregnancy has declined dramatically over the past several decades: In 2013, the U.S. pregnancy rate among 15–19-year-olds was at its lowest point in at least 80 years and had dropped to about one-third of a recent peak rate in 1990.²⁵ The adolescent birthrate has continued to fall sharply from 2013–2016, suggesting that the underlying pregnancy rates have likely declined even further.²⁶ Over these decades, adolescents' sexual activity has not increased—in fact, it has declined—while their contraceptive use has increased.

21. National data limited to adolescents attending high school document long-term increases from 1991–2015 in the share of students using contraception, and decreases over the same time period in the share of students who are sexually active.²⁷ Several studies have validated that contraceptive access reduces adolescent pregnancy without increasing sexual activity: The vast majority (86%) of the decline in adolescent pregnancy between 1995 and 2002 was the result of improvements in contraceptive use; only 14% could be attributed to a decrease in sexual activity.²⁸ Further, when examining these same two factors, all of the decline in the more recent

²⁵ Kost K, Madow-Zimet I and Arpaia A, *Pregnancies, Births and Abortions Among Adolescents and Young Women in the United States, 2013: National and State Trends by Age, Race and Ethnicity*, New York: Guttmacher Institute, 2017, <https://www.guttmacher.org/report/us-adolescent-pregnancy-trends-2013>.

²⁶ Martin JA, Hamilton BE and Osterman MJK, *Births in the United States, 2016, NCHS Data Brief*, 2017, No. 287, <https://www.cdc.gov/nchs/products/databriefs.htm>.

²⁷ National Center for HIV/AIDS, Viral Hepatitis, TD, and TB Prevention, Centers for Disease Control and Prevention (CDC), *Trends in the Prevalence of Sexual Behaviors and HIV Testing National YRBS: 1991–2015*, Atlanta: CDC, no date, https://www.cdc.gov/healthyouth/data/yrbs/pdf/trends/2015_us_sexual_trend_yrbs.pdf.

²⁸ Santelli JS et al., Explaining recent declines in adolescent pregnancy in the United States: the contribution of abstinence and improved contraceptive use, *American Journal of Public Health*, 2007, 97(1): 150–156, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1716232/>.

2007–2012 period was attributable to better contraceptive use: More adolescents were using contraception, they were using more effective methods, and they were using them more consistently, while adolescent sexual activity did not change.²⁹

22. Recent trends in adolescent contraceptive use buttress this point: During 2011–2015, 81% of adolescent girls used contraception the first time they had sex, up from 75% in 2002; the share of adolescent girls who were sexually active stayed stable.^{30,31} Similarly, use of emergency contraception among sexually active female adolescents increased from 8% in 2002 to 22% in 2011–2013; there was no significant change in sexual activity during this time.³² And in a 2010 review of seven randomized trials of emergency contraception, there was no increase in sexual activity (e.g., reported number of sexual partners or number of episodes of unprotected intercourse) in adolescents given advanced access to emergency contraception.³³

23. Along the same lines, studies of the availability of contraception in high schools provide evidence that it does not lead to more sexual activity. Rather, while several studies of school-based health care centers that provide contraceptive methods have shown contraceptives' availability increases students' use of contraception,^{34,35} other studies have not found any

²⁹ Lindberg L, Santelli J and Desai S, Understanding the decline in adolescent fertility in the United States, 2007–2012, *Journal of Adolescent Health*, 2016, 59(5): 577–583, [http://www.jahonline.org/article/S1054-139X\(16\)30172-0/fulltext](http://www.jahonline.org/article/S1054-139X(16)30172-0/fulltext).

³⁰ Martinez G, Copen CE and Abma JC, Teenagers in the United States: Sexual activity, contraceptive use, and childbearing, 2006–2010 National Survey of Family Growth, *Vital Health Statistics*, 2011, Series 23, No. 31, <https://www.cdc.gov/nchs/products/series/series23.htm>.

³¹ Abma JC and Martinez G, Sexual activity and contraceptive use among teenagers in the United States, 2011–2015, *National Health Statistics Reports*, 2017, No. 104, <https://www.cdc.gov/nchs/products/nhsr.htm>.

³² Martinez GM and Abma JC, Sexual activity, contraceptive use, and childbearing of teenagers aged 15–19 in the United States, *NCHS Data Brief*, 2015, No. 209, <https://www.cdc.gov/nchs/products/databriefs.htm>.

³³ Meyer JL, Gold MA and Haggerty CL, Advance provision of emergency contraception among adolescent and young adult women: a systematic review of literature, *Journal of Pediatric and Adolescent Gynecology*, 2011, 24(1):2–9, [http://www.jpagonline.org/article/S1083-3188\(10\)00203-2/fulltext](http://www.jpagonline.org/article/S1083-3188(10)00203-2/fulltext).

³⁴ Minguez M et al., Reproductive health impact of a school health center, *Journal of Adolescent Health*, 2015, 56(3): 338–344, <https://www.ncbi.nlm.nih.gov/pubmed/25703321>.

³⁵ Knopf FA et al., School-based health centers to advance health equity: a Community Guide systematic review, *American Journal of Preventive Medicine*, 2016, 51(1): 114–126, [http://www.ajpmonline.org/article/S0749-3797\(16\)00035-0/fulltext](http://www.ajpmonline.org/article/S0749-3797(16)00035-0/fulltext).

associated increases in sexual activity.³⁶ And a recent review of studies of school-based condom availability programs found condom use increased the odds of students using condoms, while none increased sexual activity.³⁷

Eliminating the Cost of Contraception Leads to Improved Contraceptive Use and Reduces Women’s Risk of Unintended Pregnancy

24. Extensive empirical evidence demonstrates what common sense would predict: eliminating costs leads to more effective and continuous use of contraception. That is because cost can be a substantial barrier to contraceptive choice. The contraceptive methods that can be purchased over the counter at a neighborhood drugstore for a comparatively low cost—male condoms and spermicide—are far less effective than methods that require a prescription and a visit to a health care provider,³⁸ which have higher up-front costs.³⁹

25. The most effective methods of contraception are long-acting reversible contraceptives (LARC), such as implants and IUDs. Even with discounts for volume, the cost of these devices exceeds \$500, exclusive of costs relating to the insertion procedure,⁴⁰ and the total cost of initiating one of these methods generally exceeds \$1,000.⁴¹ To put that cost in perspective, beginning to use one of these devices costs nearly a month’s salary for a woman working full

³⁶ Kirby D, *Emerging Answers 2007: Research Findings on Programs to Reduce Teen Pregnancy and Sexually Transmitted Diseases*, Washington, DC: The National Campaign to Prevent Teen and Unplanned Pregnancy, 2007, https://thenationalcampaign.org/sites/default/files/resource-primary-download/EA2007_full_0.pdf.

³⁷ Wang T et al., The effects of school-based condom availability programs (CAPs) on condom acquisition, use and sexual behavior: a systematic review, *AIDS and Behavior*, 2017, <https://www.ncbi.nlm.nih.gov/pubmed/28625012>.

³⁸ Trussell J, Aiken A, “Contraceptive Efficacy” pp. 829–928. In Hatcher RA et al., eds., *Contraceptive Technology*, 21st ed., New York: Ayer Company Publishers, 2018.

³⁹ Trussell J et al., Cost effectiveness of contraceptives in the United States, *Contraception*, 2009, 79(1):5–14.

⁴⁰ Armstrong E et al., *Intrauterine Devices and Implants: A Guide to Reimbursement*, 2015, https://www.nationalfamilyplanning.org/file/documents---reports/LARC_Report_2014_R5_forWeb.pdf.

⁴¹ Eisenberg D et al., Cost as a barrier to long-acting reversible contraceptive (LARC) use in adolescents, *Journal of Adolescent Health*, 2013, 52(4):S59–S63, [http://www.jahonline.org/article/S1054-139X\(13\)00054-2/fulltext](http://www.jahonline.org/article/S1054-139X(13)00054-2/fulltext).

time at the federal minimum wage of \$7.25 an hour.⁴² These costs are dissuasive for many women not covered by the contraceptive coverage guarantee; one pre-ACA study concluded that women who faced high out-of-pocket IUD costs were significantly less likely to obtain an IUD than women with access to the device at low or no out-of-pocket cost. And only 25% of women who requested an IUD had one placed after learning the associated costs.⁴³ Even oral contraceptives, which are twice as effective as condoms in practice, require a prescription and have monthly costs. And although some stores offer certain pill formulations at steep discounts, access to those cost savings can require a woman to change to a different formulation than the one prescribed by her clinician and increases her risk of adverse health effects.

26. The government acknowledges that without coverage, many methods would cost women \$50 per month, or upwards of \$600 per year, and in doing so, implies that such costs are a minimal burden. This is not true. For example, a national study found that about one-third of uninsured people and lower-income people in the United States would be unable to pay for an unexpected \$500 medical bill, and roughly another third would have to borrow money or put it on a credit card and pay it back over time, with interest.⁴⁴

27. Without insurance coverage to defray or eliminate the cost, the large up-front costs of the more-effective contraceptive methods put them out of reach for many women who want them, driving them to less expensive and less effective methods. In a study conducted prior to the contraceptive coverage guarantee, almost one-third of women reported that they would change

⁴² 29 U.S.C. § 206(a)(1)(C). At 40 hours a week, that amounts to \$290 a week, before any taxes or deductions.

⁴³ Gariepy AM et al., The impact of out-of-pocket expense on IUD utilization among women with private insurance, *Contraception*, 2011, 84(6):e39–e42, <https://escholarship.org/uc/item/1dz6d3cx>.

⁴⁴ DiJulio B et al., Data note: Americans' challenges with health care costs, 2017, https://www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/?utm_campaign=KFF-2017-March-Polling-Beyond-The-ACA.

their contraceptive method if cost were not an issue.⁴⁵ This figure was particularly high among women relying on male condoms and other less effective methods such as withdrawal. A study conducted after the enactment of the ACA had similar findings: among women in the study who still lacked health insurance in 2015, 44% agreed that having insurance would help them to afford and use birth control and 44% agreed that it would allow them to choose a better method for them; 48% also agreed that it would be easier to use contraception consistently if they had coverage.⁴⁶ Among insured women who still had a copayment using a prescription method (e.g., those in grandfathered plans), 40% agreed that if the copayment were eliminated, they would be better able to afford and use birth control, 32% agreed this would help them choose a better method, and 30% agreed this would help them to use their methods of contraception more consistently. Other studies have found that uninsured women are less likely to use the most expensive (but most effective) contraceptive methods, such as IUDs, implants, and oral contraceptives,⁴⁷ and are more likely than insured women to report using no contraceptive method at all.^{48,49}

28. Reducing financial barriers is critical to increasing access to effective contraception. Before the ACA provision went into effect, 28 states required private insurers that cover prescription drugs to provide coverage of most or all FDA-approved contraceptive drugs and

⁴⁵ Frost JJ and Darroch JE, Factors associated with contraceptive choice and inconsistent method use, United States, 2004, *Perspectives on Sexual and Reproductive Health*, 2008, 40(2):94–104, <https://www.guttmacher.org/journals/psrh/2008/factors-associated-contraceptive-choice-and-inconsistent-method-use-united>.

⁴⁶ Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, [http://www.whijournal.com/article/S1049-3867\(17\)30029-4/fulltext](http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext).

⁴⁷ Culwell KR and Feinglass J, The association of health insurance with use of prescription contraceptives, *Perspectives on Sexual and Reproductive Health*, 2007, 39(4):226–230.

⁴⁸ Culwell KR and Feinglass J, The association of health insurance with use of prescription contraceptives, *Perspectives on Sexual and Reproductive Health*, 2007, 39(4):226–230.

⁴⁹ Culwell KR and Feinglass J, Changes in prescription contraceptive use, 1995–2002: the effect of insurance coverage, *Obstetrics & Gynecology*, 2007, 110(6):1371–1378, <https://www.ncbi.nlm.nih.gov/pubmed/18055734>.

devices.⁵⁰ These programs gave women access at lower prices than if contraception were not covered, but (at the time) all states still allowed insurers to require cost-sharing. Experience from these states demonstrates that having insurance coverage matters.⁵¹ Privately insured women living in states that required private insurers to cover prescription contraceptives were 64% more likely to use some contraceptive method during each month a sexual encounter was reported than women living in states with no such requirement, even after accounting for differences including education and income.⁵²

29. Although these state policies reduced women's up-front costs, other actions to eliminate out-of-pocket costs entirely—which is what the federal contraceptive coverage guarantee does—have even greater potential to increase women's ability to use methods effectively. For example, when Kaiser Permanente Northern California eliminated patient cost-sharing requirements for IUDs, implants, and injectables in 2002, the use of these devices increased substantially, with IUD use more than doubling.⁵³ Another example comes from a study of more than 9,000 St. Louis-region women who were offered the reversible contraceptive method of their choice (i.e., any method other than sterilization) at no cost for two to three years, and were “read a brief

⁵⁰ Guttmacher Institute, Insurance coverage of contraceptives, *State Policies in Brief (as of July 2012)*, 2012.

⁵¹ The government argued in the interim final rules that the state mandates have not been effective, asserting that “Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.” The study the government relied on for this assertion was published in a law review rather than in a peer-reviewed scientific journal. [See New MJ, Analyzing the impact of state level contraception mandates on public health outcomes, *Ave Maria Law Review*, 2015, 13(2):345–369.] One basic flaw in this article is that, at the time, none of the state contraceptive coverage mandates eliminated out-of-pocket costs entirely, which is the major advance from the federal guarantee and the issue in this case. In addition, over the course of the period the article evaluated, contraceptive coverage quickly became the norm in the insurance industry—even in states without mandates—thus minimizing potential differences between states with laws and states without them. [Sonfield et al. U.S. insurance coverage of contraceptives and impact of contraceptive coverage mandates, 2002, *Perspectives on Sexual and Reproductive Health*, 2004, 36(2):72–79, <https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/3607204.pdf>.]

⁵² Magnusson BM et al., Contraceptive insurance mandates and consistent contraceptive use among privately insured women, *Medical Care*, 2012, 50(7):562–568.

⁵³ Postlethwaite D et al., A comparison of contraceptive procurement pre- and post-benefit change, *Contraception*, 2007, 76(5): 360–365

script informing them of the effectiveness and safety of IUDs and implants.⁵⁴ Three-quarters of those women chose long-acting methods (i.e., IUDs or implants), a level far higher than in the general population. Likewise, a Colorado study found that use of long-acting reversible contraceptive methods quadrupled when offered with no out-of-pocket costs along with other efforts to improve access.⁵⁵

30. Government-funded programs to help low-income people afford family planning services provide further evidence that reducing or eliminating cost barriers to women's contraceptive choices has a dramatic impact on women's ability to choose and use the most effective forms of contraception. Each year, among the women who obtain contraceptive services from publicly funded reproductive health providers, 57% select hormone-based contraceptive methods, 18% use implants or IUDs, and 7% receive a tubal ligation.⁵⁶ It is estimated that without publicly supported access to these methods at low or no cost, nearly half (47%) of those women would switch to male condoms or other nonprescription methods, and 28% would use no contraception at all.⁵⁷

⁵⁴ Peipert JF et al., *Preventing unintended pregnancies by providing no-cost contraception*, *Contraception*, 2012, 120(6):1291–1297.

⁵⁵ Ricketts S, Klinger G and Schwalberg G, Game change in Colorado: widespread use of long-acting reversible contraceptives and rapid decline in births among young, low-income women, *Perspectives on Sexual and Reproductive Health*, 2014, 46(3):125–132.

⁵⁶ Frost JJ and Finer LB, Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula, memo to interested parties, New York: Guttmacher Institute, June 23, 2017, <https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf>.

⁵⁷ Frost JJ and Finer LB, Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula, memo to interested parties, New York: Guttmacher Institute, June 23, 2017, <https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf>.

The ACA's Contraceptive Coverage Guarantee Has Had a Positive Impact

31. By ensuring coverage for a full range of contraceptive methods, services and counseling at no cost, the ACA's contraceptive coverage mandate has had its intended effect of removing cost barriers to obtaining contraception. Between fall 2012 and spring 2014 (during which time the coverage guarantee went into wide effect), the proportion of privately insured women who paid nothing out of pocket for the pill increased from 15% to 67%, with similar changes for injectable contraceptives, the vaginal ring and the IUD.⁵⁸ Similarly, another study found that since implementation of the ACA, the share of women of reproductive age (regardless of whether they were using contraception) who had out-of-pocket costs for oral contraceptives decreased from 21% in 2012 to just 4% in 2014.⁵⁹ These trends have translated into considerable savings for U.S. women: one study estimated that pill and IUD users saved an average of about \$250 in copayments in 2013 alone because of the guarantee.⁶⁰

32. Before the ACA, contraceptives accounted for between 30–44% of out-of-pocket health care spending for women.⁶¹ Individual women themselves say that the ACA's contraceptive coverage guarantee is working for them. In a 2015 nationally representative survey of women aged 18–39, two-thirds of those who had health insurance and were using a hormonal contraceptive method reported having no copays; among those women, 80% agreed that paying nothing out of pocket helped them to afford and use their birth control, 71% agreed this helped

⁵⁸ Sonfield A et al. Impact of the federal contraceptive coverage guarantee on out-of-pocket payments for contraceptives: 2014 update, *Contraceptive*, 2015, 91(1):44–48.

⁵⁹ Sobel L, Salganicoff A and Rosenzweig C, *The Future of Contraceptive Coverage*, Kaiser Family Foundation (KFF) Issue Brief, Menlo Park, CA: KFF, 2017, <https://www.kff.org/womens-health-policy/issue-brief/the-future-of-contraceptive-coverage/>.

⁶⁰ Becker NV and Polsky D, Women saw large decrease in out-of-pocket spending for contraceptives after ACA mandate removed cost sharing, *Health Affairs*, 2015, 34(7):1204–1211.

⁶¹ Becker NV and Polsky D, Women saw large decrease in out-of-pocket spending for contraceptives after ACA mandate removed cost sharing, *Health Affairs*, 2015, 34(7):1204–1211.

them use their birth control consistently, and 60% agreed that having no copayment helped them choose a better method for them.⁶²

33. Demonstrating the population-level impact of the ACA's coverage provision (e.g., a change in unintended pregnancy rates) is complicated, because the provision affects only a subset of U.S. women, and because there are so many additional variables that affect women's pregnancy intentions, contraceptive use and ultimately the unintended pregnancy rate in the population. The evidence on whether the ACA's provision has affected contraceptive use at the population level is not definitive, but some studies suggest the guarantee has had an impact on contraceptive use, among those benefiting from the provision.

34. A study using claims data from 30,000 privately insured women in the Midwest found that the ACA's reduction in cost sharing was tied to a significant increase in the use of prescription methods from 2008 through 2014 (before and after the ACA provision went into effect), particularly long-acting methods.⁶³ Another study of health insurance claims from 635,000 privately insured women nationwide showed that rates of discontinuation and inconsistent use of contraception declined from 2010 to 2013 (again, before and after the ACA provision went into effect) among women using generic oral contraceptive pills after the contraceptive guarantee's implementation (among women using brand-name oral contraceptives, only the discontinuation rate declined).⁶⁴

⁶² Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, [http://www.whijournal.com/article/S1049-3867\(17\)30029-4/fulltext](http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext).

⁶³ Carlin CS, Fertig AR and Down BE, Affordable Care Act's mandate eliminating contraceptive cost sharing influenced choices of women with employer coverage, *Health Affairs*, 2016, 35(9):1608–1615.

⁶⁴ Pace LE, Dusetzina SB and Keating NL, Early impact of the Affordable Care Act on oral contraceptive cost sharing, discontinuation, and nonadherence, *Health Affairs*, 2016, 35(9):1616–1624.

35. Two other studies, looking at the broader U.S. population, found no change in overall use of contraception or an overall switch from less-effective to more-effective methods among women at risk of unintended pregnancy before and after the guarantee's implementation.^{65,66} However, both studies identified some positive trends among key groups. One of them found that between 2008 and 2014, among women aged 20–24 (the age group at highest risk for unintended pregnancy), LARC use more than doubled, from 7% to 19%, without a proportional decline in sterilization.⁶⁷ The other study showed that between 2012 and 2015, use of prescription contraceptive methods, and birth control pills in particular, increased among sexually inactive women, suggesting that more women were able to start a method before becoming sexually active or use a method such as the pill for noncontraceptive reasons after implementation of the contraceptive coverage guarantee.⁶⁸

36. There is also considerable empirical data from controlled experiments to confirm that the concept of removing cost as a barrier to women's contraceptive use is a major factor in reducing their risk for unintended pregnancy, and the abortions and unplanned births that would otherwise follow. For example, a study of more than 9,000 St. Louis-region women who were offered the reversible contraceptive method of their choice at no cost found that the number of abortions performed at St. Louis Reproductive Health Services declined by 21%.⁶⁹ Study participants'

⁶⁵ Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, [http://www.whijournal.com/article/S1049-3867\(17\)30029-4/fulltext](http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext).

⁶⁶ Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, <https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012>.

⁶⁷ Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, <https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012>.

⁶⁸ Bearak JM and Jones RK, Did contraceptive use patterns change after the Affordable Care Act? A descriptive analysis, *Women's Health Issues*, 2017, 27(3):316–321, [http://www.whijournal.com/article/S1049-3867\(17\)30029-4/fulltext](http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext).

⁶⁹ Peipert JF et al., *Preventing unintended pregnancies by providing no-cost contraception*, *Contraception*, 2012,

abortion rate was significantly lower than the rate in the surrounding St. Louis region, and less than half the national average.⁷⁰ Similarly, when access to both contraception and abortion increased in Iowa, the abortion rates actually declined.⁷¹ Starting in 2006, the state expanded access to low- or no-cost family planning services through a Medicaid expansion and a privately funded initiative serving low-income women. Despite a simultaneous increase in access to abortion—the number of clinics offering abortions in the state actually doubled during the study period—the abortion rate dropped by over 20%.

Expanding Exemptions Would Harm Women

37. The Final Rules would make it more difficult, once again, for those receiving insurance coverage through companies or schools that use the exemption (i.e., employees, students and dependents) to access the methods of contraception that are most acceptable and effective for them. That, in turn, would increase those women's risk of unintended pregnancy and interfere with their ability to plan and space wanted pregnancies. These barriers could therefore have considerable negative health, social and economic impacts for those women and their families.

38. Allowing employers or schools to exclude all contraceptive methods, services and counseling from insurance plans—or to cover some contraceptive methods, services and information but not others—would prevent women from selecting and obtaining the methods of contraception that will work best for them. For example, Hobby Lobby objected to providing

120(6):1291–1297.

⁷⁰ Peipert JF et al., *Preventing unintended pregnancies by providing no-cost contraception*, *Contraception*, 2012, 120(6):1291–1297.

⁷¹ Biggs MA, Did increasing use of highly effective contraception contribute to declining abortions in Iowa? *Contraception*, 2015, 91(2):167–173.

four specific contraceptive methods, including copper and hormonal IUDs, which are among the most effective forms of pregnancy prevention and also have among the highest up-front costs.

39. Allowing employers to restrict access to the full range of contraceptive methods and to approve coverage only for those they deem acceptable would place inappropriate constraints on women who depend on insurance to obtain the methods best suited to their needs. Moreover, in the absence of coverage, the financial cost of obtaining a method, and the fact that some methods have higher costs than others, would incentivize women to select methods that are inexpensive, rather than methods that are best suited to their needs and that they are therefore most likely to use consistently and effectively (see 10–19, above).

40. Excluding coverage for some or all contraceptive methods, services and counseling could deny women the ability to obtain contraceptive counseling and services from their desired provider at the same time they receive other primary and preventive care.^{72,73} A woman going to her gynecologist for an annual examination, for example, may have to go to a different provider to be prescribed (or even discuss) contraception. This disjointed approach increases the time, effort and expense involved in getting needed contraception and interferes with her ability to obtain care from the provider of her choice.

41. Isolating contraceptive coverage in this way also would interfere with the ability of health care providers to treat women holistically. A woman's choice of contraception can be affected by her other medical conditions (e.g., diabetes, HIV, depression/mental health), and certain medications can significantly reduce the effectiveness of some methods of contraception, so a

⁷² Leeman L, Medical barriers to effective contraception, *Obstetrics and Gynecology Clinics of North America*, 2007, 34(1):19–29.

⁷³ World Health Organization, *Selected Practice Recommendations for Contraceptive Use*, Third Ed., 2016, WHO: Geneva, Switzerland, <http://apps.who.int/iris/bitstream/10665/252267/1/9789241565400-eng.pdf>.

woman's chosen provider should be able to manage all health conditions and needs at the same time.^{74,75}

42. To the extent that expanding the exemptions would burden women's contraceptive use in these ways, it would be harmful to women's health. Contraception allows women to avoid unintended pregnancies and to time and space wanted pregnancies, which has been demonstrated to improve women's health and that of their families. Specifically, pregnancies that occur too early in a woman's life or that are spaced too closely are associated with negative maternal health outcomes and/or adverse birth outcomes, including preterm birth, low birth weight, stillbirth, and early neonatal death.^{76,77,78,79} Contraceptive use can also prevent preexisting health conditions from worsening and new health problems from occurring, because pregnancy can exacerbate existing health conditions such as diabetes, hypertension and heart disease.⁸⁰ Unintended pregnancy also affects women's mental health; notably, it is a risk factor for depression in adults.^{81,82} For these reasons, the Centers for Disease Control and Prevention (CDC) included the development of and improved access to methods of family planning among

⁷⁴ Centers for Disease Control and Prevention, *US Medical Eligibility Criteria for Contraceptive Use*, 2016, <https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html>.

⁷⁵ Centers for Disease Control and Prevention, U.S. medical eligibility criteria for contraceptive use, 2010, *Morbidity and Mortality Weekly Report*, May 28, 2010, Vol. 59, <https://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf>.

⁷⁶ Kavanaugh ML and Anderson RM, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers*, New York: Guttmacher Institute, 2013, <http://www.guttmacher.org/report/contraception-and-beyond-health-benefits-services-provided-family-planning-centers>.

⁷⁷ Wendt A et al., Impact of increasing inter-pregnancy interval on maternal and infant health, *Paediatric and Perinatal Epidemiology*, 2012, 26(Suppl. 1):239–258.

⁷⁸ Conde-Agudelo A, Rosas-Bermúdez A and Kafury-Goeta AC, Birth spacing and risk of adverse perinatal outcomes: a meta-analysis, *Journal of the American Medical Association*, 2006, 295(15):1809–1823.

⁷⁹ Gipson JD, Koenig MA and Hindin MJ, The effects of unintended pregnancy on infant, child, and parental health: a review of the literature, *Studies in Family Planning*, 2008, 39(1):18–38.

⁸⁰ Lawrence HC, Testimony of American Congress of Obstetricians and Gynecologists, submitted to the Committee on Preventive Services for Women, Institute of Medicine, 2011, <http://www.nationalacademies.org/hmd/~media/8BA65BAF76894E9EB8C768C01C84380E.ashx>.

⁸¹ Herd P et al., The implications of unintended pregnancies for mental health in later life, *American Journal of Public Health*, 2016, 106(3):421–429.

⁸² U.S. Preventive Services Task Force, Screening for depression in adults: recommendation statement, *American Family Physician*, 2016, 94(4):340A–340D, <http://www.aafp.org/afp/2016/0815/od1.html>.

the 10 great public health achievements of the 20th century.⁸³

43. In the Final Rules, the government implies that there is debate about whether contraception may have negative health consequences that outweigh its benefits. In the previous interim final rules, the government implied that putative negative health consequences of contraception may outweigh its benefits. On the contrary, the government itself provides the oversight to ensure that the health benefits of contraception outweigh any potential negative consequences. Notably, the FDA's approval processes require that drugs and devices, including contraceptives, be proven safe and effective through rigorous controlled trials. In addition, the CDC publishes extensive recommendations to help clinicians and patients identify potential contraindications and decide which specific contraceptive methods are most appropriate for each patient's needs and health circumstances.^{84,85} Medical experts, such as the American College of Obstetricians and Gynecologists, concur that contraception is safe and has clear health benefits that outweigh any potential risks.⁸⁶

44. Expanding the exemptions to the contraceptive coverage requirement would also have negative social and economic consequences for women, families and society. By enabling them to reliably time and space wanted pregnancies, women's ability to obtain and effectively use contraception promotes their continued educational and professional advancement, contributing to the enhanced economic stability of women and their families.⁸⁷ Economic analyses have found

⁸³ Centers for Disease Control and Prevention, Achievements in public health, 1900–1999: family planning, *Morbidity and Mortality Weekly Report*, 1999, 48(47): 1073–1080.

⁸⁴ Centers for Disease Control and Prevention, *US Medical Eligibility Criteria for Contraceptive Use*, 2016, <https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html>.

⁸⁵ Centers for Disease Control and Prevention, U.S. medical eligibility criteria for contraceptive use, 2010, *Morbidity and Mortality Weekly Report*, May 28, 2010, Vol. 59, <https://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf>.

⁸⁶ Brief of *Amici Curiae*, American College of Obstetricians and Gynecologists, Physicians for Reproductive Health, American Academy of Family Physicians, American Nurses Association, et al., *Zubik v. Burwell*, 2016, <http://www.scotusblog.com/wp-content/uploads/2016/02/Docfoc.com-Amicus-Brief-Zubik-v.-Burwell.pdf>.

⁸⁷ Sonfield A et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children*, New York: Guttmacher Institute, 2013, <https://www.guttmacher.org/report/social-and-economic-benefits->

positive associations between women's ability to obtain and use oral contraceptives and their education, labor force participation, average earnings and a narrowing of the gender-based wage gap.⁸⁸ Moreover, the primary reasons women give for why they use and value contraception are social and economic: In a 2011 study, a majority of women reported that access to contraception had enabled them to take better care of themselves or their families (63%), support themselves financially (56%), stay in school or complete their education (51%), or get or keep a job or pursue a career (50%).⁸⁹

45. The government contends that expanding the exemption would not impose any real harm, suggesting that the women most at risk for unintended pregnancy are not likely to be covered by employer-based group health plans or by student insurance sponsored by a college or university. That argument is misleading. Low-income women, women of color and women aged 18–24 are at disproportionately high risk for unintended pregnancy,⁹⁰ and millions of these women rely on private insurance coverage—particularly following implementation of the ACA. In fact, from 2013 to 2017, the proportion of women overall and of women below the poverty level who were uninsured dropped by more than one-third nationwide, declines driven by substantial increases in both Medicaid and private insurance coverage.⁹¹ In addition, the ACA specifically expanded coverage for people aged 26 and younger, allowing them to remain covered as dependents on

womens-ability-determine-whether-and-when-have-children.

⁸⁸ Sonfield A et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children*, New York: Guttmacher Institute, 2013, <https://www.guttmacher.org/report/social-and-economic-benefits-womens-ability-determine-whether-and-when-have-children>.

⁸⁹ Frost JJ and Lindberg LD, Reasons for using contraception: perspectives of U.S. women seeking care at specialized family planning clinics, 2012, *Contraception*, <http://www.guttmacher.org/pubs/journals/j.contraception.2012.08.012.pdf>.

⁹⁰ Finer LB and Zolna MR, Declines in unintended pregnancy in the United States, 2008–2011, *New England Journal of Medicine*, 2016, 374(9):843–852.

⁹¹ Guttmacher Institute, Gains in insurance coverage for reproductive-age women at a crossroads, *News in Context*, Dec. 4, 2018, <https://www.guttmacher.org/article/2018/12/gains-insurance-coverage-reproductive-age-women-crossroads>.

their parents' plans, regardless of whether the young woman is working herself or attending college or university.

**Medicaid, Title X and State Coverage Requirements Cannot Substitute for the
Federal Contraceptive Coverage Guarantee**

46. State and federal programs and laws—such as the Title X national family planning program, Medicaid, and state contraceptive coverage requirements—cannot replicate or replace the gains in access made by the contraceptive coverage guarantee. In the interim final rules, the government claimed that “[i]ndividuals who are unable to obtain contraception coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules...have other avenues for obtaining contraception....”⁹²

47. Many women who have the benefit of the ACA's contraceptive coverage mandate are not eligible for free or subsidized care under Title X. Title X provides no-cost family planning services to people living at or below 100% of the federal poverty level (\$12,060 for a single person in 2017),⁹³ and provides services on a sliding fee scale between 100% and 250% of poverty; women above 250% of poverty must pay the full cost of care. By contrast, the federal contraceptive coverage guarantee eliminates out-of-pocket costs for contraception regardless of income.

48. Funding for Title X has not increased sufficiently for the program even to keep up with the increasing number of women in need of publicly funded care;⁹⁴ therefore, Title X cannot

⁹² Department of the Treasury, Department of Labor and Department of Health and Human Services, Religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act, *Federal Register*, 82(197):47838–47862, <https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-21852.pdf>.

⁹³ Office of the Assistant Secretary for Planning and Evaluation, U.S. federal poverty guidelines used to determine financial eligibility for certain federal programs, 2017, <https://aspe.hhs.gov/poverty-guidelines>.

⁹⁴ Women in need of publicly funded contraceptive services are defined as those women who a) are younger than 20

sustain additional beneficiaries as a result of the Final Rules. From 2010 to 2014, even as the number of women in need of publicly funded contraceptive care grew by 5%, representing an additional one million women in need,⁹⁵ Congress cut funding for Title X by 10%.⁹⁶ With its current resources, Title X is able to serve only one-fifth of the nationwide need for publicly funded contraceptive care.⁹⁷ Still, the government has proposed diverting already insufficient Title X funding to help cover the cost of care for any women affected by the Final Rules,⁹⁸ an action that would inevitably hurt patients who rely on publicly funded services.

49. Similarly, many women who would lose private insurance coverage of contraception under the federal government's expanded exemption would not be eligible for Medicaid. Eligibility for Medicaid varies widely from state to state, particularly in states that have not expanded Medicaid eligibility under the ACA. In almost all of those states, nondisabled, nonelderly childless adults do not qualify for Medicaid at any income level, and eligibility for parents is as low as 18% of the federal poverty level in Alabama and Texas.⁹⁹ Several of these states have expanded eligibility specifically for family planning services to people otherwise

or are poor or low-income (i.e., have a family income less than 250% of the federal poverty level) and b) are sexually active and able to become pregnant but do not want to become pregnant. See Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

⁹⁵ Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

⁹⁶ Department of Health and Human Services, Office of Population Affairs, Funding history, 2017, <https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html>.

⁹⁷ Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

⁹⁸ Department of Health and Human Services, Compliance with statutory program integrity requirements, *Federal Register*, 83(106):25502–25533, <https://www.gpo.gov/fdsys/pkg/FR-2018-06-01/pdf/2018-11673.pdf>.

⁹⁹ Kaiser Family Foundation, Medicaid income eligibility limits for adults as a percent of the federal poverty level, 2018, State Health Facts, <https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level>.

ineligible for full-benefit Medicaid; those income eligibility levels also vary considerably.^{100,101} Again, by contrast, the federal contraceptive coverage guarantee applies regardless of income. And because the U.S. Supreme Court has ruled that states cannot be compelled by the federal government to expand Medicaid eligibility, the federal government cannot rely on Medicaid to fill in gaps in coverage that would result from expanding the exemption.

50. The federal government's assertion that Title X and Medicaid can replace or replicate the ACA's contraception coverage guarantee is additionally problematic given that the government itself is at the same time moving to undermine Title X and Medicaid. For example, the government's recent budget proposals have sought to exclude Planned Parenthood Federation of America and its affiliates from Title X, Medicaid and other federal programs,¹⁰² and have called for massive cuts to Medicaid.¹⁰³ The Department of Health and Human Services has proposed sweeping changes to Title X regulations that would undermine quality of care and access to providers,¹⁰⁴ and it has encouraged states to revamp their Medicaid programs in ways that would restrict program eligibility (e.g., by imposing work requirements) and thereby interfere with coverage and care.¹⁰⁵ The administration has strongly backed similar congressional proposals for cutting and limiting access to Title X and Medicaid.

¹⁰⁰ Guttmacher Institute, Medicaid family planning eligibility expansions, *State Laws and Policies (as of December 2018)*, 2018, <https://www.guttmacher.org/state-policy/explore/medicaid-family-planning-eligibility-expansions>.

¹⁰¹ Kaiser Family Foundation, Status of state action on the Medicaid expansion decision, 2018, State Health Facts, <https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/>.

¹⁰² Hasstedt K, Beyond the rhetoric: the real-world impact of attacks on Planned Parenthood and Title X, *Guttmacher Policy Review*, 2017, 20:86–91, <https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x>.

¹⁰³ Luhby T, Not even the White House knows how much it's cutting Medicaid, *CNN*, May 24, 2017, <http://money.cnn.com/2017/05/24/news/economy/medicaid-budget-trump/index.html>.

¹⁰⁴ Department of Health and Human Services, Compliance with statutory program integrity requirements, *Federal Register*, 83(106):25502–25533, <https://www.gpo.gov/fdsys/pkg/FR-2018-06-01/pdf/2018-11673.pdf>.

¹⁰⁵ Sonfield A, Efforts to transform the nature of Medicaid could undermine access to reproductive health care, *Guttmacher Policy Review*, 2017, 20:97–102, <https://www.guttmacher.org/gpr/2017/10/efforts-transform-nature-medicaid-could-undermine-access-reproductive-health-care>.

51. In addition, proposed changes to Title X would make it even more unsuitable as a substitute for contraceptive coverage under the ACA. The recent proposed rule for Title X removes the requirement that the contraceptive methods offered by a Title X provider be “medically approved.”¹⁰⁶ At the same time, the proposed rule seemingly opens the door to allow Title X funding to go to antiabortion counseling centers (also called “crisis pregnancy centers”), which do not offer the broad range of FDA-approved methods of contraception and may offer only abstinence-until-marriage counseling and fertility awareness-based methods. These proposed changes, if implemented, would shift the Title X program away from its mission of offering access to a broad range of family planning methods.¹⁰⁷

52. Policymakers in many states have also restricted publicly funded family planning programs and providers, further undermining the ability of these programs to serve those affected by the expanded exemption.¹⁰⁸

53. Neither can state-specific contraceptive coverage laws replicate or replace the increase in access to contraception provided by the ACA’s contraceptive coverage guarantee. Twenty-one have no such laws at all.¹⁰⁹ Of the 29 states and the District of Columbia that do have contraceptive coverage requirements, only 10 currently bar copayments and deductibles for contraception (and another four states have new requirements not yet in effect). Additionally, the federal requirement limits the use of formularies and other administrative restrictions on women’s use of contraceptive services and supplies, by making it clear that health plans may

¹⁰⁶ Department of Health and Human Services, Compliance with statutory program integrity requirements, *Federal Register*, 83(106):25502–25533, <https://www.gpo.gov/fdsys/pkg/FR-2018-06-01/pdf/2018-11673.pdf>.

¹⁰⁷ Hasstedt K, A Domestic gag rule and more: the administration’s proposed changes to Title X, *Health Affairs Blog*, June 18, 2018, <https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x>.

¹⁰⁸ Gold RB and Hasstedt K, Publicly funded family planning under unprecedented attack, *American Journal of Public Health*, 2017, 107(12):1895–1897, <http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304124>.

¹⁰⁹ Guttmacher Institute, Insurance coverage of contraceptives, *State Laws and Policies (as of December 2018)*, 2018, <http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

seek to influence a patient's choice only within a specific contraceptive method category (e.g., to favor one hormonal IUD over another) and not across methods (e.g., to favor the pill over the ring).¹¹⁰ Few of the state laws include similar protections. Similarly, most of the state requirements do not specifically require coverage of all the distinct methods that the federal requirement encompasses. For example, only eight states currently require coverage of female sterilization, and few state laws make explicit distinctions between methods that some insurance plans have attempted to treat as interchangeable (such as hormonal versus copper IUDs, or the contraceptive patch versus the contraceptive ring).¹¹¹ Finally, state laws cannot regulate self-insured employers at all, and those employers account for 60% of all workers with employer-sponsored health coverage.¹¹²

State-Specific Impacts

54. The Final Rules would have public health and fiscal consequences in states across the country. If unable to access contraception coverage through their employer or university, some lower-income women who meet the strict income requirements of public programs would rely on publicly funded services to access this beneficial service. Many women who lose or lack contraceptive coverage because their employer or university objects, however, would not meet the strict income and eligibility requirements of public programs, and if as a result they are not using their preferred or the most effective methods for them, or if cost forces them to forgo

¹¹⁰ Department of Labor, FAQs about Affordable Care Act implementation (part XXVI), May 11, 2015, <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf>.

¹¹¹ Guttmacher Institute, Insurance coverage of contraceptives, *State Laws and Policies (as of December 2018)*, 2018, <http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

¹¹² Claxton G et al., *Employer Health Benefits: 2017 Annual Survey*, Menlo Park, CA: Kaiser Family Foundation; and Chicago: Health Research & Educational Trust, 2017, <https://www.kff.org/report-section/ehbs-2017-section-10-plan-funding/>.

contraceptive use periodically or altogether, they would be at increased risk of unintended pregnancy. The costs of the resulting unintended pregnancies often then fall to the states because the federal government cannot or will not withstand these costs.

Pennsylvania

55. In Pennsylvania, some women impacted by the Final Rules would not qualify for Medicaid or Title X because they would not meet the income eligibility requirements for coverage or subsidized care under these programs.

56. For example, in Pennsylvania, childless adults and parents are only eligible for full-benefit Medicaid if they have incomes at or below 138% of the federal poverty level,¹¹³ and individuals are eligible for coverage of family planning services specifically up to 220% of poverty.¹¹⁴ This means that affected women who lose coverage as a result of the rules may not be eligible.

57. As a result, some women would be at increased risk of unintended pregnancy, either because they are not able to afford the methods that work best for them, or because cost would force them to forgo contraception use entirely.

58. Other women would be eligible for and rely on publicly funded family planning services through programs such as Medicaid and Title X. Those women could be denied the ability to obtain contraceptive counseling and services from their desired provider at the same time they receive other primary and preventive care, increasing the time, effort and expense involved in getting needed contraception. In addition, isolating contraceptive coverage in this way would

¹¹³ Kaiser Family Foundation, Medicaid income eligibility limits for adults as a percent of the federal poverty level, 2018, State Health Facts, <https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level>.

¹¹⁴ Guttmacher Institute, Medicaid family planning eligibility expansions, *State Laws and Policies (as of December 2018)*, 2018, <https://www.guttmacher.org/state-policy/explore/medicaid-family-planning-eligibility-expansions>.

interfere with the ability of health care providers to manage all of a woman's health conditions and needs at the same time.

59. The increase in the number of women relying on publicly funded services would increase the strain on the state's family planning programs and providers, making it more difficult for them to meet the existing need for publicly funded care. In 2014, 746,000 women were in need of publicly funded family planning in Pennsylvania, and the state's family planning network was able to only meet 29% of this need.¹¹⁵

60. Another indicator of the existing unmet need for contraception in Pennsylvania is that substantial numbers of state residents experience unintended pregnancy each year. In 2010, 115,000 unintended pregnancies occurred among Pennsylvania residents, a rate of 47 per 1,000 women aged 15–44.¹¹⁶

61. Of those unintended pregnancies that ended in birth, 54% were paid for by Medicaid and other public insurance programs.¹¹⁷ Unintended pregnancies cost the state approximately \$248 million and the federal government approximately \$479 million in 2010. The Final Rules are likely to increase the number of unintended pregnancies experienced by state residents, and thus to increase state and federal expenditures.

¹¹⁵ Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

¹¹⁶ Kost K, *Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002*, New York: Guttmacher Institute, 2015, <https://www.guttmacher.org/report/unintended-pregnancy-rates-state-level-estimates-2010-and-trends-2002>.

¹¹⁷ Sonfield A and Kost K, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, New York: Guttmacher Institute, 2015, <https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy>.

62. In conclusion, adding to the number of women at risk of unintended pregnancy by expanding the exemption is not in the public health or economic interest of Pennsylvania or its residents.

New Jersey

63. In New Jersey, some women impacted by the Final Rules would not qualify for Medicaid or Title X because they would not meet the income eligibility requirements for coverage or subsidized care under these programs.

64. For example, in New Jersey, childless adults and parents are only eligible for full-benefit Medicaid if they have incomes at or below 138% of the federal poverty level.¹¹⁸ (New Jersey has not expanded Medicaid eligibility specifically for family planning services.) This means that affected women who lose coverage as a result of the rules may not be eligible.

65. As a result, some women would be at increased risk of unintended pregnancy, either because they are not able to afford the methods that work best for them, or because cost would force them to forgo contraception use entirely.

66. Other women would be eligible for and rely on publicly funded family planning services through programs such as Medicaid and Title X. Those women could be denied the ability to obtain contraceptive counseling and services from their desired provider at the same time they receive other primary and preventive care, increasing the time, effort and expense involved in getting needed contraception. In addition, isolating contraceptive coverage in this way would interfere with the ability of health care providers to manage all of a woman's health conditions and needs at the same time.

¹¹⁸ Kaiser Family Foundation, Medicaid income eligibility limits for adults as a percent of the federal poverty level, 2018, State Health Facts, <https://www.kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level>.

67. The increase in the number of women relying on publicly funded services would increase the strain on the state's family planning programs and providers, making it more difficult for them to meet the existing need for publicly funded care. In 2014, 455,000 women were in need of publicly funded family planning in New Jersey, and the state's family planning network was able to only meet 22% of this need.¹¹⁹

68. Another indicator of the existing unmet need for contraception in New Jersey is that substantial numbers of state residents experience unintended pregnancy each year. In 2010, 97,000 unintended pregnancies occurred among New Jersey residents, a rate of 56 per 1,000 women aged 15–44.¹²⁰

69. Of those unintended pregnancies that ended in birth, 52% were paid for by Medicaid and other public insurance programs.¹²¹ Unintended pregnancies cost the state approximately \$186 million and the federal government approximately \$291 million in 2010. The Final Rules are likely to increase the number of unintended pregnancies experienced by state residents, and thus to increase state and federal expenditures.

70. In conclusion, adding to the number of women at risk of unintended pregnancy by expanding the exemption is not in the public health or economic interest of New Jersey or its residents.

¹¹⁹ Frost JJ, Frohwirth L and Zolna MR, *Contraceptive Needs and Services, 2014 Update*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

¹²⁰ Kost K, *Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002*, New York: Guttmacher Institute, 2015, <https://www.guttmacher.org/report/unintended-pregnancy-rates-state-level-estimates-2010-and-trends-2002>.

¹²¹ Sonfield A and Kost K, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, New York: Guttmacher Institute, 2015, <https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy>.

Ample evidence demonstrates that the Final Rules would interfere with women's ability to identify and consistently use the contraceptive methods that would work best for them, thus putting them at heightened risk of unintended pregnancy and the health, social and economic harms that would result.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: December 14, 2018

A handwritten signature in black ink, appearing to read "Kathryn Kost". The signature is fluid and cursive, with the first name "Kathryn" written in a larger, more prominent script than the last name "Kost".

By: Kathryn Kost
Acting Vice President for Domestic Research
The Guttmacher Institute

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

No. 2:17-cv-04540-WB

DONALD J. TRUMP, *et al.*,

Defendants.

DECLARATION OF CYNTHIA H. CHUANG, M.D., MSc¹

I, Cynthia H. Chuang, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. My Background and Experience

1. I am a practicing general internist, primary care provider, professor, and health services researcher, with a principal research interest in unintended pregnancy prevention and contraceptive decision-making in adult women.

A. My Job, Educational Training and Academic Practice

2. I work as a Professor of Medicine, Public Health Services, and Obstetrics and Gynecology in the Departments of Medicine, Public Health Sciences, and Obstetrics and Gynecology at the Pennsylvania State University College of Medicine, where I also serve as the Chief of the Division of General Internal Medicine, a division of over 70 physicians with clinical practice in primary care medicine, hospital medicine, palliative care, and post-acute care.

¹ I attach a true and correct copy of my curriculum vitae hereto as Exhibit 1.

3. I am also the Research Director of the Penn State K12 BIRCWH (Building Interdisciplinary Research Careers in Women's Health) Program.

4. I have been on faculty at the Penn State College of Medicine since 2004.

5. I earned a Bachelor of Science degree from the University of Michigan in 1992 and earned my Medical Degree from the New York University School of Medicine in 1997.

6. Thereafter, I completed my residency and chief residency in Internal Medicine at Temple University Hospital, in Philadelphia, Pennsylvania, in 2001.

7. I earned a Masters of Science in Epidemiology (MSc) from the Boston University School of Public Health in 2003 and completed my General Internal Medicine fellowship and residency in Preventive Medicine at Boston University School of Medicine, in 2004.

8. During my training, some of my most formative experiences were when I worked with patients in the areas of pregnancy prevention and contraceptive care at a family planning clinic in rural California; a primary care clinic at Temple University in North Philadelphia, Pennsylvania; and a women's health clinic at Boston Medical Center in Boston, Massachusetts.

9. Throughout my career, I have been an investigator on a number of studies and projects regarding contraception and reproductive health. For example, I was the Principal Investigator of a Patient-Centered Outcomes Research Institute (PCORI) contract to design and evaluate interventions aimed at assisting women with personalized contraceptive choices that best meet their individual needs (CD-1304-6117), and recipient of a National Institutes of Health (NIH) K23 career development award to study unintended pregnancy in women with chronic medical conditions. I am the Penn State site Principal Investigator for the PCORNet PaTH Clinical Data Research Network, a multi-institutional integrated research network in partnership with the University of Pittsburgh/University of Pittsburgh Medical Center, Temple University Health

System, Johns Hopkins University Health System, Geisinger Health System, and the University of Utah Health System.

10. I have authored over 70 scholarly publications, a significant portion of which focus on women's healthcare and preventive services. Among other topics, I have written about: reducing unintended pregnancies through reproductive planning and contraceptive action planning, contraceptive decision-making in women with and without chronic medical conditions, and the meaning of pregnancy intention.

11. Some of my recent articles include:

- a. Snyder A, Weisman CS, Liu G, Leslie D, Chuang CH. The impact of the Affordable Care Act on contraceptive use and costs among privately insured women. *Women's Health Issues* 2018, 28(3): 219-223.
- b. "Measuring Oral Contraceptive Adherence Using Self-Report Versus Pharmacy Claims Data," *Contraception*, 2017 Sep 04, Nelson HN, Borrero S, Lehman E, Velott DL, Chuang CH;
- c. "How Do Pregnancy Intentions Affect Contraceptive Choices When Cost Is Not a Factor? A Study of Privately Insured Women," *Contraception*, 2015 Nov; 92(5):501-7, Weisman CS, Lehman EB, Legro RS, Velott DL, Chuang CH; and
- d. "Making the Most of the Affordable Care Act's Contraceptive Coverage Mandate for Privately-Insured Women," *Women's Health Issues*, 2014 Sep-Oct; 24(5):465-8, Weisman CS, Chuang CH.

12. I have received multiple awards and recognitions for my academic work including delivering the 2017 Spring Dean's Lecture (Contraceptive Use: Before, During and After the Affordable Care Act). I received the Dean's Award for Innovation in Team Science in 2014, the

Department of Medicine Excellence in Mentoring Award in 2014 and the Junior Faculty Award for Excellence in Research in 2008. I have also received the Dean's Award for Excellence in Teaching in 2010 and 2014, and the Special Recognition for Education Leadership and Service Award on 2005.

B. *My Medical Practice*

13. In addition to my academic work, I am also a clinician and maintain an active adult primary care practice in Hershey, Pennsylvania, in which a portion of my patients are women of child-bearing age.

14. My practice is focused on preventive medicine and chronic disease management.

15. For my female patients of child-bearing age, preventive medicine includes reproductive life planning, including the use of contraceptives.

16. For medical reasons, the ideal "spacing" between pregnancies is eighteen months, because there is a greater risk of poor birth outcomes, like low birthweight and preterm birth, if pregnancies are not properly spaced.

17. I routinely have conversations with my patients about spacing out their pregnancies due to their medical health and educational, work and economic goals. Indeed, the Centers for Disease Control and Prevention (CDC) recommends that doctors counsel their patients about issues of "reproductive life planning," including their life, financial and job goals.

18. These conversations routinely result in changes to patients' contraceptive care. Indeed, I have found that it is important to be flexible with respect to contraceptive care because patients' changing life situations will frequently call for changes in their contraceptive method choice.

19. Through my medical practice, I have found that the most important thing about

providing preventive contraceptive care is to counsel my patients to use the method of contraception that is best suited for their individual needs at their particular place in life.

20. My patients are generally highly insured and mostly white.

21. Some live in highly rural areas and drive long distances to see me.

22. I direct low-income patients without insurance to the Medicaid program (if eligible). I direct other uninsured or underinsured women without contraceptive coverage to seek care through Planned Parenthood, or another Federally Qualified Health Center (FQHC), where they may qualify for contraceptive coverage under Title X.

23. Some of my patients also work for and receive their health insurance through Catholic Schools and other institutions which might seek to eliminate contraceptive coverage through their employer-sponsored plans under the new religious and moral exemptions.

II. My Opinion on the Final Religious Exemption Rule and Final Moral Exemption Rule

24. I have reviewed both the final Religious Exemption Rule and the final Moral Exemption Rule (together, the “Final Exemption Rules”), as well as the amended Complaint filed by the Commonwealth of Pennsylvania in the above-captioned matter that challenges them.

25. Based upon my knowledge, education, training and experience, it is my professional opinion that the Final Exemption Rules will cause immediate and irreversible harm because they will cause women to lose preventive contraceptive care under their employer group health plans.

A. Cost is a Barrier to Contraceptive Access

26. It is my understanding, and it has been my experience, that cost is a barrier to access to contraceptives. This has been corroborated in research studies.

27. Prior to passage of the Affordable Care Act (the “Affordable Care Act” or “ACA”),

before preventive contraceptive care was provided at no out-of-pocket cost under the ACA's contraceptive mandate, I regularly counseled my patients about the cost related to their recommended contraceptive choices.

28. At that time, it was not unusual for my patients to reject the specific contraceptive I had recommended due to its cost; instead, they would request that I prescribe a less effective, but cheaper, method of contraception. Or they would forego use of contraception altogether.

29. Such requests were most frequent when I had recommended intrauterine Devices (IUDs) or contraceptive implants. IUDs and implants carried heavy cost-sharing responsibilities and, therefore, were most expensive to patients pre-ACA. But they are also a much more effective method of contraceptive care (<1% failure rate) than birth control pills (9% failure rate).

30. After the ACA passed and the contraceptive mandate was instituted, however, I saw that my patients were free to make contraceptive choices on the basis of their medical and personal needs and concerns, alone, without the burden of having to weigh the cost of the preferred medical choice. Put otherwise, post-ACA, the only concern has become what is best for the patient.

31. Since the ACA passed, no patient has contacted me to ask for a different, cheaper method of contraception than the one I had prescribed due to the cost under private insurance plans.

32. Furthermore, as a result of the ACA's contraceptive mandate, I have seen patients switch from a cheaper, less effective method to a more effective, expensive method that was better for their medical health and personal needs.

B. *Because Patients Will Lose Contraceptive Coverage under the New Final Exemption Rules, They Will Make Less Medically Sound Contraceptive Choices and, Therefore, Will Be Harmed*

33. It is apparent, however, that under the new Final Exemption Rules this post-ACA focus on what is best for the patient will change.

34. This is so because, as a result of the Final Exemption Rules, some women will lose insurance coverage for preventive contraceptive care.

35. As a result, their costs for contraceptive care will rise.

36. Based upon my own experience and existing scientific and empirical information that I have reviewed and am aware of, under the new Final Exemption Rules, cost will, again, become a barrier to women's access to and use of the contraceptive that is medically recommended for them.

37. Many of these women who will no longer receive contraceptive coverage will not only face financial harm, but will also face medical harm.

38. This harm will manifest itself in the disruption of these patients' medical treatment, whether by substituting a less effective but cheaper method of contraception or by being forced to stop using contraceptives at all, due to financial reasons.

39. Some of these women will face unintended pregnancy and other adverse medical consequences.

C. *The New Final Exemption Rules Are Not Based Upon Sound Scientific or Empirical Evidence*

40. It is also my opinion that the new Final Exemption Rules are not based upon sound scientific or empirical evidence.

41. The Final Exemption Rules indicate, among other things, that contraceptives are not effective in preventing unintended pregnancy. This is false.

42. This claim in the Final Exemption Rules is inconsistent with the weight of scientific and empirical authority.

43. Indeed, well-established research indicates that contraceptives are, in fact, effective preventing unintended pregnancy. To be sure, while various methods of contraception can be effective at preventing unintended pregnancy, some are more effective than others.

44. Several other statements in the Final Exemption Rules are also not scientifically credible.

45. The Final Exemption Rules state that some commenters criticized the 2011 IOM Report for citing studies that assert associative relationship between contraceptive use and decreases in unintended pregnancy, and not causal relationships. Establishing a causal relationship would be unethical and unrealistic. Studies of association have shown that women using specific contraceptive methods are less likely to become pregnant than women not using those methods. A causal relationship could only be established if a study were conducted where women were randomly assigned to receive a specific contraceptive method and compared with women who were randomly assigned to use no contraceptive method. Studies of association have provided the rationale for the knowledge that smoking causes lung cancer, HIV causes AIDS, and Pap smears reduce cervical cancer.

46. The Final Exemption Rules acknowledge commenters who report that hormonal contraceptives cause depression, citing one large study from Denmark. This report should not be evaluated in isolation, as other studies have found no consistent association between hormonal contraceptive use and depressive symptoms, while others have found hormonal contraception has reduced levels of depressive symptoms. These studies are difficult to conduct, since women who are receiving hormonal contraception must be enrolled in health care services, where they are more

likely to be screened and treated for depression.

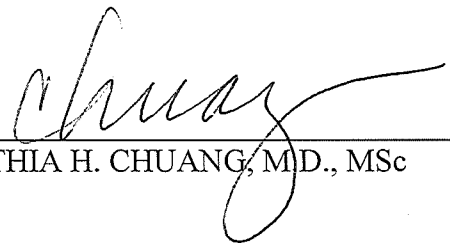
47. The Final Exemption Rules acknowledge commenters who report that hormonal contraceptives may increase the risk of certain health conditions, such as venous thromboembolic disease (VTE) (i.e., deep venous thrombosis and pulmonary embolism). While it is true that the risk of VTE is increased with use of estrogen-containing hormonal contraception, pregnancy and the postpartum state increase VTE risk significantly more so. Thus, preventing unintended pregnancy is a more effective way to reduce risk of VTE than avoiding hormonal contraception.

48. Similarly, the Final Exemption Rules acknowledge commentators who expressed concern over the possible increased risk of certain cancers. There is conflicting evidence as to whether long-term hormonal contraceptive use may increase the risk of breast cancer, however there is strong evidence that hormonal contraception reduces the risk of ovarian and uterine cancer, and some evidence that it reduces the risk of colorectal cancer. The magnitude of the reductions in ovarian, uterine, and colorectal cancer greatly outweigh the potential increased risk in breast cancer.

49. For these reasons, I believe that an injunction of the Final Exemption Rules is necessary to prevent immediate and irreparable harm to women in Pennsylvania and around the Country, who will lose ongoing preventive care coverage under their group health plans due to the Final Exemption Rules.

I hereby affirm that the foregoing is true and correct based upon my knowledge, information and belief, and I make these statements subject to the penalty of perjury.

Date: 12/14/2018

By: 
CYNTHIA H. CHUANG, M.D., MSc

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

No. 2:17-cv-04540-WB

DONALD J. TRUMP, *et al.*,

Defendants.

DECLARATION OF CAROL S. WEISMAN, Ph.D.¹

I, Carol S. Weisman, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. My Background and Experience

1. I am originally from Pittsburgh, Pennsylvania and, since 2003, I have served as a Distinguished Professor of Public Health Sciences, Obstetrics and Gynecology, and Health Policy and Administration at the Pennsylvania State University College of Medicine. Since 2009, I have also served at the Associate Dean for Faculty Affairs at the College of Medicine. I am also a faculty associate at the Penn State Population Research Institute.

2. My area of academic specialization is women's healthcare, with a focus on preventive services, including contraceptives and family planning.

3. I earned a Bachelor of Arts degree, with High Honors, in Sociology and Anthropology from Wellesley College in 1969, and a Ph.D. in Social Relations (Sociology) from Johns Hopkins University in 1973.

¹ I attach a true and correct copy of my curriculum vitae hereto as Exhibit 1.

4. Prior to working at the Penn State College of Medicine, I taught doctoral courses, conducted research, and authored scholarly articles at two schools of public health.

5. From 1974 until 1997, I worked at Johns Hopkins University in Baltimore, Maryland, as an Assistant Professor at the School of Health Services (1974-1978), an Assistant Professor in the School of Hygiene and Public Health (1974-1981), an Associate Professor in the School of Hygiene and Public Health (1981-1988) and, from 1988 until 1997, as a Professor in the Department of Health Policy and Management in the School of Hygiene and Public Health.

6. In my 23 years at Johns Hopkins, I held several leadership roles. I served as the Director of the MHS Program in Health Finance and Management (1988-1992), the Director of the Doctoral Program in Health Care Organization and Financing (1992-1994) and the Associate Chair for Health Services Research (1997).

7. From 1997 until 2002, I served as a Professor in the Department of Health Management and Policy at the University of Michigan School of Public Health. I had a joint appointment in the Department of Obstetrics and Gynecology at the University of Michigan Medical School, and was the Founding Director of the Interdepartmental Concentration in Reproductive and Women's Health at the University of Michigan School of Public Health.

8. Throughout my career, I have published over 175 scholarly articles, books, books chapters, monographs, and reports in the area of women's healthcare, including on the following topics:

- a. access to health care services and systems for women of reproductive age;
- b. contraceptive decision processes;
- c. contraceptive counseling in managed care and preventing unintended pregnancy in adults;

- d. contraceptive action planning among privately insured women; and
- e. contraceptive choices and cost.

9. In addition, I have been an investigator and lead investigator, on more than 40 studies and projects, many regarding women's healthcare. Most recently, I was a co-investigator on the project, "Reducing Unintended Pregnancies through Reproductive Life Planning and Contraceptive Action Planning," PCORI CD-1304-6117, 2013-2017.

10. I have also lectured and made almost 75 presentations throughout the country, in connection with my academic work, at various schools and professional organizations. My recent presentations include:

- a. "The Affordable Care Act and Women's Preventive Services: The 2011 IOM Report," keynote lecture as Distinguished Professor in Women's Health, Society of General Internal Medicine 35th annual meeting, Orlando, FL, May 10, 2012;
- b. "The Patient Protection and Affordable Care Act's Implications for Women's Health Care," invited seminar at the Pennsylvania Department of Health, Harrisburg PA, May 27, 2014; and
- c. "Implications of Proposed Changes to the Affordable Care Act for Women's Reproductive Health Care," invited panelist for The Future of Reproductive Health Policy, Penn State College of Medicine, March 9, 2017.

11. Throughout my career, I have received accolades and recognitions. For example, in 1997, I received the National Award for Excellence in Women's Health Research from the National Association of Professionals in Women's Health; in 2008, I received the Leader in the Field Award from the Family Health Council of Central Pennsylvania; and, in 2012, I received the award of Distinguished Professor in Women's Health from the Society of General Internal

Medicine.

12. I also participate, and have participated, in a variety of professional activities. Among them, I have been on the Editorial Board of *Women's Health Issues* since 1990, serving as Editor-in-Chief (2003-2006) and Associate Editor (1995-2002 and 2007-present), and have been a Full Fellow of the Society of Family Planning since 2016. Since 1988, I have been a member of AcademyHealth, a professional organization dedicated to advancing the fields of health services research and health policy.

II. My Service on the Institute of Medicine Committee Convened by the U.S. Department of Health and Human Services, and the Committee's Report

13. Throughout my career, I have been engaged as a consultant to numerous governmental and academic institutions.

A. *My Service on the Institute of Medicine Committee on Preventive Services for Women*

14. From 2010 to 2011, I served as one of only sixteen invited members of the Institute of Medicine Committee on Preventive Services for Women (the "Committee").

15. This Committee was convened at the request of the United States Department of Health and Human Services ("HHS") to identify existing gaps in women's preventive care and to recommend services and screenings that HHS should consider to fill those gaps.

16. The sixteen experts on the Committee had backgrounds in preventive care, disease prevention, women's health issues, and other areas.

B. *Committee Recommends FDA-Approved Contraception, Sterilization Procedures, and Patient Education and Counseling as Part of Women's Preventive Care*

17. In 2011 the Committee issued its report, titled, *Clinical Preventive Services for Women: Closing the Gaps* (National Academies Press, 2011) (the "Report").

18. The Report made specific recommendations to the Health Resources and

Services Administration (“HRSA”), a department of HHS, regarding evidence-based preventive services to be incorporated in the guidelines promulgated pursuant to the Affordable Care Act, 42 U.S.C. § 18001 *et seq.* (2010) (the “Affordable Care Act” or “ACA”).

19. The Committee found that contraceptives are preventive medical services because they prevent unintended pregnancies and that contraceptives should be included in the list of recommended preventive services for women under the ACA, specifically, the “the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.” *See* Ex. B, Report at 109-10.

i. Reducing Unintended Pregnancies

20. In making this finding, the Committee relied on evidence that “contraception and contraceptive counseling” are “effective at reducing unintended pregnancies” and observed that “[n]umerous health professional associations recommend” that such family planning services be included as part of standard preventive care for women. *Id.* at 109.

21. In making this recommendation, the Committee considered recommendations from the American Academy of Pediatrics, the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, the American College of Obstetricians and Gynecologists, and the Association of Women’s Health, Obstetric and Neonatal Nurses. *Id.* at 109-10.

22. But the Committee’s recommendation was based on a review of the evidence, including the prevalence of unintended pregnancy in the United States.

23. As the Committee stated in its Report, in 2001, an estimated “49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time

of conception.” *Id.* at 102 (internal citations omitted).

24. The Committee found that these “unintended” pregnancies disproportionately impact the most vulnerable: Although one in every 20 American women has an unintended pregnancy each year, unintended pregnancy is “more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group.” *Id.*

25. Furthermore, the Committee reported that unintended pregnancies are more likely than intended pregnancies to result in abortions; specifically, “[i]n 2001, 42 percent of [] unintended pregnancies [in the United States] ended in abortion.” *Id.*

26. The Committee also concluded that evidence proved that women carrying babies to term are less likely to follow best health practices when their pregnancies were unintended.

27. According to the Institute Committee on Unintended Pregnancy, “women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy.” *Id.* at 103.

28. Women facing unintended pregnancies are also more likely to be “depressed during pregnancy, and to experience domestic violence during pregnancy.” *Id.*

29. The Committee also considered evidence that the “odds of preterm birth and low birth weight among unintended pregnancies ending in live births” was “significantly increased compared with pregnancies that were intended.” *Id.*

30. Importantly, the Committee determined that contraceptives are effective in preventing unintended pregnancies, citing evidence of contraceptive effectiveness from the Food and Drug Administration and from Contraceptive Technology. *Id.* at 105.

31. The Committee also noted that “greater use of contraception within the population

is associated with lower unintended pregnancy and abortion rates nationally.” *Id.* at 105.

32. In making this determination, the Committee relied on a study showing that, as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, their rates of unintended pregnancy and abortion both declined. *Id.*

33. The Committee also considered other studies that showed increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a “decline in teen pregnancies” and, conversely, that “periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use.” *Id.*

ii. Minimizing Health Risks, Promoting Recommended Spacing, and Recognizing Additional Health Benefits Unrelated to Preventing Unintended Pregnancy

34. While all pregnancies carry inherent health risks, the Committee also considered that some women have serious medical conditions for which pregnancy is strictly contraindicated or inadvisable.

35. The Committee considered, for example, that “women with serious medical conditions such as pulmonary hypertension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and ... Marfan Syndrome,” are advised against becoming pregnant. *Id.*

36. The Committee also considered that the use of contraceptives also promotes medically recommended “spacing” between pregnancies. *Id.*

37. The Committee found that such spacing is important because there is an “increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)” and “[s]hort interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small for gestational age births.” *Id.*

38. The Committee also considered the risks and benefits of contraception and

recognized that contraceptives have other significant health benefits unrelated to preventing unintended pregnancy, including “treatment of menstrual disorders, acne or hirsutism, and pelvic pain,” and that long-term use of oral contraceptives has been shown to “reduce a woman’s risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases.” *Id.* at 105 and 107.

iii. Recognizing the Need for Family Planning Services and that Cost is a Barrier

39. The evidence reviewed by the Committee demonstrated that, as of 2008, there were still “approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years)” who were “estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant.” *Id.* at 103.

40. Citing a Kaiser Permanente study that found “when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods,” the Committee recognized that cost is a meaningful barrier to contraceptive access and found that “[d]espite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years.” *Id.* at 109.

41. For these and the other reasons set forth in the Report, the Committee recommended that “the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity” be included in women’s preventive care. *Id.* at 109-10.

42. The Committee’s recommendation was based upon reaching consensus following consideration of evidence presented by its members and a variety of professionals and

academics.

III. My Opinion on the final Religious Exemption Rule and final Moral Exemption Rule

43. I have reviewed both the final Religious Exemption Rule and the final Moral Exemption Rule promulgated by the Defendants (the “final Exemption Rules”), as well as the amended Complaint filed by the Commonwealth of Pennsylvania in this matter that challenges them.

44. In addition to my relevant background and experience set forth above, by virtue of being one of the sixteen members of the Institute of Medicine Committee on Preventive Services for Women, I have direct knowledge regarding the Report, promulgated by the HRSA pursuant to the Affordable Care Act, which gave rise to the ACA’s original guidelines regarding contraceptives as a preventive service.

45. Based upon my knowledge, education, training and experience, it is my professional opinion that the final Exemption Rules will cause immediate and irreversible harm because they will cause women to lose contraceptive care under their employer group health plans.

46. As set forth above and credited by the Committee, cost to patients has been shown to be a barrier to access to contraceptive care. Women are more likely to use contraceptives – and use them properly and consistently – if they have no cost-sharing responsibilities.

47. Conversely, when women are required to shoulder financial responsibility for preventive care, they are less likely to seek preventive care.

48. Several studies conducted after the ACA went into effect have shown that women are paying less for contraception and that they are using more effective contraceptive methods as a result of having contraceptive coverage under ACA.

49. A study we conducted at Penn State using national health claims data for privately insured women showed a post-ACA decrease in out-of-pocket contraceptive costs and an increase in uptake of long-acting reversible contraceptives, the most effective contraceptives on the market (Snyder AH, Weisman CS, Liu G, Leslie D, Chuang CH. The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women. *Women's Health Issues* 28(3):219-223, 2018).

50. For these reasons, some women who lose contraceptive coverage through their employers as a result of the final Exemption Rules, will choose a less effective contraceptive option for their medical needs, will use contraception inconsistently, or will discontinue using contraceptives entirely.

51. This, in turn, will have irreparable negative physical and mental health impacts on women, including disruptions in ongoing medical treatment and/or unintended pregnancies.

52. It is also my opinion that the new final Exemption Rules are not based upon sound scientific or empirical evidence.

53. The final Exemption Rules indicate, among other things, that contraceptives are not effective in preventing unintended pregnancy, that they are harmful to women's health, and that they promote promiscuity.

54. These representations conflict with peer-reviewed and medically-accepted data, and are not credible.

55. For these reasons, I believe that an injunction of the final Exemption Rules is necessary to prevent immediate and irreparable harm to women in Pennsylvania and around the Country, who will lose ongoing preventive care coverage under their group health plan due to the final Exemption Rules.

I hereby affirm that the foregoing is true and correct based upon my knowledge, information and belief, and I make these statements subject to the penalty of perjury.

Date: 12/17/2018

By: Carol S. Weisman
CAROL S. WEISMAN, Ph.D

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

No. 2:17-cv-04540-WB

DONALD J. TRUMP, *et al.*,

Defendants.

DECLARATION OF SAMANTHA F. BUTTS, M.D., MSCE¹

I, Samantha F. Butts, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. My Background and Experience

1. I am a doctor, teacher, and clinical researcher in the area of women's reproductive health. Of the time I spend working, I spend approximately 15% on education and administration, 10%-15% on clinical research, and 70%-75% on patient care.

A. My Education, Licensure and Board Certifications

2. I earned a Bachelor of Arts degree, *cum laude*, from Harvard University, in 1994, and a Medical Degree from the Harvard University School of Medicine, in 1998.

3. I completed both my residency in Obstetrics and Gynecology (1998-2002) and a Fellowship in Reproductive Endocrinology and Infertility (2002-2005) at the Hospital of the University of Pennsylvania.

4. After that, I earned a Masters of Science in Epidemiology (MSCE) from the

¹ I attach a true and correct copy of my curriculum vitae hereto as Exhibit A.

University of Pennsylvania School of Medicine in 2006.

5. I have been licensed to practice medicine in Pennsylvania since 2001.

6. I have also been certified by the American Board of Obstetrics and Gynecology with a specialty in Obstetrics and Gynecology since 2006 and subspecialty in Reproductive Endocrinology & Infertility since 2009.

B. My Teaching, Research and Additional Qualifications

7. I have held a faculty position at the University of Pennsylvania School of Medicine since 2005.

8. I started as an Assistant Professor and, since 2014, I have served as an Associate Professor of Obstetrics and Gynecology, in the Division of Reproductive Endocrinology and Infertility (REI). From 2014-2016, I was honored to serve as the Ombudsman for the Students at the University of Pennsylvania School of Medicine, Perelman School of Medicine.

9. As an Associate Professor of Obstetrics and Gynecology, I am actively involved in the clinical training of medical students, residents and fellows. I participate in didactic education programs and mentor resident-driven clinical research projects.

10. I also developed the first comprehensive reproductive endocrinology and infertility curriculum for trainees at the Hospital of the University of Pennsylvania and supervise resident training in reproductive endocrinology and infertility. In 2011, my achievements in resident education were recognized with a National Faculty Teaching Award from the American College of Obstetricians and Gynecologists and the Council on Resident Education in Obstetrics and Gynecology.

11. I also spend a meaningful amount of my time acting as a clinical researcher.

12. In this capacity, I serve and have served as an investigator and principal

investigator on a number of studies and projects regarding women's healthcare, many of which have been fully funded by grants. For example, I was one of the first people to receive a National Institute of Health training grant as part of the NIH's National Training Program in Reproduction (NIH T32 grant), and I was the inaugural recipient of the New Investigator Award from the Center of Excellence in Environmental Toxicology at the University of Pennsylvania.

13. I have published more than 100 scholarly articles, abstracts, research publications, reviews, book chapters, and committee reports related to women's reproductive healthcare. Among these, I have researched and written peer-reviewed articles about treating hormonal disorders, such as polycystic ovary syndrome, using contraceptives as a first-line medication. See, e.g., *Polycystic Ovary Syndrome: How Best to Manage?*, *Consultant*, 46:745-749, (2006) and *Abnormal Uterine Bleeding*, *NMS Series for Independent Study: Obstetrics and Gynecology*, Chap. 23, (6th. Ed. 2008).

14. I am often engaged to consult and collaborate with academic and private institutions. Recently, for example, as a member of the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice (ACOG Committee), I was asked to develop an opinion regarding treatment of Primary Ovarian Insufficiency. In connection with my work on this issue, the ACOG Committee published an opinion in May of 2017 recommending that contraceptives be considered among the options to provide as hormone replacement therapy to treat Primary Ovarian Insufficiency. See Opinion 698, *Hormone Therapy for Primary Ovarian Insufficiency*, *Obstetrics and Gynecology*, 129(5): 963-964 (May 2017).

15. In connection with my work, I have lectured throughout the country, by invitation, about reproductive health. For example, at the 2016 Women in Statistics Conference in Charlotte, North Carolina, I delivered a presentation called "Reproductive Decision Making

and Your Career: Embracing Biology, Debunking Myths, and Gaining Control.”

16. I have also organized and moderated multiple scientific meetings throughout my career, including annual meetings of the American Society of Reproductive Medicine.

17. I have held various professional appointments, as well. Among these, I have been a Member of the Center for Research on Reproduction and Women’s Health since 2005; an Associate Scholar for the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania since 2006; and a Member of the Center for Excellence in Environmental Toxicology, Endocrine Disruptors Core, since 2008.

18. I also maintain memberships in a number of professional, academic, and scientific societies, both nationally and internationally, including the American Society for Reproductive Medicine (since 2002), the Society for Reproductive Endocrinology and Infertility (since 2002), the American College of Obstetricians and Gynecologists (since 1998) and the Endocrine Society (since 2012). I have received many professional accolades, awards, and honor society memberships throughout my career.

C. My Medical Practice

19. In addition to my academic work, I maintain an active medical practice and, in 2017, was listed as one of *Philadelphia Magazine*’s “Top Doctors”.

20. Since 2005, I have served as an Attending Physician in the Department of Obstetrics and Gynecology, and also in the Reproductive Surgical Facility at the Hospital of the University of Pennsylvania.

21. Last year I saw and treated approximately 1,500 to 2,000 patients.

22. Some of my patients travel thousands of miles for the specialty medical treatment I can provide at Penn Medicine.

23. But in many ways, my medical practice reflects the reality that the Hospital of the University of Pennsylvania is also the community hospital of West Philadelphia.

24. In addition to specialty patients and residents of West Philadelphia, I also treat many members of the academic community at the University of Pennsylvania.

25. My clinical expertise includes reproductive endocrinology, with a focus on managing hormonal disorders such as polycystic ovary syndrome, primary ovarian insufficiency/premature ovarian failure, amenorrhea, dysmenorrhea/chronic pelvic pain, and abnormal uterine bleeding, as well as in infertility, in vitro fertilization, and reproductive surgery.

26. Many of these medical conditions and disorders are common among women.

27. As part of my practice, I regularly prescribe contraceptives for both contraceptive and non-contraceptive purposes.

II. Benefits of Contraceptive Use

A. Contraceptives Are Effective and Approved for Uses Other Than Preventing Pregnancy

28. Contraceptives are effective, and approved, to be used as medication for purposes other than preventing pregnancy. Indeed, I regularly use all kinds of contraceptives for non-contraceptive uses, including for the treatment of life-threatening problems.

29. For example, contraceptives are the standard first-line of care for a number of hormonal, and other, disorders, including poly-cystic ovarian syndrome, primary ovarian insufficiency/premature ovarian failure, amenorrhea, dysmenorrhea/chronic pelvic pain, and abnormal uterine bleeding.

30. These conditions greatly impact the quality of life of the many women who suffer from them. In fact, about 10% percent of all women have irregular periods caused by poly-cystic

ovarian syndrome or other hormonal disorders which can significantly harm well-being and quality of life. Extreme cases of heavy menstrual bleeding due to hormonal or anatomic problems of the uterus that I see and treat can at times be life-threatening.

31. I frequently use contraceptives to treat these conditions in my own medical practice and, in fact, prescribe “birth control pills” more for these other purposes than to prevent pregnancy given the population of patients who make up my practice.

32. Throughout my career, I have been required to perform non-operative blood transfusions for at least 50 women due to loss of blood caused by heavy periods and acute menstrual bleeding that can cause anemia.

33. In 2009, the FDA approved use of the Mirena Inter-Uterine Device (IUD) to treat women with heavy bleeding and hemophilia. Among my patients who use the Mirena IUD, the vast majority (90%-95%) use it for purposes other than birth control.

34. The hormonal and other disorders I treat inflict direct and indirect personal and financial costs upon the women who suffer from them; they prevent women from participating fully in the workplace and, more broadly in society.

35. Contraceptives are a cost-effective and clinically proven way to treat these often debilitating disorders.

B. Contraceptives Are Effective in Preventing Unintended and Ill-Advised Pregnancies, and Their Use Causes Other Long-Term Health Benefits

36. Contraceptives also play an important role in preventing unintended pregnancy.

37. For some women, this treatment is not optional – it is necessary to prevent serious illness and even death.

38. There are multiple high risk conditions for which pregnancy is relative or absolutely contraindicated. These conditions include cardiac problems and history of stroke.

39. For survivors of breast cancer, pregnancy hormones can cause serious medical harm until the patient is well into remission.

40. Contraceptives help patients avoid unintended pregnancies in such situations; they prevent medical harm and save lives.

41. Contraceptives use also carries long-term health benefits for women.

42. For instance, it has been shown that long-term users of the standard oral contraceptive pill (at least 5-10 years of usage) are 50-80% less likely to develop ovarian or uterine cancer.

III. My Opinion on the “Religious Exemption Rule” and “Moral Exemption Rule”

43. I have reviewed both the “Religious Exemption Rule” and the “Moral Exemption Rule” (together, the “Rules”), as well as the Complaint filed by the Commonwealth of Pennsylvania in the above-captioned matter that challenges them.

44. Based upon my knowledge, education, training and experience, it is my professional opinion that the Rules will cause immediate and irreversible harm because they will cause women to lose preventive contraceptive care under their employer group health plans.

A. Cost is a Barrier to Contraceptive Access

45. It is my understanding, and it has been my experience, that cost is a barrier to patient access to contraceptives.

46. Prior to passage of the Affordable Care Act (the “Affordable Care Act” or “ACA”), before preventative contraceptive care was provided at no additional cost under the ACA’s contraceptive mandate, I regularly counseled my patients about the cost related to their recommended contraceptive choices.

47. I would estimate that, prior to the ACA, about 10-20% of the patients for whom I

had prescribed contraceptives would come back from the pharmacy without filling their prescriptions; they would, instead, request that I prescribe a less effective, but cheaper, method of contraception. Or they would forego use of contraception altogether.

48. Such requests were most frequent when I had prescribed an IUD because, pre-ACA, IUDs were one of the most expensive forms of contraception for patients. But they are also a much more effective method of contraceptive care than are birth control pills.

49. And, for therapeutic reasons, some patients cannot take estrogen birth control pills, at all.

50. After the ACA passed and the contraceptive mandate was instituted, however, I saw that my patients were free to make contraceptive choices on the basis of their medical needs and concerns, alone, without the burden of having to weigh the cost of the preferred medical choice. Post-ACA, the only concern has been what is best for the patient.

51. As a result, I have seen my patients making more medically informed contraceptive choices and have not had the experience of patients rejecting the contraceptives I prescribed due to their cost under private insurance plans.

C. Because Patients Will Lose Contraceptive Coverage under the New Rules, They Will Make Less Medically Sound Contraceptive Choices and, Therefore, Will Be Harmed

52. It is apparent, however, that under the new Rules this post-ACA focus on what is best for the patient will change.

53. This is so because, as a result of the Rules, some women will lose insurance coverage for preventative contraceptive care.

54. As a result, their cost for contraceptive care will rise.

55. Based upon my own experience and existing scientific and empirical information that I have reviewed and am aware of, under the new Rules, cost will, again, become a barrier to

women's access to and use of the contraceptive that is medically recommended for them.

56. Many of these women who will no longer receive contraceptive coverage will not only face financial harm, but will also face medical harm.

57. This harm will manifest itself in the disruption of these patients' medical treatment, whether by substituting a less effective but cheaper method of contraception or by being forced to stop using contraceptives at all, due to financial reasons.

58. Some of these women will face unintended pregnancy and other adverse medical consequences.

D. The New Rules Are Not Based Upon Sound Scientific or Empirical Evidence

59. It is also my opinion that the new Rules are not based upon sound scientific or empirical evidence.

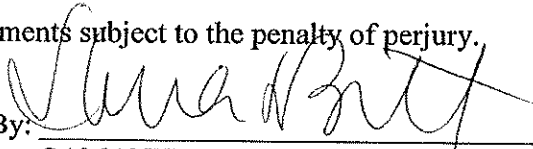
60. The Rules indicate, among other things, that contraceptives are not effective in preventing unintended pregnancy, that they are harmful to women's health, and that they promote promiscuity. This is false.

61. These representations conflict with peer-reviewed and medically-accepted data, and are not credible.

62. For these reasons, I believe that an injunction of the Rules is necessary to prevent immediate and irreparable harm to women in Pennsylvania and around the Country, who will otherwise lose ongoing preventive care coverage under their group health plans due to the Rules.

I hereby affirm that the foregoing is true and correct based upon my knowledge, information and belief, and I make these statements subject to the penalty of perjury.

Date: 10/25/17

By: 

SAMANTHA F. BUTTS, M.D., MSCE

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

NO. 2:17-cv-04540-WB

DONALD J. TRUMP *et al.*

Defendants.

DECLARATION OF SETH A. MENDELSON

I, Seth A. Mendelsohn, declare and state as follows:

1. I am the Executive Deputy Insurance Commissioner for the Pennsylvania Department of Insurance (the "Department"). In this capacity I oversee, *inter alia*, the Office of Insurance Product Regulation and Administration, including the Bureau of Life, Accident and Health Insurance.

2. The Department is the primary regulator for all health insurance products sold in the Commonwealth of Pennsylvania.

3. Insurance providers are subject to a complex set of federal and state laws and regulations, and federal and state agencies have distinct but overlapping responsibilities in regulating these entities.

4. For instance, the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.* (ERISA), governs most employee health care coverage and other benefit plans offered by private employers. ERISA preempts certain state laws relating to the regulation of insurance.

5. As a result of the preemption provisions of ERISA, the Department does not regulate self-funded health care coverage plans offered by private employers, which are plans established and maintained by an employer or by an employee organization for which the employer or employee organization bears the direct financial risk for the cost of claims for health care benefits. These plans are subject to ERISA and are regulated primarily by the U.S. Department of Labor.

6. The Department does regulate fully-insured employer group health insurance policies. These are health plans that an employer group purchases from an insurer, for which the insurer assumes the direct financial risk for the cost of claims for health care benefits.

7. In addition, the Department regulates health insurance policies offered in the individual market.

8. I am familiar with the Affordable Care Act's requirement that group health plans and health insurance issuers offering group or individual health insurance coverage cover preventive health services, including FDA-approved methods of contraception, without any cost-sharing requirements (the "Contraceptive Care Mandate").

9. The Contraceptive Care Mandate applies both to ERISA-regulated plans as well as almost all insured group and individual health insurance plans that are regulated by the Department.

10. More than 2.5 million women in Pennsylvania could benefit from the Contraceptive Care Mandate. This total includes women who receive insurance through their employer or through a spouse or other family member's employer, along with those who purchase insurance for themselves and their families through the individual market.

11. The Department estimates that the women in Pennsylvania who have benefited from the Contraceptive Care Mandate have saved over \$250 million annually as a result.

12. Many states have enacted laws requiring insurers that cover prescription drugs to provide coverage for any Food and Drug Administration-approved contraceptive. These statutes are commonly referred to as “contraceptive parity” laws.

13. Pennsylvania, however, does not have a “contraceptive parity” statute. As a result, employers offering Department-regulated plans that opt out of the ACA’s Contraceptive Care Mandate will not be subject to any requirement to provide contraceptives to their employees and beneficiaries. Thus, women in plans provided by these employers will not receive contraceptive coverage through these plans.

14. Similarly, employers offering plans that are subject to ERISA that opt out of the Contraceptive Care Mandate will also not be subject to any requirement to provide contraception to their employees and beneficiaries.

15. The Department anticipates that women who lose contraceptive coverage through employer plans – whether the plan of their own employer or that of another family member – may seek contraceptive coverage from other sources, including state-funded programs, or face the financial burden of paying for the full cost of contraceptives themselves.

16. Further, insofar as the Final Rules¹ effectively expand the universe of employers that may claim a contraceptive coverage exemption, even more women may be denied access to contraceptive coverage.

¹ “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act”, 83 Fed. Reg. 57536 et seq. (Nov. 15, 2018) and “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act”, 83 Fed. Reg. 57592 et seq. (Nov. 15, 2018) (the “Final Rules”).

17. Moreover, because the Final Rules contemplate that individuals, covered by employer plans that provide contraceptive care, may nevertheless opt out of the ACA's Contraceptive Care Mandate, and, in so doing, effectively deny contraceptive care to all of the individual's female dependents covered by the same plan, still more women may be denied access to contraceptive coverage.

18. In any case, whether it is the employer's choice or the individual's choice or the choice of the individual as to whom a woman is a dependent, women who have access to affordable employer-based coverage but who lose contraceptive coverage as a result of the Final Rules will be unable to purchase individual coverage on the marketplace with any applicable premium tax credit and cost sharing reductions. Again, the Department anticipates that women put in this position may seek contraceptive coverage from other sources, including state-funded programs, or face the financial burden of paying for the full cost of contraceptives themselves.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.



SETH A. MENDELSON

Dated: December 12, 2018

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

NO. 2:17-cv-04540-WB

DONALD J. TRUMP *et al.*

Defendants.

DECLARATION OF LEESA ALLEN

I, Leesa Allen, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, I state as follows:

I. Background

1. I serve as the Acting Executive Deputy Secretary for the Pennsylvania Department of Human Services (“DHS” or “the Department”). Before assuming my current position, I was the Deputy Secretary for Medical Assistance Programs at DHS. I have worked for the Department of Public Welfare, now DHS, since 1993, serving in various roles within the Office of Medical Assistance Programs since 2000. I was most recently the Deputy Secretary for Medical Assistance Programs, the Executive Medicaid Director, Chief of Staff, and Director of the Bureau of Policy. In my current role, I oversee all of the Department’s operations and report directly to the Acting Secretary of DHS, who serves as a member of the Governor’s cabinet.

2. DHS is responsible for administering a variety of services and benefits to residents of Pennsylvania, including health care services, support for individuals with

disabilities, child support enforcement, treatment for substance use disorder, and services for children and families.

II. Pennsylvania's Medical Assistance Program

3. DHS's Office of Medical Assistance Programs has primary responsibility for overseeing Commonwealth programs that offer health benefits to Pennsylvania residents. Those programs include the Medicaid program, known as Medical Assistance in Pennsylvania. In my prior role as Deputy Secretary for Medical Assistance Programs, I oversaw the Office of Medical Assistance Programs.

4. Medicaid is a program jointly funded by the states and the federal government that makes health care available to low-income individuals and families. States have responsibility for administering Medicaid, but are subject to federal oversight.

5. Medicaid is funded according to a formula under which the federal government contributes a specific amount for every dollar spent by Pennsylvania. If additional Pennsylvanians enroll in the Medical Assistance program, the federal and state government will both spend more on the program, thereby shifting costs from the private to the public sector.

6. As of August 2017, there were 2,869,246 Pennsylvanians enrolled in the Medical Assistance program. For the period April 1, 2016, through March 31, 2017, a total of \$28.8 billion in state and federal funding was spent on Medical Assistance. Of that amount, \$11.2 billion was provided by the Commonwealth, and the remainder was provided by the federal government.

7. Eligibility for Medical Assistance is based primarily on income level. The Affordable Care Act expanded Medicaid eligibility so that individuals and families with incomes up to 138% of the federal poverty limit would generally be eligible for the program. However, in

National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012), the Supreme Court ruled that states could not be required to expand Medicaid under the ACA, and therefore the expansion was rendered optional.

8. Governor Tom Wolf elected to expand the Medical Assistance program in 2015, so that individuals and families in Pennsylvania with incomes up to 138% of the federal poverty limit are eligible for the program. Over 700,000 Pennsylvanians have enrolled in the Medical Assistance program as a result of the expansion.

9. For women who are pregnant, Medical Assistance eligibility requirements are different. Pregnant women are eligible if they have incomes at or below 215% of the federal poverty limit. In 2017, 215% of the federal poverty limit is \$25,929 for an individual and \$52,890 for a family of 4.

10. Medical Assistance provides beneficiaries with a variety of contraception options. In November 2016, DHS announced that it was making changes to its payment policies to hospitals to encourage the use of long-acting reversible contraception (LARC), which includes intrauterine devices and birth control implants.

11. Although LARCs are more effective than other methods of contraception and save money in the long run, they can have high upfront costs. By changing its fee-for-service payment policies for hospital providers for these costs, DHS has made it easier for women to use LARCs.

12. Over half of all unplanned pregnancies occur within two years of delivery of a child. For this reason, the Commonwealth encourages the use of LARCs as post-partum contraception to reduce the rate of such unplanned pregnancies.

13. In addition, Medical Assistance offers specific benefits for eligible pregnant women. Those benefits include full scope medical benefits, as well as other benefits including proper prenatal care and early detection and treatment of health problems.

III. Pennsylvania's Family Planning Services Program

14. DHS also administers Pennsylvania's Family Planning Services program. The Family Planning Services program provides family planning benefits to individuals who are not eligible for full Medical Assistance benefits but satisfy other conditions. The Family Planning Services program receives federal and state Medicaid funds.

15. The Family Planning Services program was launched in 2008 as the SelectPlan for Women. Originally, it operated pursuant to a "Section 1115 waiver" granted by the U.S. Secretary of Health and Human Services. Section 1115 waivers free states from certain requirements of the Medicaid program so they can implement demonstration projects using federal and state Medicaid funds. Section 1115 waivers must be renewed every 5 years.

16. In 2015, the SelectPlan for Women Program authorized under the Section 1115 Waiver was transitioned to the Family Planning Services program authorized under the Medicaid State Plan. Under a provision of the ACA, states were provided the option to provide family planning and family planning-related services to individuals with incomes at or below 215% of the federal poverty limit who would not otherwise be eligible for Medicaid. With the transition, the program began to provide family planning and family planning-related services to men as well. As a result of this new authority, the Commonwealth no longer needs to seek a waiver from the Department of Health and Human Services every five years.

17. The Family Planning Services program is open to individuals and families with incomes at or below 215% of the federal poverty limit. Pregnant women (who would be eligible for Medical Assistance) are not eligible.

18. In August 2017, 17,333 individuals were enrolled in the Family Planning Services program.

19. Women and men who are employed and who receive health insurance through their employer may participate in Family Planning Services, provided they satisfy the eligibility criteria, and many beneficiaries of the program are employed. However, individuals who receive coverage for family planning services through their employer or from another source are not eligible for the program. Therefore, those participants in Family Planning Services who are employed either do not receive health coverage from their employers or receive coverage that does not include family planning services.

20. Because the Family Planning Services program is funded under Medicaid, total spending on the program depends on enrollment. If more individuals participate in the program, federal and state spending increase.

21. The Family Planning Services program provides contraceptive benefits, including coverage for birth control pills and LARCs. The program also provides a variety of other benefits, including pregnancy counseling, HIV and STD testing and treatment, and male and female sterilization.

22. These services are provided to beneficiaries without copays, deductibles, or other cost-sharing arrangements.

23. It is not unreasonable to expect that women who do not receive contraceptive care from their employers or private insurance will turn to government-funded programs,

such as Medical Assistance, to the extent they are eligible for these programs. Therefore, some eligible women who require contraceptive care but who work for employers that choose to opt out under the new exemption rules will likely seek out other coverage options, including the Commonwealth-funded programs discussed above.

IV. The Administration's Executive Orders

24. I am generally familiar with the Affordable Care Act's Contraceptive Care Mandate, which requires non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for FDA-approved methods of contraception without imposing cost-sharing requirements.

25. I understand that the Administration issued two rules on October 6, 2017, that expanded the exemptions from the Contraceptive Care Mandate. Under these rules, covered entities may opt out of complying with the mandate on the basis of a sincerely held moral or religious conviction.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

A handwritten signature in cursive script, reading "Debra M. Allen", is written over a horizontal line.

Dated: October 27, 2017

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

NO. 2:17-cv-04540-WB

DONALD J. TRUMP *et al.*

Defendants.

DECLARATION OF DAYLE STEINBERG

I, Dayle Steinberg, hereby submit this declaration in support of the Motion for Preliminary Injunction filed by the Commonwealth of Pennsylvania in the above-captioned matter and, in support thereof, state as follows:

1. I am the CEO of Planned Parenthood Southeastern Pennsylvania. Planned Parenthood is one of the nation's largest providers of health care to women, men, and teenagers.

2. Nationwide, Planned Parenthood operates more than 600 health centers providing a variety of health services, including family planning services. Each year, 2.4 million women, men, and young people visit a Planned Parenthood health center to obtain services or information. Approximately 75% of these patients seek services to prevent unintended pregnancy.

3. Planned Parenthood Southeastern Pennsylvania provides services in Chester, Delaware, Montgomery, and Philadelphia Counties. We operate 8 health centers in the area and, in fiscal year 2016, provided services to 36,779 women, men, and teens in these centers.

I. The Title X Program Provides Federal Grants for Family Planning Services

4. Title X of the Public Health Service Act¹ provides grants to both public and private agencies for family planning services. Specifically, Title X authorizes grant money “to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services.”

5. Title X grants are awarded through a competitive process. They fund services provided by state and local health departments, hospitals, university health centers, and non-profit agencies. The Title X program is overseen by the Office of Population Affairs of the U.S. Department of Health and Human Services (HHS-OPA) oversees the Title X grant program.

6. Since 2010, Title X funding has decreased by \$31 million, nationally. In 2010, the nationwide program received \$317.5 million; in 2017, it received \$286.5 million.² In addition, there are frequent efforts by some in Congress to eliminate funding for the program entirely.

7. In Pennsylvania, Title X grant money is provided directly to four private, non-profit, regional Family Health Councils. They are: AccessMatters (formerly the Family Planning Council) in Philadelphia; Adagio Health in Pittsburgh, Maternal and Family Health Services, Inc. in Wilkes Barre, and the Family Health Council of Central Pennsylvania in Camp Hill. The Alliance of Pennsylvania Councils supports and coordinates the efforts of the four Family Health Councils.

8. These four Family Health Councils also receive funding from the Commonwealth of Pennsylvania as well as local sources. For instance, in the fiscal year ending June 30, 2016, AccessMatters received approximately \$8.2 million in federal funding and \$3.9 million in state

¹ 42 U.S.C. § 300 *et seq.*

² National Family Planning & Reproductive Health Association, Title X Budget & Appropriations, *available at* https://www.nationalfamilyplanning.org/title-x_budget-appropriations.

and local funding. The vast majority of this \$3.9 million was provided by the Pennsylvania Department of Health and the Pennsylvania Department of Human Services.³

II. Pennsylvania's Family Planning Clinics

9. These four Family Health Councils in turn provide funding to a variety of organizations in Pennsylvania. These organizations operate clinic-based health centers throughout the Commonwealth.

10. As of December 2016, there were 162 facilities in Pennsylvania receiving Title X funding. Each county in Pennsylvania has at least one such clinic.

11. These clinics provide women and men with access to a variety of family planning services. These services include contraception, HIV and STD testing, counseling services, pregnancy testing, certain infertility services, and breast and cancer screening. They are important to the citizens of Pennsylvania and to the overall health of Pennsylvania, as a whole.

12. Although facilities that receive Title X grants are typically referred to as "Title X clinics," they actually receive funding from a variety of sources and only a small part through Title X. In fact, Title X accounts for less than one-fifth of their revenue.

13. According to the 2016 Title X Family Planning Annual Report⁴ (at ES-3), the top three sources of revenue for Title X clinics nationwide were Medicaid and CHIP (the Children's Health Insurance Program) (39% of revenue); Title X (19%); and state government funding (10%).

³ AccessMatters, *Consolidated Financial Statements and Supplemental Information, Years Ended June 30, 2016, and 2015*, at 4, available at <http://www.govwiki.info/pdfs/Non-Profit/PA%20Accessmatters%202016.pdf>.

⁴ Department of Health and Human Services Office of Population Affairs, *Title X Family Planning Annual Report, 2016 National Summary* (August 2017), available at <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>.

14. Title X acts as “the payer of last resort” for these clinics. In other words, each clinic can only use Title X funds to pay for services if no other source of funding is available. This includes funding from the Commonwealth or other federal funding. As a result, many of our patients receive services that are funded by multiple sources.

15. For this reason – and to ensure that clinic patients can receive the best possible care – Title X clinics work to educate patients about available government health programs and help patients enroll in programs for which they are eligible.

16. In Pennsylvania, these programs include Medical Assistance (Medicaid) and the Family Planning Service Program, both of which received Commonwealth funding. Title X clinics will assist patients who are eligible for (but not enrolled in) these programs with the necessary paperwork so that they can be enrolled. Doing so not only ensures that the patient has all the coverage for which she is eligible for, but it allows the clinic to save Title X and Commonwealth grant money.

17. While the priority of the Family Health Councils is to assist low income families, each Title X clinic in Pennsylvania provides family planning services to any individual seeking *services*, regardless of income or insurance status. Family planning services are provided based on a sliding scale fee structure depending on the individual/family income level.

18. According to the 2016 Annual Report (at B-3), in 2016, family planning services through Title X grants were provided to 198,825 Pennsylvania residents.

19. Of these recipients of care, 73% had some form of insurance. Among this 73%, 46% had insurance through Medicaid or another government-funded program (vs. 37% nationwide) and 27% had private insurance (vs. 18% nationwide) (2016 Annual Report at B-7).

20. Many Title X patients are currently employed or have a family member who is currently employed. Many of these patients receive insurance through their employer or their family member's employer.

21. In some cases, Title X clinics are reimbursed by the insurance company; however, private insurance often does not provide sufficient coverage. Thus, while 18% of all Title X users nationwide have private insurance, private sources of funding account for only 10% of clinic revenue (2016 National Report at B-7).

III. The Effects of the Contraceptive Care Mandate

22. I understand that the Administration has issued new regulations that will make it easier for employers and others to opt out of the Affordable Care Act's contraceptive mandate.

23. My colleagues at Planned Parenthood Southeastern Pennsylvania and I are very concerned that this action will lead to an increase in the number of employers in Pennsylvania that do not provide their employees with adequate insurance coverage for contraceptive care.

24. Women who need contraceptive care but whose employers refuse to provide coverage for it will be forced to get care elsewhere. Many of these women will seek assistance from government programs.

25. In fact, for many low-income women in this situation, a government-funded program will be the only viable option for obtaining contraceptive care.

26. Therefore, we expect that many women in Pennsylvania who lose their contraceptive coverage will seek care from one of the 162 Title X clinics in the Commonwealth.

27. Some of these women will likely be eligible for either Medical Assistance (Medicaid) or Pennsylvania's Family Planning Services program. If they seek care at a Title X clinic in Pennsylvania, the clinic will help them enroll in either program.

28. Low-income women who seek services from a Title X clinic and are not eligible for these programs will receive contraceptive care funded by other sources. In most instances, their care will be funded through Title X and funding provided by the Commonwealth of Pennsylvania.

29. We expect that the new exemptions from the Contraceptive Care Mandate will lead to an increase in the number of women who get contraception through Medicaid and Family Planning Services, as well as an increase in the number of women who obtain contraception from Title X clinics paid for by federal and state funding.

30. We are also concerned that some women who lose their coverage will stop using contraception altogether. Women who stop using contraception are more likely to have unplanned pregnancies and to require additional medical attention. According to an analysis of 2010 data by the Guttmacher Institute, 68% of unplanned births are paid for by public insurance programs, including Medicaid, while 38% of planned births are paid for by these programs.⁵

31. As I explained above, meeting this increased need will require additional state funds.

32. For all these reasons, I believe that the new exemptions to the contraceptive mandate will have a negative effect on the health of Pennsylvania women; that they will increase the number of women who receive contraceptive coverage through Medical Assistance and Family Planning Services; and that they will impose additional economic and other burdens on Title X clinics across the Commonwealth.

⁵ Guttmacher Institute, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010* (Feb. 2015), available at <https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy>.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.

A handwritten signature in black ink, reading "Doyle Steinberg", written over a horizontal line.

Dated: October 31, 2017

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA,
and STATE OF NEW JERSEY

Plaintiffs,

v.

DONALD J. TRUMP, *et al.*

Defendants.

Civil Action No:
2:17-cv-04540-WB

DECLARATION OF SARAH ADELMAN

I, Sarah Adelman, declare and state as follows:

1. I serve as Deputy Commissioner of the New Jersey Department of Human Services.

In this capacity I oversee the Division of Medical Assistance and Health Services (“DMAHS”).

2. DMAHS administers New Jersey’s \$17 billion state- and federally- funded Medicaid and Children’s Health Insurance Programs (collectively referred to as “NJ FamilyCare”) that provide health coverage for certain low to moderate income residents. Through its programs, DMAHS serves more than 1.7 million people in New Jersey.

3. NJ FamilyCare provides comprehensive medical coverage and family planning services to its beneficiaries.

4. New Jersey also has Title X family planning clinics within the state that are not affiliated with DMAHS.

5. Medicaid is a program jointly funded by the states and the federal government that makes health care available to low-income individuals and families. States have responsibility for administering Medicaid, but are subject to federal oversight.

6. Medicaid is funded according to a formula under which the federal government contributes a specific amount for every dollar spent by New Jersey. If additional New Jerseyans enroll in the Medical Assistance program, the federal and state government will both spend more on the program, thereby shifting costs from the private to the public sector.

7. As of October 2018, there were 1,747,375 NJ FamilyCare beneficiaries in New Jersey. For State fiscal year 2018, a total of approximately \$16,267,000,000 in state and federal funding was spent on NJ FamilyCare. Of that amount, roughly \$9,843,000,000 was provided by the federal government, and \$6,424,000,000 was provided by New Jersey.

8. For fiscal year 2018, DMAHS's estimated cost to provide contraceptive and family planning coverage through NJ FamilyCare was approximately \$15 million, with the federal government covering 90% of that cost.

9. Eligibility for NJ FamilyCare is based primarily on income level. The Affordable Care Act expanded Medicaid eligibility so that individuals and families with incomes up to 138% of the federal poverty level would generally be eligible for the program. However, in National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012), the Supreme Court ruled that states could not be required to expand Medicaid under the Affordable Care Act, and therefore the expansion was rendered optional.

10. New Jersey elected to expand Medicaid in January 2014, so that single adults, childless couples, parents, and caretakers with incomes up to 138% of the federal poverty limit

are eligible for the program. Over 500,000 of these individuals have enrolled in NJ FamilyCare since its expansion.

11. For women who are pregnant, NJ FamilyCare has expanded income-based eligibility so that pregnant women are eligible if they have incomes at or below 205% of the federal poverty level. At present, 205% of the federal poverty level is \$4,302 per month for a family of four.

12. DMAHS is planning the 2019 rollout of a family planning benefit program called Plan First for individuals with income ranging from 133% to 205% of the federal poverty level.

13. DMAHS projects that there will be 10,000 to 12,000 Plan First participants in the first year of the program, and between 31,000 to 55,000 participants by the fifth program year.

14. DMAHS designed the Plan First program to allow pregnant women to transition seamlessly into the Plan First program after the 60-day postpartum period and to allow Plan First beneficiaries who become pregnant to easily transition to a DMAHS program ensuring early prenatal treatment. The eligibility standards for Plan First will mirror the current NJ FamilyCare requirements for pregnant women.

15. NJ FamilyCare provides beneficiaries with a variety of contraception options, and there is no co-pay for family planning preventive services.

16. Among those options is long-acting reversible contraception ("LARC"), which includes intrauterine devices and birth control implants. While NJ FamilyCare has always covered LARC devices in an outpatient setting or as part of a bundled inpatient payment, it began to allow providers to bill separately for devices and insertion in the immediate postpartum period (defined as within 10 minutes after delivery of the placenta) in July 2018. In addition, the Plan First program will provide for access to LARCs for additional individuals in 2019.

17. New Jersey recognizes the importance of allowing members who wish to utilize LARC devices to have free and open access to them to reduce the rate of unplanned pregnancies. Although LARCs can have high upfront costs, they are not associated with compliance issues that can cause failures with other comparable methods of birth control, and as such are more effective than most other methods of contraception and would likely result in better outcomes and better long-term savings to the State when compared to other contraceptive methods.

18. LARCs facilitate optimal “birth spacing,” defined as a minimum 18 month interval between pregnancies. Without birth spacing, babies are more likely to be premature, of low birthweight, small for their gestational age, and, consequently, more likely to face long-term health problems and higher mortality rates. In 2017, the prematurity rate in New Jersey was one in eleven babies.¹

19. DMAHS anticipates that some women, particularly low-income women, who lose contraceptive coverage through their employer’s plans may seek contraceptive coverage from other sources, such as NJ FamilyCare, Plan First, and Title X. This will result in additional costs to New Jersey, which will be forced to absorb additional costs presently borne by private insurers.

20. Other women who lose their contraceptive benefits may forego contraceptive use entirely, which would result in increased numbers of unintended pregnancies and a dramatic increase in costs to State-funded programs designed to ensure the health of women and infants.

21. The loss of employer-sponsored health insurance coverage for contraception can be expected to disproportionately impact New Jersey’s women of color. In 2015, 28% of New

¹ March of Dimes, *A Profile of Prematurity in New Jersey*, available at <https://www.marchofdimes.org/peristats/tools/prematurityprofile.aspx?reg=34>.

Jersey pregnancies were unplanned, including 53.1% among non-Hispanic black women and 31.8% among Hispanic women.²

22. I am generally familiar with the Affordable Care Act's Contraceptive Care Mandate, which requires non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for FDA-approved methods of contraception without imposing cost-sharing requirements.

23. I understand that the Administration has issued rules that expanded the exemptions from the Contraceptive Care Mandate. Under these rules, covered entities may opt out of complying with the mandate on the basis of a sincerely held moral or religious conviction.

24. The expanded exemptions are expected to result in greater financial expenditures by both the State of New Jersey and women in New Jersey on contraceptive coverage and on healthcare generally for women and infants.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.


Sarah Adelman

Dated: 12/7/18

² The Centers for Disease Control and Prevention and New Jersey Department of Health, *Pregnancy Risk Assessment Monitoring Report on Pregnancy Intention 2012-2015*, available at <https://www.nj.gov/health/lhs/maternalchild/documents/NJ%20Pregnancy%20Intention%20Topic%20Report%202012-2015.pdf>.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA,
and STATE OF NEW JERSEY,

Plaintiffs,

v.

DONALD J. TRUMP, *et al.*

Defendants.

Civil Action No:
2:17-cv-04540-WB

DECLARATION OF PHILIP GENNACE

I, Philip Gennace, declare and state as follows:

1. I am the Assistant Commissioner of Life and Health in the New Jersey Department of Banking and Insurance (“DOBI”). In this capacity, I oversee, *inter alia*, the licensing and oversight of health insurance regulated by the State of New Jersey. I make this affidavit based on my personal knowledge and information provided to me in my official capacity.
2. DOBI is the primary regulator for all fully-insured health insurance plans sold in the State of New Jersey.
3. Insurance carriers are subject to a complex set of federal and state laws and regulations, and federal and state agencies have distinct but overlapping responsibilities in regulating these entities.
4. For instance, the federal Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001, *et seq.* (“ERISA”), governs most employee benefit plans offered by private employers, including private employers’ self-funded employee health benefit plans. ERISA

preempts most state laws relating to such plans.

5. As a result of the preemption provisions of ERISA, DOBI does not regulate self-funded health coverage plans offered by private employers, which are plans established and maintained by an employer or by an employee organization for which the employer or employee organization bears the direct financial risk for the costs of claims for health care benefits. These plans are subject to ERISA and are regulated primarily by the U.S. Department of Labor, and are often colloquially referred to as “ERISA plans.”

6. DOBI does regulate fully-insured employer group health plans issued in the State. These are health plans that an employer group purchases from an insurer, for which the insurer assumes the direct financial risk for the cost of claims for health care benefits.

7. In addition, DOBI regulates health insurance policies offered in the individual market.

8. I am familiar with the Affordable Care Act’s (ACA) requirement that group health plans and health insurance issuers offering group or individual health insurance coverage cover preventive health services, including FDA-approved methods of contraception, without any cost-sharing requirement (the “Contraceptive Care Mandate”).

9. The Contraceptive Care Mandate applies both to non-grandfathered ERISA-regulated plans, as well as almost all insured group and individual health insurance plans that are regulated by DOBI.

10. In addition, New Jersey law requires employers who offer fully-insured plans to provide coverage for expenses incurred in the purchase of prescription female contraceptives to the same extent as any other outpatient prescription drug under the policy (“New Jersey

Mandate”).¹

11. Unlike the ACA’s Contraceptive Care Mandate, however, the New Jersey Mandate does not require insurers to cover women’s contraceptive services without cost sharing. Also, the ACA contraceptive mandate covers all FDA-approved female contraceptive methods. By contrast, the New Jersey mandate covers only those methods which are obtained via prescription (not those that are available over the counter or through an inpatient or out-patient procedure).

12. In addition, a religious employer (defined as a church, association or convention of churches, or an elementary or secondary school controlled, operated, or principally supported by a church) is statutorily entitled to an exclusion from the New Jersey Mandate if the required coverage conflicts with the employer’s *bona fide* religious beliefs and practices. The exemption is not available for prescription drugs that may act as contraceptives but are prescribed for a particular user for medical reasons other than contraception. Also, the exemption is not available for prescription female contraceptives that are necessary to preserve the life or health of an insured.

13. Approximately 3,434,000 New Jersey residents who have health coverage are covered by employer plans that are self-funded.² Under ERISA, such plans offered by private employers are exempt from state regulation, including the New Jersey Mandate.

14. Private employers offering self-funded plans that opt out of the Contraceptive Care

¹ See N.J.S.A. 17B:27A-7.12 (for individual health benefits plans); N.J.S.A. 17B:26-2.1y (for individual health insurers); N.J.S.A. 17:48A-7bb (for medical service corporations); N.J.S.A. 17:48-6ee (for hospital service corporations) and N.J.S.A. 17:48E-35.29 (for health service corporations); N.J.S.A. 17:48F-13.2 (for prepaid prescription service organizations); N.J.S.A. 26:2J-4.30 (for health maintenance organizations); N.J.S.A. 17B:27A-19.15 (for small employer health benefits plans); N.J.S.A. 52:14-17.29j (for the State Health Benefits Plan); and N.J.S.A. 17B:27:46.1ee (for group health insurers).

² This includes residents covered under New Jersey’s state health benefits programs, as well as self-funded plans offered by private employers.

Mandate under the newly expanded exemptions will not be subject to any federal or state requirement to provide contraception to their employees and beneficiaries. Thus, women in plans provided by these employers will not receive contraceptive coverage through these plans.

15. Upon information and belief, a number of these newly-exempted employers are expected to be New Jersey employers. As a result, those newly-exempted entities that offer self-funded plans, or that are church-affiliated schools eligible for New Jersey's religious exemption,³ would no longer have an obligation to provide any contraceptive coverage for their employees and their employees' female dependents.

16. Moreover, because the ACA's Contraceptive Care Mandate is broader than the New Jersey Mandate and prohibits cost sharing, even employees and female dependents of newly-exempt employers who offer fully-insured plans subject to the New Jersey Mandate will lose coverage for certain contraceptive methods and be subject to cost sharing that was previously prohibited.

17. Therefore, many New Jersey women are likely to lose the medical coverage for contraceptive care to which they are otherwise entitled under the ACA.

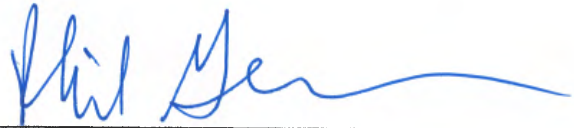
18. DOBI anticipates that some women who lose contraceptive coverage through their employer's plans, particularly low-income women, will seek contraceptive coverage from other sources, including state-funded programs, such as the New Jersey Prescription Assistance Program, Medicaid, and Title X clinics. Women who do not seek outside funding or who seek it but do not qualify for financial assistance likely will face substantial additional costs. Among

³ Churches and associations and conventions of churches have been exempted from the ACA's Contraceptive Care Mandate since 2011. *See* 76 Fed. Reg. 46621-01 (Aug. 3, 2011). However, unlike Defendants' broad new religious exemption, the 2011 exemption was not applicable to most church-affiliated schools.

these women, some likely will forgo regular contraceptive use or use cheaper, less effective contraceptive methods, resulting in more unintended pregnancies.

19. Women who lose their contraceptive coverage obtained through their employers' plans, even if they are in plans that remain subject to the New Jersey Mandate, likely will in many cases face copays and deductibles when attempting to obtain necessary contraceptive coverage. These financial constraints likely will cause some women to change their preferred choice of contraceptive method, fail to consistently maintain their use of contraceptives, or forgo contraceptive use entirely, which will result in more unintended pregnancies.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.



PHILIP GENNACE

Dated:

12/12/18

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and
STATE OF NEW JERSEY,

Plaintiffs,

v.

DONALD J. TRUMP, *et al.*

Defendants.

Civil Action No:
2:17-cv-04540-WB

DECLARATION OF ELIZABETH COULTER

I, Elizabeth Coulter, declare and state as follows:

1. I serve as Deputy Director of the Office of Women's Health ("OWH") within the New Jersey Department of Health ("DOH"). I make this affidavit based on my personal knowledge and information provided to me in my official capacity.

2. DOH's priority is to strengthen New Jersey's health system by investing in population health, promoting equity, and achieving better health outcomes for all residents. DOH is committed to providing access to high quality, affordable, culturally competent, and trauma-informed care, as well as reducing and eliminating disparities in health outcomes across all healthcare services.

3. OWH is charged with eradicating health disparities and fostering women's equity and equality in healthcare and health outcomes. The office works closely with local, state, and federal government agencies, as well as private-sector partners, to oversee programs and services that, among other things, provide family planning and reproductive healthcare and provide science-backed sexual and reproductive health information and education.

I. New Jersey's Family Planning Clinics

4. The non-profit New Jersey Family Planning League (“NJFPL”) has ten sub-grantee agencies that provide health services, including family planning services, through 47 service sites (“Family Planning Clinics”) covering all 21 counties in the state.

5. New Jersey’s Family Planning Clinics provide women and men with access to family planning services. These services include contraceptive services and counseling, HIV and STD testing, pregnancy testing, certain infertility services, and breast and cervical cancer screening. The Family Planning Clinics are integral to the family planning provider supply in New Jersey. Indeed, in 2017, NJFPL provided family planning and reproductive health care services to 99,844 New Jersey residents, including 89,945 female patients.

a. Funding to New Jersey’s Family Planning Clinics

6. DOH awards family planning funds within New Jersey. These funds are aggregated from the following sources: Social Services Block Grant (“SSBG”) funds, Maternal and Child Health (“MCH”) Block Grant funds (administered within DOH’s Maternal and Child Health Division), the State of New Jersey’s budgeted family planning funds. DOH has awarded these funds to NJFPL.

7. OWH sets the programmatic, data reporting, and budget priorities with the NJFPL through the annual grant application process and oversees those priorities through quarterly reporting requirements.

8. In addition to receiving DOH-awarded funding, NJFPL receives funds from patient service revenues (which include Medicaid, private insurance, and patient self-pay) and from federal Title X grants, as the sole New Jersey grantee.¹

¹ Although the Family Planning Clinics are sometimes colloquially referred to as “Title X clinics,” Title X accounts for only about one-quarter of NJFPL’s funding.

9. Title X of the Public Health Service Act² provides federal grants to both public and private agencies for family planning services. Specifically, Title X authorizes grant money “to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services.”

10. Since 2010, Title X funding has decreased by \$31 million, nationally. In 2010, the nationwide program received \$317.5 million; in 2017, it received \$286.5 million.³ In addition, there are frequent efforts by some in Congress to eliminate funding for the program entirely.

11. According to the 2016 Title X Family Planning Annual Report, the top three sources of revenue for Family Planning Clinics nationwide were Medicaid and CHIP (the Children’s Health Insurance Program) (39% of revenue); Title X (19%); and state government funding (10%).⁴

12. OWH is not involved with the application for or administration of federal Title X funds.

b. Provision of Services and Payment at New Jersey’s Family Planning Clinics

13. NJFPL’s mission is to provide high quality comprehensive family planning and accompanying preventative reproductive health care to every person seeking services. All patients, regardless of income or insurance coverage, are offered a full range of contraceptive methods and services.

² 42 U.S.C. § 300, *et seq.*

³ National Family Planning & Reproductive Health Association Title X Budget & Appropriations, available at https://www.nationalfamilyplanning.org/title-x_budget-appropriations.

⁴ Department of Health and Human Services Office of Population Affairs, *Title X Family Planning Annual Report, 2016 National Summary* (August 2017), available at <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>.

14. Family Planning Clinics bill private insurance or Medicaid if the patient presents such coverage. If the patient does not present coverage, family planning services are provided based on a sliding fee scale depending on the individual/family income level.

15. In 2017, NJFPL provided family planning and reproductive health care services to 99,844 New Jersey residents, including 89,945 female patients.

16. In 2017, approximately 51.9% of NJFPL patients had some form of insurance coverage (35.5% had insurance coverage through Medicaid or another government-funded program and 16.4% had private insurance coverage).

17. Many Family Planning Clinic patients are currently employed or have a family member who is currently employed. Many of these patients receive insurance through their employer or as dependents on coverage provided by their family member's employer.

18. In some cases, Family Planning Clinics are reimbursed by a patient's insurance plan, however, private insurance may not provide sufficient coverage. Thus, while 18% of all such clinic users nationwide have private insurance, private third-party sources of funding account for only 10% of clinic revenue (2016 National Report at B-7).

II. The Effects of the New Exemption Rules

19. The Affordable Care Act ("ACA"), together with its implementing regulations, requires coverage for all FDA-approved methods of contraception. As a result, New Jersey women have enjoyed widespread contraceptive coverage beyond that required by New Jersey's state contraceptive coverage requirement

20. I understand that the Trump Administration has issued new regulations ("Exemption Rules") that will make it easier for employers and others to opt out of the Affordable Care Act's contraceptive mandate.

21. My colleagues at DOH and I are very concerned that the Exemption Rules will reduce access to family planning care for New Jerseyans because there will be an increase in the number of New Jersey employers that do not provide their employees with adequate insurance coverage for contraceptive care.

22. Women whose employers opt out of providing contraceptive coverage face a dilemma: forego using contraception or find a way to pay for contraception without insurance coverage. This decision will be most challenging for lower income women. Without private insurance coverage and without the means to pay for contraception out of pocket, many such women will turn to assistance from government funded contraceptive care to prevent pregnancy.

23. Women who lose coverage for contraceptive care and therefore seek publicly-funded services at a Family Planning Clinic, rather than pay out of pocket for contraceptives, are more likely to be high need, lower-income patients. Many such women would likely utilize the Family Planning Clinics' sliding fee scale, drawing more heavily on the limited public funds for reproductive services.

24. In fact, for many low-income women in this situation, government-funded care will be the only viable option for obtaining contraceptive care.

25. Therefore, we expect that many women in New Jersey who lose their contraceptive coverage will seek care from one of the 47 New Jersey Family Planning Clinics. In order to ensure continued access to the most effective (and most expensive) forms of contraception, limited public funds, *state funds in particular*, would need to be expended.

26. Notably, the most effective methods of contraception are typically the most expensive.

27. If the increased need for contraceptive care were to exceed capacity without accompanying increases to funding, service reductions would be likely -- with clinic closures, decreased clinic hours of operation, and staff reductions as potential outcomes.

28. We are also concerned that New Jersey women who lose coverage (as a result of their employers opting out of the ACA's contraceptive mandate) will stop using contraception altogether. Women who stop using or never use contraception are more likely to have unplanned pregnancies and to require additional medical attention. According the Guttmacher Institute, 68% of unplanned births are paid for by public insurance programs, including Medicaid, while 38% of planned births are paid for by these programs. In New Jersey in 2010, the federal and state governments spent a combined \$477.1 million on unintended births; of this, \$186.1 million was paid by the State.⁵

29. Because women experiencing unintended pregnancies are less likely to receive timely prenatal care (or any prenatal care at all), access to contraception is vital to New Jersey's efforts to reduce both infant and maternal mortality. Lack of access to prenatal care yields poor outcomes for mother and baby.

30. Pregnancy carries significant risk, especially in New Jersey. Currently, New Jersey is ranked 45th worst nationally in maternal mortality, and the maternal mortality rate for black women is more than double the national average.⁶ New Jersey women are more likely than women in other states to suffer injury and death related to pregnancy. Many costs associated with New

⁵ Guttmacher Institute, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010* (Feb. 2015), available at <https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy>.

⁶ United Health Foundation, *America's Health Rankings, 2018 Health of Women and Children Report, New Jersey in 2018*, available at https://www.americashealthrankings.org/explore/health-of-women-and-children/measure/overall_mch/state/NJ.

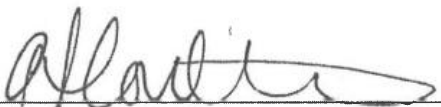
Jersey's high rate of maternal mortality are paid for using public funding. Planned pregnancies, through the use of contraception, are essential to curbing the tide of maternal mortality and morbidity in the State.

31. Other negative outcomes associated with unintended pregnancy include reduced likelihood of breastfeeding, increased risk of maternal depression, and increased risk of physical violence during pregnancy, in addition to severe limitations on participation in the economy.

32. Children born from unintended pregnancies are more likely to experience poor mental and physical health during childhood and, as teenagers, are more likely to experience lower rates of educational attainment and higher rates of behavioral issues. Many of these outcomes lead to conditions and circumstances for which social supports are publicly funded.

33. For all these reasons, I believe that the Exemption Rules to the contraceptive coverage mandate will have a negative effect on the health of New Jersey women; that they will increase the number of women who receive contraceptive coverage through NJFPL; and that they will impose additional economic and other burdens on the State.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief.


Elizabeth Coulter

Dated: 12/12/2018

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA et al.,

Plaintiffs,

v.

DONALD J. TRUMP et al.,

Defendants.

No. 2:17-cv-04540-WB

SUPPLEMENTAL DECLARATION OF KATHRYN KOST

I, Kathryn Kost, hereby submit this supplemental declaration in support of the Motion for Preliminary Injunction filed by Plaintiffs in the above-captioned matter and, in support thereof, state as follows:

1. I am the Acting Vice President for Domestic Research at the Guttmacher Institute, a private, independent, nonprofit, nonpartisan research and policy organization committed to advancing sexual and reproductive health and rights in the United States and globally.
2. On December 14, 2018, I submitted a declaration in support of the Motion for Preliminary Injunction in this matter as an expert on reproductive health care, family planning, and unintended pregnancy, and the impact on individuals, families, and the public health from access to contraception and related care, or interference with that care, in the United States.
3. I understand that this lawsuit involves a challenge to the federal government's Final Rules ("Final Rules") regarding the Affordable Care Act's ("ACA") contraceptive coverage mandate. In my expert opinion, the Final Rules would compromise women's ability to obtain contraceptive methods, services and counseling and, in particular, to consistently use the best methods for them, thus putting them at heightened risk of unintended pregnancy.

4. The Final Rules would have public health and fiscal consequences in states across the country. If unable to access contraceptive coverage through their employer or university, some lower-income women who meet the strict income requirements of public programs would rely on publicly funded services to access this beneficial service. Many women who lose or lack contraceptive coverage because their employer or university objects, however, would not meet the strict income and eligibility requirements of public programs, and if as a result they are not using their preferred or the most effective methods for them, or if cost forces them to forgo contraceptive use periodically or altogether, they would be at increased risk of unintended pregnancy. The costs of the resulting unintended pregnancies often then fall to the states because the federal government cannot or will not withstand these costs.

5. Examples of this impact for the plaintiff states were included in my original declaration. In this supplemental declaration, I include data for all 50 states and the District of Columbia in a table as Exhibit A.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: January 7, 2019



By: Kathryn Kost
Acting Vice President for Domestic Research
The Guttmacher Institute

Exhibit A: State-Specific Data on Impact

	Medicaid eligibility, as % of federal poverty level (as of January 2018)			Women needing publicly supported contraceptive services and supplies, 2014		Unintended pregnancies, 2010		% of births paid for by public insurance programs, 2010	Public costs for unintended pregnancies, 2010	
				% of need met by publicly supported providers		Rate per 1,000 women 15–44				
	Childless adults	Parents	Family planning specific	Number	providers	Number	15–44		State (in millions)	Federal (in millions)
Alabama	—	18%	146%	332,750	31%	46,000	48	61.6%	\$72.6	\$250.5
Alaska	138%	139%	—	41,200	63%	8,000	54	64.3%	42.9	70.8
Arizona	138%	138%	—	465,450	15%	61,000	49	64.6%	161.5	509.4
Arkansas	138%	138%	—	204,850	29%	29,000	50	72.3%	61.9	266.8
California	138%	138%	200%	2,643,580	50%	393,000	50	64.3%	689.3	1,062.1
Colorado	138%	138%	—	326,490	38%	43,000	42	63.8%	91.1	146.1
Connecticut	138%	138%	263%	183,070	38%	32,000	46	60.8%	80.1	128.4
Delaware	138%	138%	—	50,100	30%	11,000	62	71.3%	36.0	58.2
District of Columbia	215%	221%	—	44,910	84%	10,000	58	84.6%	13.3	50.9
Florida	—	33%	—	1,216,520	17%	207,000	58	70.6%	427.1	892.8
Georgia	—	36%	200%	695,120	16%	119,000	57	80.5%	229.7	687.7
Hawaii	138%	138%	—	73,090	25%	16,000	61	49.9%	37.8	76.7
Idaho	—	26%	—	113,020	21%	12,000	38	60.4%	18.5	70.2
Illinois	138%	138%	—	772,510	20%	128,000	49	78.3%	352.2	571.5
Indiana	139%	139%	146%	446,230	19%	55,000	43	64.6%	91.4	284.6
Iowa	138%	138%	—	190,270	29%	23,000	39	61.5%	48.3	127.6
Kansas	—	38%	—	188,100	17%	24,000	43	47.2%	50.4	115.7
Kentucky	138%	138%	—	284,530	24%	34,000	40	66.8%	75.0	302.8
Louisiana	138%	138%	138%	321,480	15%	53,000	57	78.7%	120.6	530.4
Maine	—	105%	214%	78,880	33%	9,000	37	74.7%	14.6	43.6
Maryland	138%	138%	200%	298,190	25%	71,000	60	58.2%	180.9	285.4
Massachusetts	138%	138%	—	373,060	25%	54,000	40	56.4%	138.3	219.6
Michigan	138%	138%	—	635,660	16%	93,000	49	71.9%	177.0	485.1
Minnesota	138%	138%	200%	294,680	29%	38,000	36	66.7%	128.7	203.9
Mississippi	—	27%	199%	213,930	28%	35,000	57	81.9%	40.4	226.7
Missouri	—	22%	—	391,510	18%	54,000	46	72.2%	132.6	385.9
Montana	138%	138%	216%	66,380	41%	7,000	42	47.8%	9.1	31.7
Nebraska	—	63%	—	118,170	20%	14,000	41	63.1%	41.7	91.9
Nevada	138%	138%	—	194,430	10%	29,000	54	60.0%	37.1	65.8
New Hampshire	138%	138%	201%	65,530	29%	8,000	32	52.7%	10.3	16.5
New Jersey	138%	138%	—	455,260	22%	97,000	56	52.4%	186.1	291.0
New Mexico	138%	138%	255%	151,950	28%	22,000	56	77.1%	47.9	191.2
New York	138%	138%	223%	1,227,170	32%	246,000	61	70.2%	601.1	937.7
North Carolina	—	43%	200%	667,910	20%	95,000	49	74.8%	214.7	643.5
North Dakota	138%	138%	—	44,180	26%	5,000	41	36.8%	7.7	17.9
Ohio	138%	138%	—	730,110	14%	109,000	49	68.7%	218.8	605.8
Oklahoma	—	45%	138%	256,880	31%	36,000	49	80.7%	77.0	254.0
Oregon	138%	138%	250%	270,990	39%	31,000	41	69.9%	47.2	122.7
Pennsylvania	138%	138%	220%	745,550	29%	115,000	47	53.5%	248.2	478.6
Rhode Island	138%	138%	—	71,320	35%	9,000	43	70.1%	27.5	48.7
South Carolina	—	67%	199%	323,140	31%	42,000	46	78.6%	84.0	327.3
South Dakota	—	50%	—	52,610	27%	7,000	46	46.2%	14.4	35.0
Tennessee	—	98%	—	434,440	26%	62,000	49	73.7%	130.7	400.0
Texas	—	18%	—	1,795,160	10%	298,000	56	73.7%	842.6	2,056.8
Utah	—	60%	—	207,350	22%	24,000	40	53.3%	30.4	127.6
Vermont	138%	138%	—	35,810	59%	4,000	36	73.5%	9.6	21.8
Virginia	—	38%	205%	447,970	17%	84,000	51	45.4%	194.6	312.0
Washington	138%	138%	260%	429,300	26%	61,000	45	63.1%	177.1	290.7
West Virginia	138%	138%	—	110,910	47%	15,000	43	76.0%	24.9	120.5
Wisconsin	100%	100%	306%	353,620	22%	42,000	38	62.0%	92.1	221.4
Wyoming	—	55%	—	34,630	30%	4,000	42	67.4%	21.3	34.1

Sources: References 113–117.

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF
PENNSYLVANIA,

Plaintiff,

v.

DONALD J. TRUMP, *et al.*

Defendants,

LITTLE SISTERS OF THE POOR
SAINTS PETER AND PAUL HOME,

Proposed Defendant-Intervenors

Civil No. 2:17-CV-4540

**DECLARATION OF MOTHER
SUPERIOR MARIE
VINCENTE**

I, Mother Superior Marie Vincente, hereby declare as follows:

1. I am over the age of 21 and am capable of making this declaration pursuant to 28 U.S.C. § 1746. I have not been convicted of a felony or crime involving dishonesty. I make this declaration based on my personal knowledge and experience of the Little Sisters, our organization, our ministry, and our religious beliefs and practices. My statements about the history of the Little Sisters, the scope of our ministry internationally, and the founding dates of our homes are drawn from organizational and historical documents that I believe to be correct.

2. I am the Mother Superior of the Saints Peter and Paul Home of the Little Sisters of the Poor in Pittsburgh, Pennsylvania.

3. I have been a Little Sister for 63 years, and have served as the Mother Superior of the Saints Peter and Paul Home for over 12 years.

I. History, Organization, and Structure of the Little Sisters of the Poor

4. The Little Sisters of the Poor is an international Roman Catholic Congregation of Sisters that has provided loving care to needy elderly persons of any race, sex, or religion for over 175 years.

5. The Little Sisters of the Poor were founded in France, in the winter of 1839, when St. Jeanne Jugan carried a blind elderly woman off the streets and into her home and laid the woman in her own bed. Over time, other women joined St. Jeanne in a religious ministry designed to protect and care for the elderly poor.

6. By the time St. Jeanne died forty years later, the Little Sisters of the Poor had established homes in eight countries, including the United States, where the first home was founded in 1868 in Brooklyn, New York.

7. Today, there are Little Sisters homes in over thirty countries around the world serving over 13,000 poor elderly people.

8. The Little Sisters of the Poor have founded and operate over twenty-five homes in the United States, which are located in twenty states and the District of Columbia. These homes are hosted by over 300 Little Sisters of various nationalities.

9. All Little Sisters homes share the same fidelity to the Catholic beliefs. Every home is operated under the control of the Little Sisters, and every Little Sister takes a vow of obedience to God, which assumes obedience to the Pope, the Church's teaching, and the authority of the Church in her hierarchy.

10. While Catholic and committed to following Church teaching, the Little Sisters' homes are not under the civil legal ownership and control of the dioceses in

which they are located. Instead, the Little Sisters of the Poor own and control the homes ourselves, through local corporations that are entirely within the civil legal control of the Little Sisters.

11. The Little Sisters' homes are not directly funded by the dioceses in which we are located. Instead, we take responsibility for funding our own operations. For most homes, about half of the budget comes from voluntary gifts, largely in response to the begging for funds and gifts in kind that the Little Sisters do to support our ministry.

II. Little Sisters of the Poor Pittsburgh

12. The Saints Peter and Paul Home of the Little Sisters of the Poor in Pittsburgh ("Little Sisters Pittsburgh"), is a Pennsylvania non-profit corporation that qualifies as a tax-exempt organization under section 501(c)(3) of the Internal Revenue Code of 1986 ("the Code"). The Pittsburgh home is under my direct authority as Mother Superior.

13. Little Sisters Pittsburgh currently employs about 67 full-time employees.

14. Little Sisters Pittsburgh have adopted the Christian Brothers Employee Benefit Trust (the "Christian Brothers Trust") to provide medical benefits coverage for their employees.

15. It is my understanding that Christian Brothers Trust is a Catholic entity designed to serve the Catholic Church and related faith-based entities. It is my understanding that, like the Little Sisters, the Christian Brothers Trust operates in a manner consistent with our mutual Catholic beliefs. One of the reasons the Little Sisters chose to use the Christian Brothers Trust for our health benefits is because it

shares and is administered in accordance with our religious beliefs and provide benefits accordingly.

III. Religious Beliefs and Commitments of the Little Sisters of the Poor

16. Jesus taught that “in so far as you did it to the least of these brothers of mine, you did it to me.” *See* Matthew 25:34. This teaching is a fundamental part of who the Little Sisters are. St. Jeanne urged her fellow Little Sisters, “Never forget that the poor are Our Lord; in caring for the poor say to yourself: This is for my Jesus—what a great grace!” Thus, each Little Sister makes a vow of Hospitality, through which she promises to care for the aged as if they were Christ himself.

17. As Little Sisters, we strive to witness to the value of the elderly by believing in their inviolable dignity, by recognizing their unique contributions to the Church and society, and by involving them in the activities of our Homes to develop their human potential.

18. Caring for the dying is the summit of the Little Sisters’ service to the elderly poor. The Little Sisters maintain a constant presence with those who have entered the dying process and their families. We try to relieve their sufferings as much as possible, which includes giving emotional and prayerful support. Our provision of spiritual support is always consistent with the faith of the person we are serving; we do not force religious observance on anyone.

19. Because the Little Sisters care for those who are weak and dying, we strive to emphasize our respect for the uniqueness and dignity of each elderly person as they reach the end of their life. We offer this respect for two reasons. First, to treat

the individual with the dignity they are due as a person loved and created by God, with the same respect and compassion as if he or she was Jesus Christ. Second, to convey a public witness of respect for life, in the hope that we can help build a Culture of Life in our society.

20. We care for the elderly poor of all races and religions, or of no religion at all. We do not care for people because they are Catholic, but because we are Catholic.

21. We also hire employees of all races and religions, or of no religion at all. Because staff members are an important extension of our ministry to the elderly, they must support the Little Sisters' mission by welcoming the elderly poor, helping to make them happy and caring for them with respect or dignity until death. Failure to do so is one of the relatively few explicit grounds for staff dismissal.

22. The Little Sisters have also taken a vow of obedience to God, which assumes obedience to the Pope. We carefully follow all of his guidance, and obey all the decisions of the Church. Thus, we develop all of our programs, policies, and procedures in accord with the teachings of the Catholic Church, including its ethical teachings on the inviolable dignity of every human life.

23. These teachings include Catholic religious teachings about abortion, contraception, sterilization, and cooperation with acts that are intrinsically immoral.

24. Authoritative Catholic teachings are located in sacred Scripture and sacred tradition, and are set forth and specified in the Catechism of the Catholic Church, documents of ecumenical councils (such as the Second Vatican Council), papal encyclicals, directives issued by bishops' conferences, and other teaching documents

of the Church. *See generally* Catechism of the Catholic Church Nos. 888-892 (describing the teaching office of the Church); *Dei Verbum* No. 10 (describing how “[s]acred tradition and Sacred Scripture form one sacred deposit of the word of God, committed to the Church”).

25. Sections 2270 and 2271 of the Catechism of the Catholic Church (1994) affirm that life begins at conception, that directly intending to take innocent human life is gravely immoral. Thus a post-conception contraceptive is an abortifacient and “gravely contrary to moral law.” *See also* section 2274 (“Since it must be treated from conception as a person, the embryo must be defended in its integrity, cared for, and healed, as far as possible, like any other human being.”)

26. The Catholic Church also teaches that contraception and sterilization are intrinsic evils. *Id.* at Section 2370.

27. The Church teaches that programs of “economic assistance aimed at financing campaigns of sterilization and contraception” are “affronts to the dignity of the person and the family.” *See* Section 234 of the Compendium of the Social Doctrine of the Church (2004).

28. In a landmark encyclical, Blessed Pope John Paul II made clear that Catholics may never “encourage” the use of “contraception, sterilization, and abortion[.]” *See* Section 91 of *Evangelium Vitae* (1995).

29. Similarly, the United States Conference of Catholic Bishops (“USCCB”) has issued a series of directives to inform the provision of health services in every U.S. Catholic health institution. These directives prohibit providing, promoting,

condoning, or participating in the provision of abortions, abortion-inducing drugs, contraceptives, and sterilization. Exhibit A, USCCB Directives for Catholic Health Care Services at Nos. 45, 52, & 53.

30. The directives specifically warn against partnering with other entities in a manner that could involve Catholic health care services in the provision of such “intrinsically immoral” services. *Id.* at Nos. 67-72.

31. Rather, the USCCB Directives instruct us to “distinguish [ourselves] by service to and advocacy for” people who are “at the margins of society” and “particularly vulnerable to discrimination,” such as “the poor, the uninsured and underinsured; children and the unborn; single parents; the elderly; those with incurable diseases and chemical dependencies; racial minorities; immigrants and refugees.” *Id.* at No. 3.

32. The Little Sisters are particularly concerned about the possibility that our conduct may lead others to do evil, or think that the Little Sisters condone evil. *See* Catechism No. 2284, 86 (instructing Catholic institutions to avoid “scandal” and defining “scandal” as “an attitude or behavior which leads another to do evil”; scandal can be caused “by laws or institutions”). The Little Sisters beg for funds and goods at Catholic parishes and elsewhere to support our ministry. Thus, participating in the provision of health benefits that violate Catholic teaching poses a grave risk for the Little Sisters as they interact with Catholic faithful and others who share our beliefs.

33. Catholic teaching also instructs us to provide our employees and their families adequate health benefits. “In return for their labor, workers have a right to

wages and other benefits sufficient to sustain life in dignity.” *Economic Justice For All: Pastoral Letter on Catholic Social Teaching and the U.S. Economy* ¶ 103, http://www.usccb.org/upload/economic_justice_for_all.pdf (“The dignity of workers also requires adequate health care”).

34. These religious teachings binding on how the Little Sisters carry out our religious ministry of caring for the elderly poor. We believe that the health plans that each home offers should be consistent with Catholic teaching.

IV. The Impact of the Mandate on the Little Sisters

35. The HHS contraceptive mandate (the “Mandate”) requires the Little Sisters to participate in the provision of contraception, abortion, and sterilization to our employees via the use of our health plans, health plan information, and health plan infrastructure. If we do not comply with the Mandate, we face massive penalties, which places enormous pressure on the Little Sisters to violate our religious beliefs.

36. Our vow of hospitality, which asks us to treat each person in our care as if he or she were Christ himself, commits us just as much to respecting the dignity of human life at its beginning as at its end. We can no more participate in the provision of contraception, abortion, and sterilization than we could participate in the provision of euthanasia or assisted suicide.

37. Because of the religious beliefs set forth above, the Little Sisters cannot:

- a. participate in the Mandate’s program to promote and facilitate access to the use of sterilization, contraceptives, and abortion-inducing drugs and devices,

- b. provide health benefits to our employees and plan beneficiaries that will include or facilitate access to sterilization, contraception, and abortion-inducing drugs and devices,
- c. designate, authorize, or incentivize any third party to provide our employees or plan beneficiaries with access to sterilization, contraception, and abortion-inducing drugs and devices,
- d. sign, execute, deliver, or otherwise file documents with a third party or with the government which could then be used to require, authorize, or incentivize that third party to provide our employees with access to sterilization, contraception, and abortion-inducing drugs;
- e. agree to refrain from speaking with a third party to ask or instruct it not to deliver contraceptives, sterilization, and abortifacients to Little Sisters' employees and plan beneficiaries in connection with Little Sisters' health plans;
- f. create or facilitate a provider-insured relationship (between the Little Sisters and Christian Brothers Services or any other third-party administrators), the sole purpose of which would be to provide contraceptives, sterilization, and abortifacients in connection with the Little Sisters' health plans;
- g. create, maintain, support, and facilitate health insurance plans, information, and infrastructure that is used to provide contraceptives,

sterilization, and abortifacients to Little Sisters' employees and plan beneficiaries;

- h. take any action that would require, authorize, or incentivize Christian Brothers Trust or Christian Brothers Services to violate their own Catholic religious beliefs.

38. Obeying the Mandate's requirement to participate in the provision of abortion-inducing drugs would violate our public witness to the respect for life and human dignity that we are committed to displaying at all times through our vow of hospitality and our fidelity to Church teaching. It would similarly violate our duty to "advoca[te] for those people whose social condition puts them at the margins of our society and makes them particularly vulnerable," such as "the unborn." Exhibit A, USCCB Directives, at No. 3.

39. The Little Sisters believe that our ministry and all of our resources—including our health insurance plans and the efforts we make to maintain those plans—are gifts from God that we must use to God's glory and for the good of all, to help bear the burdens and sufferings of others. We cannot allow those gifts to be co-opted to serve ends that we believe dishonor God and the dignity of the human person.

40. The Mandate threatens the Little Sisters with large fines and penalties if we continue to act in accordance with our religious beliefs.

41. For example, if we continue our practice of providing health benefits to our employees and their families without including or facilitating free access to sterilization, contraception, and abortion-inducing drugs and devices, we will face

finest of “\$100 for each day in the noncompliance period with respect to each individual to whom such failure relates.” 26 U.S.C. § 4980D(b)(1).

42. Depending on how the I.R.S. applied this penalty, the Little Sisters homes could face tens of millions of dollars of fines *each year* for our inability to facilitate the required coverage.

43. Little Sisters Pittsburgh currently employs about 67 full-time employees. If the I.R.S. levies the fine on a per-full-time-employee basis, we would be facing daily fines of \$6,700 and annual fines of \$2,445,500. If the I.R.S. levies the fine on the basis of total number of employees and dependents receiving benefits, the fines would be orders of magnitude larger.

44. The entire annual budget for Little Sisters Pittsburgh, which currently provides care for about 95 needy elderly individuals, is about \$8 million.

45. Nor can we avoid these fines by choosing not to provide health benefits at all. Cutting off all benefits for our employees would be unconscionable. We love and respect our employees and are dedicated to providing adequate health benefits.

46. Cutting off all employee benefits would also have a severe negative impact on our employees and their families, and on our ability to hire and retain qualified medical staff and other employees. Benefits plans are an important reason that many employees make choices about which jobs to pursue, to keep, and to abandon.

47. Even if we could cut off all benefits in good conscience and without harming our employees or our homes, we would face large government fines for doing so. For

example, Little Sisters Pittsburgh would face annual fines of approximately \$134,000 for dropping health benefits altogether.

48. For these reasons, the Mandate imposes enormous pressure on the Little Sisters to participate in activities prohibited by our sincerely held religious beliefs.

49. Prior to the Mandate, we engaged in conduct motivated by our sincerely held religious beliefs: providing benefits plans that do not include sterilization, contraception, and abortion-inducing drugs and devices. The Mandate penalizes our participation in that religious exercise.

50. The Mandate also places enormous pressure on the Little Sisters to engage in conduct contrary to our sincerely held religious beliefs. I am charged with making decisions for the Little Sisters Pittsburgh. The severe threats of fines and punishment create enormous pressure on me to violate my religious beliefs as the price of continuing our mission of helping the needy elderly.

51. We object to the Mandate not because it makes us *use* drugs or devices against our religious beliefs, but because it forces us to participate as a necessary part of the government's scheme to provide those drugs and devices.

The Little Sisters' Litigation Against the Mandate

52. The Little Sisters tried to avoid having to sue the federal government to protect our ministry. We made multiple public statements and filed a detailed public comment with the federal government to inform it of our sincere religious objection to incorporating us into its scheme. But the government refused to exempt us. Which meant that on January 1, 2014, we would start facing massive penalties.

53. We filed suit on September 24, 2013, and filed a motion for preliminary injunction one month later, on October 24. *Little Sisters of the Poor v. Sebelius*, No. 13-cv-2611 (D. Colo.).

54. Over the next four years, we would remain in constant litigation with the federal government. We twice had to go to the Supreme Court to be protected from the imposition of massive financial penalties.

55. The first time came on December 31, 2013, when just hours before the start of the penalties we filed for and received a temporary emergency injunction from Justice Sotomayor just hours. Later in January 2014, the rest of the Supreme Court would grant an injunction pending appeal without noted dissent. *Little Sisters of the Poor v. Sebelius*, 134 S. Ct. 1022 (2014).

56. And the second time came after the Supreme Court granted certiorari in our case, when it vacated a Tenth Circuit ruling against us, remanded the case for further consideration, and ordered that “the Government may not impose taxes or penalties” on us while the case remained pending. *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

57. Our case has remained pending at the Tenth Circuit since that time.

The Interim Final Rule

58. On May 4, 2017, President Trump invited members of the Little Sisters of the Poor to the White House for the traditional proclamation of the National Day of Prayer and the signing of an Executive Order related to religious liberty.

59. At the signing ceremony, the President made clear that the Mandate’s application to the Little Sisters had been inappropriate and illegal. The President

described the Mandate as an “attack[] against the Little Sisters of the Poor” that had put them through “a long, hard ordeal,” and he listed it as an example of past “abuses” of religious liberty. See <https://www.c-span.org/video/?428059-1/president-trump-signsreligious-liberty-executive-order> (starting at 28:30).

60. The agencies issued an Interim Final Rule on October 6, 2017. See Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47792 (Oct. 13, 2017). The rule explicitly referred to the Little Sisters’ lawsuit and the Supreme Court decision in our case as the impetus for the regulatory change: “Consistent with the President’s Executive Order and the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.” 82 Fed. Reg. 47799; *see also id.* at 47798 (describing lawsuits and *Zubik* decision).

61. The Interim Final Rule conceded that “requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA,” and that because “requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest, we now believe that requiring such compliance led to the violation of RFRA in many instances.” *Id.* at 47800, 47806.

Conclusion

62. Being forced into four years of litigation, including two trips to the Supreme Court, has been a difficult and burdensome experience for the Little Sisters. We do not want to alarm in any way the elderly poor whom we serve, nor their families, our employees, or our benefactors. But to protect our ability to serve them as we always have, and to avoid violating and publicly rejecting our religious beliefs, our only recourse was a lawsuit.

63. It is deeply troubling to us that, after years of respectfully seeking recourse in federal court to be protected from the *federal* government, we are being forced to defend those same rights that are threatened by a *state* government. We had never been required to provide these objectionable services by Pennsylvania, and do not understand why Pennsylvania asks this Court to force us to provide them now. We hope a day will come when government will cease threatening our ministry in this way.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 18th day of November, 2017,

Mother Superior Marie Vincente S.P.
Mother Superior Marie Vincente

JA 350

	A	B	C	D	E	F	G	H	I	J
	Case	Plaintiffs	Type: For-profit (F), Non-profit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number counted towards final total	Total employees (minus HO/W/IA and SICFs)	Total students at relevant universities
1	Am. Pulverizer Co. v. U.S. Dep't of Health and Human Servs., No. 6:12-cv-03459, 2012 WL 6951316 (W.D. Mo. Dec. 20, 2012); American Family Association v. Sebelius, 1:13-cv-00032-SA-DAS (N.D. Miss. Feb. 20, 2013)			175 employees	Complaint	Yes		175		
2	Amex Med. Inc. v. Burwell, No. 13-1118, 2013 WL 1276025 (8th Cir. Feb. 1, 2013)			135 employees	Complaint	Yes		135		
3	Archdiocese of St. Louis v. Burwell, No. 4:13-cv-02500 (E.D. Mo.), No. 14-3016 (8th Cir.)	Archdiocese of St. Louis Catholic Charities of St. Louis		18 employees	Complaint	Yes		18		
4	Amstrong v. Burwell, No. 1:13-cv-00563-RB7 (D. Colo. Sept. 17, 2013); govt't appeal dismissed Sept. 4, 2014 (10th Cir. order)			7,800 employees/staff	Complaint	No	Diocese self-insured plan (see Brant v. Burwell note below same)	0	0	
5	Association of Christian Schools International v. Burwell, No. 1:14-cv-2366 (D. Colo.), No. 14-1492 (10th Cir.)	Association of Christian Schools International		1600 employees	Complaint	No		0	0	
6				730 employees	Complaint	Yes		730		
7				140 employees	Complaint	Yes		140		
8				133 employees	Complaint	Yes		133		
9				1,900 students; 641 Employees	Complaint	Students = no employees = yes	Complaint does not state that they offer a student health plan, therefore students and counted	641		
10				15,000 students; 3,565 employees (1,018 FT and 2,547 PT)	Complaint	Students = no employees = partial	Complaint does not state that they offer a student health plan, therefore students and counted	641	0	
11	Indiana Wesleyan University v. Autocam	Indiana Wesleyan University		478 employees	Complaint	Yes		1,435	1,435	
12	Autocam Corp. v. Burwell, 730 F.3d 618 (6th Cir. Sept. 17, 2013).	Autocam Medical		183 employees	Complaint	Yes		478	478	
13	Ave Maria Foundation v. Burwell, No. 2:13-cv-15198 (E.D. Mich.), Nos. 14-1310 (6th Cir.)	The Ave Maria Foundation		51 employees	Estimated number based on online information	Yes		183		
14				19 employees	Form W-3 filing	Yes		51	51	
15				18 employees	Form W-3 filing	Yes		19	19	
16				26 employees	Form W-3 filing	Yes		18	18	
17				14 employees	Website	Yes		26	26	
18				68 employees	Form W-3 filing	Yes		14	14	
19	Ave Maria School of Law v. Burwell, No. 2:13-cv-00795 (M.D. Fla.), Nos. 14-15777 (11th Cir.)	Rhonda J. Donahue Academy, Inc. Thomas More Law Center		150 employees	Complaint	Employees = yes; students = no	Complaint does not state that they offer a student health plan, therefore students not counted	68	68	0
20	Ave Maria Foundation v. Burwell, No. 2:13-cv-00630 (M.D. Fla.), Nos. 14-15780 (11th Cir.)			150 employees	Complaint	Employees = yes; students = no	Complaint does not state that they offer a student health plan, therefore students not counted	150	150	0
21	Barron Indus., Inc. v. Burwell, No. 1:13-cv-01330-KB1 (D.D.C. Sept. 25, 2013); Beckwith Elec. Co. v. Burwell, No. 8:16-cv-1944 (M.D. Fla.)			56 employees	Complaint	Yes		56	56	
22	Belmont Abbey College v. Sebelius, et al., No. 1:11-cv-01989 (D.D.C. Nov. 10, 2011)			126 employees	Complaint	Yes		126	126	
23	Black Holdings, Inc. v. Burwell, No. 4:13-cv-00462-AGF (E.D. Mo. Apr. 1, 2013); Brant v. Burwell, No. 2:14-cv-00681 (W.D. Pa.), Nos. 14-3663, 14-4087 (2d Cir.)			1,600 students; 305 employees	Complaint	Yes		1,600 students; 305 employees	305	1,600
24				196 employees	Complaint	Yes		196	196	
25		Diocese of Greensburg		3,100 employees; 5,000 other participants in plan (this is a high number- it includes employees from other Dioceses)	Complaint	No	Diocese self-insured plan; Government argued that these and all similar Catholic diocese-sponsored self-insured plans and entities participating in such plans that are litigants represented by Jones Day likely qualify to be church plans exempt from ERISA. See, e.g., Doc. # 23, 2:14-cv-00681-AJS (W.D. Pa.). We cannot force such plan TPAs to offer contraceptive payments, and it is likely the churches will tell them not to, and the TPAs will not make the offers.	0	0	
26		Catholic Charities		18 employees	Complaint	No		0	0	
27		St. John School		13 employees	Complaint	No	Diocese self-insured plan	0	0	

	A Case	B Plaintiffs	C Type: For-profit (F), Nonprofit (N), Diocese of Washington IA (H), Catholic Charities (C), Pro-life (P), Grandfathered (G)	D Number of Employees/Students	E Document employee number located within	F Are students/employees counted in final total?	G If not counted, explanation why	H Number counted towards final total	I Total employees (minus HR/FA and SICPs)	J Total students at relevant universities
1										
28	Briscoe v. Burwell, No. 1:13-cv-00285-WYD-BNB (D. Colo. Sept. 6, 2013); gov't appeal dismissed Sept. 4, 2014 (10th Cir. order);	Briscoe owns all plaintiff organizations involved: Continuum Health Partnerships, Inc./ Mountain States Health Properties, LLC/ Continuum Health Management, LLC/ CH/ Greeley, LLC	F	200 employees	Complaint	Yes	CBA does not carry its own insurance	200	200	
29	Catholic Benefits Association/LCA v. Burwell CBA I), No. 5:14-cv-00240(W.D. Okla.), Catholic Benefits Association/LCA v. Burwell (CBA II), No. 5:14-cv-00685 (W.D. Okla.),Nos. 14-6171, 14-6163, 15-6028, 15-6037, 15-6139, 16-6030, 16-6217 (10th Cir.)	Catholic Benefits Company Archdiocese of Baltimore	N	Unknown	N/A	To estimate the number in CBA plans that may be effected, 10,000 used.	CBA owns CIC, so we assume CIC also does not offer insurance	0	10,000	
30		Catholic Insurance Company	H	Unknown	N/A	No	Diocese self-insured plan	0	0	
31		Archdiocese of Baltimore	N	5,500 participants	Complaint	No	Diocese self-insured plan	0	0	
32		Cathedral Foundation (AKA Catholic Review Media)	C	32 employees	Complaint	No	Diocese self-insured plan	0	0	
33		Archdiocese of Oklahoma	C	Unknown (see St. Aim, Mount St. Mary and Office of Catholic Schools below)						
34		City-Complaint lists Mount St. Mary, St. Aim, and Office of Catholic Schools as sub- ministries	H	78 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
35		St. Aim	C	Unknown		No	Diocese self-insured plan	0	0	
36		Mount St. Mary	C	Unknown	Form W-3 filing	No	Diocese self-insured plan	0	0	
37		Office of Catholic Schools	C	100 participants	Complaint	Yes	Diocese self-insured plan	100	100	
38		Care Center	N	140 participants	Complaint	Yes	Diocese self-insured plan	140	140	
39		Goodwill Publishers	N	102 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
40		Catholic Charities Oklahoma	C	Unknown	Form W-3 filing	No	Diocese self-insured plan	0	0	
41		All State	C	69 employees		No	Diocese self-insured plan			
42		Catholic Charities, Diocese of Family Services, Diocese of Norwich	N	636 employees	Second Complaint	Yes	Diocese self-insured plan	69	69	
43	Catholic Charities of the Archdiocese of Philadelphia v. Burwell, No. 2:14-cv-0096 (E.D. Pa.), No. 14-3126 (3d Cir.)	Catholic Social Services St. Francis Homes for Boys St. Edmund's Home for Children	C	227 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
44		Don Guadalupe Village	C	226 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
45		Divine Providence Village	C	413 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
46		St. Gabriel's System	C	667 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
47		Catholic Community Services	C	458 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
48		Nutritional Development Services	C	92	Form W-3 filing	No	Diocese self-insured plan	0	0	
49		Villa St. Martha	C	64	Form W-3 filing	No	Diocese self-insured plan	0	0	
50		St. Monica Manor	C	117 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
51		St. John Neumann Nursing Home	C	356 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
52		Immaculate Mary Home	C	360 Employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
53		St. Francis Country House	C	490 Employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
54		St. Martha Manor	C	488 Employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
55		St. Mary Manor	C	232 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
56		St. John Vianney Center	C	339 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
57		Catholic Clinical Consultants	C	84 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
58	Catholic Diocese of Beaumont v. Burwell, No. 1:13- cv-00709 (E.D. Tex.), No. 14-40212 (5th Cir.)	Catholic Clinical Consultants	C	19	Form W-3 filing	No	Diocese self-insured plan	0	0	
59		Diocese	H	950 employees; 232 staff at schools	Complaint	No	Offers coverage though Christian Brothers Employee Benefit Trust-a self insured church plan	0	0	
60		Catholic Charities of Southeast Texas, Inc.	C	18 employees	Complaint	No	Offers coverage though Christian Brothers Employee Benefit Trust-a self insured church plan	0	0	
61	Catholic Diocese of Biloxi v. Burwell, No. 1:14-cv- 00146 (S.D. Miss.)	Diocese of Jackson	H	900 employees	Complaint	No	Diocese self-insured plan	0	0	
62		Catholic Charities Vicksburg	C	140 employees	Complaint	No	Diocese self-insured plan	0	0	
63		St. Joseph	C	70 employees	Website	No	Diocese self-insured plan	0	0	
64		Diocese of Biloxi	H	85 employees	Website	No	Diocese self-insured plan	0	0	
65		De La Salle Center	C	606 employees	Complaint	No	Diocese self-insured plan	0	0	
66		Catholic Social & Community Services Inc.	C	3 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
67		Resurrection Catholic and Sacred Heart	C	20 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
68					Complaint	No	Diocese self-insured plan	0	0	

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A Case	B Plaintiffs	C Type: For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)	D Number of Employees/Students	E Document employee number located within	F Are students/employees counted in final total?	G If not counted, explanation why	H Number towards final total	I Total employees (minus Hov/IA and SICPs)	J Total students at relevant universities
1	St. Dominic-Jackson Memorial Hospital and affiliated locations and programs	G	2,200 employees	Complaint	No	Self-insured plan sponsored by Catholic affiliated hospital, grandfathered and already omits contraceptives, so could retain grandfathered status or pursue church plan status to continue omitting.	0	0	
69	Cardinal Bishop of Catholic Diocese of Joliet v. Sobellus, 1:12-cv-03932 (N.D. Ill. May 21, 2012)	H	At least 1,570 employees	Complaint	No	Diocese self-insured plan	0	0	
70	Catholic Charities of Joliet	H	240 employees	Complaint	No	Diocese self-insured plan	0	0	
71	Diocese of Springfield	C	2585 employees	Complaint	No	Diocese self-insured plan	0	0	
72	Catholic Charities of Springfield	C	200 employees	Complaint	No	Diocese self-insured plan	0	0	
73	Catholic Charities of Springfield	C	2700 employees	Complaint	No	Self-funded welfare benefit plan but not sure if church plan grandfathered	0	0	
74	Chicago	N	1200 employees	Complaint	Yes	House of Worship, fully insured	2,700	2,700	
75	Diocese of Nashville	H	115 employees	Complaint	Yes	Website/news reports indicate recent drastic downsizing of workforce; students not counted because complaint does not allege a student plan	115	115	
76	Catholic Charities	N	16 employees	Website	employees; yes; students no		16	16	0
77	Aquinas College	N	75 employees	Complaint	Yes		75	75	
78	Gann Marquette	N	85 employees	Complaint	Yes		85	85	
79	MQA	N	50 employees	Complaint	Yes		50	50	
80	St. Mary Villa	N	23 employees	Complaint	No	Religious order	0	0	
81	Dominican Sisters	H				Diocese self-insured plan (court order 2013 WL 74240), and grandfathered			
82	Catholic Diocese of Peoria v. Sobellus, 1:12-cv-01276 JES-BGC (C.D. Ill. August 9, 2012)	H	Unknown		No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp.2d at 242.	0	0	
83	Archdiocese of New York	H	10,000 employees	Complaint	No	Catholic hospital self-insured plan	0	0	
84	ArchCare	C	4,000 employees	Complaint	No	Catholic hospital self-insured plan	0	0	
85	Catholic Health Services of Long Island	C	17,000 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp.2d at 242.	0	0	
86	The Diocese of Rockville Centre	H	2,000 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp.2d at 242.	0	0	
87	Monsignor Farel High School	C	73 employees	Website	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp.2d at 242.	0	0	
88	Cardinal Spellman High School	C	100 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp.2d at 242.	0	0	
89	CMA d/b/a Shell Point Retirement Center	C	1,247 employees	Form W-3 filing	Yes		1,247	1,247	
90	Alliance Community for Retirement Living	C	344 employees	Form W-3 filing	Yes		344	344	
91	Alliance Home of Carlisle	C	219 employees	Form W-3 filing	Yes		219	219	
92	Town and Country Manor	C	365 employees	Form W-3 filing	Yes		365	365	
93	Simpson University	C	815 employees	Complaint	employees; yes; students no	Complaint does not seek relief for any student plan	815	815	0
94	Christian & Missionary Alliance Foundation, Inc. No. 2:14-cv-00580 (M.D. Fla. Nos. 15-11437, 15-11635 (11th Cir.))	C	114 employees	Form W-3 filing: student enrollment: https://www.crown.edu/about/quick-facts/ ("nearly 1,300 students")	Yes	No claim was made for CEA plans, and no list of members beyond TBC and TIC.	1,275 students; 114 employees	114	1,275
95	Christian Employees Alliance 309 (D.N.D.)	C	Unknown		No	complaint does not mention student plan	0	0	
96	Christian Employees Alliance	C	249 employees	Form W-3 filing	employees; yes; students no		249	249	
97	Trinity Bible College	C	9 staff	Website	Yes		9	9	
98	Treasure Island College	C	5,300 students; 680 employees	Complaint	Yes		5,300 students; 680 employees	680	5,300
99	Colorado Christian University	C							
	Conestoga Wood Specialties Corp. (Individual operators of Conestoga Wood Specialties Corporation are the three other named plaintiffs)	C	950 employees	Complaint	Yes		950	950	

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Page 3

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669266

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A Case	B Plaintiffs	C Type For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)	D Number of Employees/Students	E Document employee number located within	F Are students/employees counted in final order?	G If not counted, explanation why	H Number counted towards final total	I Total employees (minus HOA/IA and SICPs)	J Total students at relevant universities
1. Diocese of Cheyenne v. Burwell, No. 2:14-cv-00021 (D. Wyo.), No. 14-8040 (10th Cir.)	Diocese of Cheyenne Catholic Charities		16 employees plus over 100 teachers	Complaint	No	Diocese self-insured plan	0	0	
100 St. Anthony School			6 employees	Complaint	No	Diocese self-insured plan	0	0	
101 St. Joseph's Home			41 employees	Complaint	No	Diocese self-insured plan	0	0	
102 JPHCS			130 orphans, 62 orphan children	Complaint	No	Diocese self-insured plan	0	0	
103 Wyoming Catholic College			20	Complaint	No	Diocese self-insured plan	0	0	
104 Diocese of Fort Wayne-South Bend Inc. v. Burwell, No. 1:12-cv-00159 (N.D. Ind.), No. 14-1431 (7th Cir.)	Diocese of Fort Wayne-South Bend Catholic Charities		32 employees	Complaint	No	Diocese self-insured plan, also self-insured church plan	0	0	0
105			2,741 employees	Complaint	No	Diocese self-insured plan	0	0	
106			39 employees	Complaint	No	Diocese self-insured plan	0	0	
107			310 employees	Complaint	Yes	Self-insured plan, but not sure if it is a church plan	310	310	
108	St. Anne Home		2,300 students, 413 employees	Complaint	employees; yes; students no	No student plan discussed; Employees are offered a self-insured health plan, but not sure if it is a church plan, so included	413	413	0
109	University of St. Francis		300 employees	Complaint	Yes	Self-insured plan, but not sure if it is a church plan	300	300	
110	Our Sunday Visitor		342 employees	Complaint	Yes		342	342	
111	Specialty Physicians								
112	Franciscan Alliance		18,000 employees	Complaint	Partial	All but 1,733 employees are on a church plan exempt from ERISA. See https://www.franciscanhealth.org/sites/default/files/2015/20employee%20benefit%20booklet.pdf (Only employees in Illinois are in BCBS plans and there are 1733 of those employees according to complaint)	1,733	1,733	
113	Dobson v. Burwell, No. 03-48-JNE-FLN (D. Minn. Nov. 11, 2013); Dobson v. Burwell, No. 13-12-cv-03526 (D. Colo.), No. 14-1233 (10th Cir. 2014)		32 employees	Complaint	Yes		32	32	
114	Dominio's Farms, Co., LLC v. Sebelius et al., No. 12-cv-15488 (E.D. Mich. Dec. 20, 2012)		28 employees	Complaint	Yes		28	28	
115	Dart College		89 employees	Complaint	Yes		89	89	
116	Coriaville University		1,400 students, 280 employees	Complaint	Yes		1,400 students, 280 employees	280	1,400
117	East Texas Baptist Univ. v. Burwell, No. 4:12-cv-03009 (S.D. Tex.), No. 14-20112 (5th Cir.)		2,933 students, 294 employees	Complaint	employees; yes; students no	No student plan discussed	294	294	0
118	East Texas Baptist University		2,589 students, 416 employees	Complaint	No	Self-insured church plan	0	0	0
119	Westminster Theological Seminary (Intervenor)		1,236 students, 283 employees	Complaint	Yes	complaint does not mention student plan	1,290 students, 283 employees	283	1,290
120	Eden Foods, Inc. v. Burwell, No. 13-1677 (6th Cir. June 28, 2013)		60 FT 65 PT employees, 639 students	Complaint in intervention	employees; yes; students no		125	125	0
121	Eternal Word Television Network, Inc. v. Burwell, No. 1:13-cv-00521 (S.D. Ala.), No. 14-12696 (11th Cir.)		128 employees	Complaint	Yes		128	128	
122	Relationship of Catholic University Students v. Burwell, No. 1:13-cv-03263-MSC-KMT (D. Colo. Apr. 23, 2014)		350 employees	Complaint	Yes		350	350	
123	Felt & Co., Inc. v. Burwell, No. 13-CV-2635 DWF/JRK (D. Minn. Nov. 8, 2013); Franciscan University v. Sebelius, 2:12-CV-440 (S.D. Ohio)		450 employees	Complaint	No	Case resolved on basis that plaintiff is integrated auxiliary	0	0	0
124	Geneva College v. Burwell, No. 2:12-cv-00207 (W.D. Pa.), Nos. 13-3536, 14-1374 (3rd Cir.)		4 employees	Website	Yes	Sued while grandfathered and then dropped student plan. With no additional suit, no apparent affect from rule.	4	4	
125	Seneca Hardwood Lumber		Unknown	Complaint	No		0	0	0
126	Freshway Foods		1,850 students, 350 employees	Complaint	Yes	Permanent injunction shields from previous rule	1,850 students, 350 employees	350	1,850
127	Grace College and Seminary		22 employees	Complaint	No		0	0	
128			340 employees	Complaint	Yes		340	340	
129			55 employees	Complaint	Yes		55	55	
130			2,700 students, 457 employees	Complaint	Yes		2,700 students, 457 employees	457	2,700
131			6,222 students, 856 employees	Complaint	Yes		6,222 students, 856 employees	856	6,222

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Page 4

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669267

Draft-For Discussion Purposes

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1. Grote Indus. LLC v. Burwell, No. 13-1077, 2013 WL 5960692 (7th Cir. Nov. 8, 2013), cert. denied sub nom. Burwell v. Grote, No. 13-937 (U.S. July 1, 2014);			1,148 employees	Complaint	Yes		1,148		
132. Hall v. Burwell, No. 013-cv-00295-JRT-LIB (D. Minn. Apr. 2, 2013);	Hart Electric HLI Hart		Approximately 50 employees	Complaint and online news reports	Yes		50		
133. Harnebover v. U.S. Dep't of Health and Human Servs., No. 1:13-cv-00253 (N.D. Ill. May 18, 2013);			54 employees (including contract)	Complaint	Yes		54		
134. Harnebover v. U.S. Dep't of Health and Human Servs., No. 1:13-cv-00253 (N.D. Ill. May 18, 2013);			7 employees	Complaint	Yes		7		
135. Harnebover v. U.S. Dep't of Health and Human Servs., No. 1:13-cv-00253 (N.D. Ill. May 18, 2013);			60 employees	Complaint	Yes		60		
136. Harnebover v. U.S. Dep't of Health and Human Servs., No. 1:13-cv-00253 (N.D. Ill. May 18, 2013);			13,240 employees	Complaint	Yes		13,240		
137. Hobby Lobby Stores, Inc. et al. v. Sebelius, et al., No. 12-345 (W.D. Okla. Oct. 2, 2012); Burwell v. Hobby Lobby Stores, Inc., No. 12-345 (W.D. Okla. Oct. 2, 2012); Burwell v. Hobby Lobby Stores, Inc., No. 12-345 (W.D. Okla. Oct. 2, 2012); Burwell v. Hobby Lobby Stores, Inc., No. 12-345 (W.D. Okla. Oct. 2, 2012);	Hobby Lobby Mandi		372 employees	Complaint	Yes		372		
138. Hobby Lobby Stores, Inc. et al. v. Sebelius, et al., No. 12-345 (W.D. Okla. Oct. 2, 2012); Burwell v. Hobby Lobby Stores, Inc., No. 12-345 (W.D. Okla. Oct. 2, 2012);			150 employees	Complaint	Yes		150		
139. Hobby Lobby Stores, Inc. et al. v. Sebelius, et al., No. 12-345 (W.D. Okla. Oct. 2, 2012); Burwell v. Hobby Lobby Stores, Inc., No. 12-345 (W.D. Okla. Oct. 2, 2012);			70 employees	Complaint	Yes		70		
140. Hobby Lobby Stores, Inc. et al. v. Sebelius, et al., No. 12-345 (W.D. Okla. Oct. 2, 2012); Burwell v. Hobby Lobby Stores, Inc., No. 12-345 (W.D. Okla. Oct. 2, 2012);			108 employees	Form W-3 filing	Yes		108		
141. Insight for Living Ministries v. Burwell, No. 4:14-cv-00031-RU (W.D. Mich. Sept. 30, 2013);			421 employees (including Lili Johnson)	Complaint	Yes		421		
142. Insight for Living Ministries v. Burwell, No. 4:14-cv-00031-RU (W.D. Mich. Sept. 30, 2013);			90 employees	Complaint	Yes		90		
143. Kurt v. Burwell, No. 12-5841, 2013 WL 5960692 (7th Cir. Nov. 8, 2013), cert. denied No. 13-937 (U.S. July 1, 2014);	Legatus		69 employees	Complaint	Yes		69		
144. Legatus v. Burwell, No. 2:12-cv-12061-RHC-MH (E.D. Mich. Dec. 20, 2013)	Legatus		170 employees	Complaint	Yes		170		
145. Lindsay v. U.S. Dep't of Health and Human Servs., No. 13-cv-1210 (N.D. Ill. Mar. 20, 2013);	Weigantz Supply Company, W&P Management LLC, and subsidiaries		70 employees	Complaint	Yes		70		
146. Little Sisters of the Poor Home for the Aged v. Burwell, No. 1:13-cv-2611 (D. Colo.), No. 13-1540 (10th Cir.)	Christian Brothers Employee Benefit Trust (Little Sisters uses Christian Brothers Employee Benefit Trust, and Christian Brothers Services is the TPA for the Christian Brothers Employee Benefit Trust)								
147. Louisiana Coll. v. Burwell, No. 1:12-cv-00463 (W.D. La.), No. 14-31167 (5th Cir.)			5,000 employees	Complaint	No	Self-insured church plan	0	0	
148. March for Life v. Burwell, No. 1:14-cv-1149 (D.D.C.), No. 15-5301 (D.C. Cir.)			1,450 students, 260 employees	Complaint	No	Self-insured church plan	0	0	0
149. Media Research Center v. Sebelius, No. 1:14-cv-379 (E.D. Virginia)			2 employees covered in plan less than 10 overall		No	All employees must do oppose the coverage; therefore not counting as affected by rule	0	0	
150. Messino Mgmt. Co. v. Burwell, No. 13-1944 (8th Cir. July 9, 2014)			114 employees	Complaint	Yes		114		114
151. Michigan Catholic Conf. v. Burwell, No. 1:13-cv-1247 (W.D. Mich.), No. 13-2723 (6th Cir.)	Michigan Catholic Charities		110 employees	Complaint	Yes		110		110
152. Midwest Fastener Corp. v. Burwell, No. 1:13-cv-01337-ESH (D.D.C. Oct. 16, 2013);	Catholic Charities		6,429 employees	Complaint	No	Self-insured church plan	0	0	0
153. MK Chambers Co. v. Dep't of Health and Human Servs., No. 13-cv-11379 (E.D. Mich. Nov. 21, 2014)			187 employees	Complaint	Yes		187		187
154. Naigle Christopher, et al. v. Kathleen Sebelius, et al.; No. 2:13-cv-12036-VAR-DRG (E.D. Mich. May 10, 2013) (AKA "M&N Plastics")			106 employees	Business profile on manta.org	Yes		106		106
155. Newland v. Burwell, 881 F. Supp. 2d 1287 (D. Colo. July 27, 2012), affirmed on appeal, No. 12-1380 (10th Cir. Oct. 3, 2013)			109 employees	Complaint	Yes		109		109
156. O'Brien v. U.S. Dep't of Health & Human Servs., No. 12-3357 (8th Cir. Nov. 28, 2012)			Unknown	Complaint	No	Permanent injunction	0		
157. Ozanga v. Burwell, No. 1:13-cv-3292 (N.D. Ill.), No. 15-3648 (7th Cir.)			87 employees	Complaint	Yes		87		87
158. Persico v. Burwell, No. 1:13-cv-0303 (W.D. Pa.), Nos. 14-1376 (3d Cir.);	Catholic Diocese of Erie		675+ employees	Complaint	Partial	Only 110 obtain insurance through the plan that would be affected by the exemption. This is upscaled to 110/65%=178	178		178
159. St. Martin Center	St. Martin Center		1,500 employees	Complaint	No	Diocese self-insured plan	0	0	0
160. Formerly Most Reverend Donald W. Trautman, Bishop of the Roman Catholic Diocese of Erie, et al., v. Sebelius, No. 1:12-cv-00125-SPB (W.D. Pa. May 30, 2013)	Prince of Peace Center		61 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	0
161. School of the Holy Spirit, No. 1:13-cv-01261 (D.D.C.), No. 13-5368 (D.C. Cir.)	Erie Catholic Preparatory School		20 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	0
162. School of the Holy Spirit, No. 1:13-cv-01261 (D.D.C.), No. 13-5368 (D.C. Cir.)			80 employees	Complaint	No	Diocese self-insured plan	0	0	0
163. Priests for Life, No. 1:13-cv-01261 (D.D.C.), No. 13-5368 (D.C. Cir.)			60 employees	Website	Yes		60		60

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Page 5

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669268

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A	B	C	D	E	F	G	H	I	J
Case	Plaintiffs	Type For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number towards final total	Total employees (minus How/IA and SICPs)	Total students at relevant universities
1. Randy Reed Auto, Inc. v. Burwell, No. 5:13-cv-6117-SLD (W.D. Mo. Dec. 3, 2013);			approximately 179 employees	Complaint	Yes	Self insured church plan	179	179	
165. Roaching South Int'l, Inc. v. Burwell, No. 5:13-cv-01092 (W.D. Okla.), No. 14-6028 (10th Cir.)			78,000 participants (pastors, employees, and their families)	Complaint	No	All employees must do opt-out coverage; therefore not counting as affected by rule	0	0	
166. Real Alternatives, Inc. v. Burwell, No. 1:15-cv-105 (M.D. Pa.), No. 16-1275 (3d Cir.)			3 employees	Complaint	No	All employees must do opt-out coverage; therefore not counting as affected by rule	0	0	
167. Right to Life of Michigan v. Kathleen Sebelius; No. 1:13-cv-01202 (W.D. Mich. Nov. 22, 2013).			43 employees	Complaint	No		0	0	
168. Roman Catholic Archbishop of Washington v. Burwell, No. 1:13-cv-01441 (D.D.C.), Nos. 13-5571, 14-5021 (D.C. Cir.)	Catholic University		7,000 students, 1,766 employees	Complain	Yes		7,000 students, 1,766 employees	1,766	7,000
169. Archdiocese of Washington			21,100 eligible employees, 1,200 teachers/employees	Complaint	No	Diocese self-insured plan	0	0	
170. Thomas Aquinas College			370 students, 78 eligible employees	Complaint	No	Church plan and complaint does not state that it offers student insurance	0	0	0
171. Gonzaga University			119 employees	Complaint	No	Diocese self-insured plan	0	0	
172. Archbishop Carroll			70 employees	Complaint	No	Diocese self-insured plan	0	0	
173. Diocese of Des Moines			51 employees	Complaint	No	Diocese self-insured plan	0	0	
174. Catholic Information Center			9 employees	Complaint	No	Diocese self-insured plan	0	0	
175. Mary of Nazareth			44 employees	Complaint	No	Diocese self-insured plan	0	0	
176. Catholic Charities			890 employees	Complaint	No	Diocese self-insured plan	0	0	
177. Victory Housing			184 employees	Complaint	No	Diocese self-insured plan	0	0	
178. Roman Catholic Archdiocese of Atlanta v. Burwell, No. 1:12-cv-03469 (N.D. Ga.), Nos. 14-12890, 14-13239 (11th Cir.)			9,800 students, 4,200 employees	Complaint	No	Diocese self-insured plan	0	0	
179. Catholic Charities			75 employees	Complaint	No	Diocese self-insured plan	0	0	
180. CIENG			200 employees	Complaint	No	Diocese self-insured plan	0	0	
181. Diocese of Savannah			5,000 students; hundreds of employees	Complaint	No	Diocese self-insured plan	0	0	
182. Roman Catholic Diocese of Dallas v. Sebelius, No. 3:12-cv-01569-B (N.D. Tex.)			900 teachers/staff, 100+ employees	Complaint	No	Diocese self-insured plan	0	0	
183. School of the Ozarks v. Rightchoice Managed Care, Inc., No. 6:13-cv-03157 (W.D. Mo.), No. 15-1330 (8th Cir.)			1,442 students, 601 employees	Students - online employees - Form w-3 Filing	Employees only	Complaint does not say they offer a student plan	601	601	
184. Sharpe Holdings, Inc. v. Burwell, No. 2:12-cv-92 (E.D. Mo.) and CNS Int'l Ministries, No. 14-1507 (8th Cir.)	Sharpe Ozark		50 employees	2dam complaint and Linked in	Yes		50	50	
185. CNS International Ministries			51 employees	2dam complaint and Linked in	Yes		51	51	
186. NIS Financial			204 employees	Form W-3 filing	Yes		204	204	
187. CNS Corp			49 employees	2dam Complaint	Yes		49	49	
188. Heartland Christian College			12 employees	2dam Complaint	Yes	Complaint does not say they offer a student plan	49	49	
189. Sioux Chief Mfg. Co. v. Burwell, No. 13-0036-CV-W ODS (W.D. Mo. Feb. 28, 2013);			370 employees	Form W-3 filing	Employees only		12	12	0
190. SMA, LLC v. Burwell, No. 13-cv-01375-ADM-LIB (D. Minn. July 8, 2013);			35 employees	Complaint	Yes		370	370	
191. Southern Nazarene Univ. v. Burwell, No. 5:13-cv-1015 (W.D. Okla.), No. 14-6026 (10th Cir.)	Southern Nazarene University		35 employees	Complaint	Yes		35	35	
192. OK Wesleyan University			2,100 students, 505 employees	Complaint	Yes		2,100 students, 505 employees	505	2,100
193. OK Baptist University			1,228 students, 557 employees	Complaint	Yes	Complaint does not say they offer a student plan	557	557	0
194. Mid America Christian University			1,900 students, 328 employees	Complaint	Yes		1,900 students, 328 employees	328	1,900
195. Encampment Develop. Design & Construct, LLC			1,447 students, 298 employees	Complaint	Yes	Mid America Christian Univ. is on Guidestones, a self-insured church plan	0	0	0
196. Stewart v. Burwell, No. 1:13-cv-01879 (D.D.C. Apr. 3, 2014);			43 employees	Complaint	No		43	43	
197. Suncoast Electric, Inc. v. Burwell, No. 14-00830-PJS-JIG (D. Minn. April 20, 2014);			19 employees	Business profile on manua.org	Yes		19	19	
198. The C.W. Zantman Co., Inc. v. Burwell, No. 1:13-cv-01611 (D.D.C. Nov. 27, 2013);			350 employees	Complaint	Yes		350	350	
199. The Glawell College v. Sebelius, No. 3:12-cv-04404-N (N.D. Tex.)			322 students, 50 employees	Complaint	Employees only	Complaint does not say they offer a student plan	50	50	
200. The QC Grp., Inc. v. Burwell, No. 0:13-cv-01726-JRT-SER (D. Minn. Sept. 11, 2013);			62 employees	Complaint	Yes		62	62	
201. Thomas G. Weisbe v. Kathleen Sebelius; No. 12-cv-23820-Graham Goodman (S.D. Fla. Nov. 7, 2012)	Archdiocese of Miami Catholic Health Services		Unknown	Complaint	Yes	House of worship	2,000	2,000	0
202. Catholic Hospice			610 employees	Form W-3 filing	Yes		610	610	610

for DOJ

Page 6

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Draft-For Discussion Purposes

A Case	B Plaintiffs	C Type: For-profit (F), Nonprofit (N), House of Worship or IA (H), Church Plan (C), Pro-life (P), Grandfathered (G)	D Number of Employees/Students	E Document employee number located within	F Are students/employees counted in final total?	G If not counted, explanation why	H Number counted towards final total	I Total employees (minus How/IA and SICPs)	J Total students at relevant universities
1									
205	Tom & Blank Constr. v. Burwell, No. 1:12-cv-00325 ID-RRC (N.D. Ind. Apr. 1, 2013);	St. Thomas University	Unknown		No	Lawsuit mentions St. Thomas University but asserts no claims for its health plans	0	0	0
206	Trillion, Inc. v. Burwell, No. 1:13-cv-1207 (D.D.C.)		60 employees	Complaint	Yes		60	60	
207	Tyndale House Publishers, Inc. v. Burwell, 904 F. Supp. 2d 106 (D.D.C. Nov. 16, 2012);		469 employees	Complaint	Yes		469	469	
208	Union University v. Burwell, No. 1:14-cv-1075 (W.D. Tenn.)		260 employees	Complaint	Yes		260	260	
209	Univ. of Dallas v. Burwell, No. 4:12-cv-00314 (N.D. Tex.)	Roman Catholic Diocese of Fort Worth	2,829 students, 1,116 employees	Students - online employees - Form w/3 Filing	Employees only	Complaint does not say they offer a student plan	1,116 employees	1,116	0
210	No. 14-10241 (5th Cir.), Nos. 14-10661 (5th Cir.)		6,500 students, 2,000 employees	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust - a self-insured church plan	0	0	
211		University of Dallas	2,600 students, 725 employees	Complaint	Yes		2,600 students, 725 employees	725	2,600
212		Catholic Charities	332 employees	Complaint	Yes		332	332	
213		Our Lady Of Victory Catholic School	22 employees	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust - a self-insured church plan	0	0	
214	Univ. of Notre Dame v. Burwell, No. 3:13-cv-1276 (N.D. Ind.), No. 13-3853 (7th Cir.)		11,500 students, 5,000 employees	Complaint	yes		11,500 students, 5,000 employees	5,000	11,500
215	Valley Forge Christian College of the Assemblies of God v. Burwell, No. 14-4622 (E.D. Pa. Aug. 14, 2014)		Unknown	Complaint	No	Plaintiff voluntarily dismissed suit; our understanding is they were satisfied with previous accommodation	0	0	0
216	Weingartz Supply Co. v. Burwell, No. 2:12-cv-12661 (E.D. Mich.), No. 14-1183 (6th Cir.)		170 employees	DC Ruling	Yes		170	170	
217	Wheaton College v. Burwell, No. 1:13-cv-008910 (N.D. Ill.), No. 14-2386 (7th Cir.)		870 Employees	Complaint	Yes	Note: Students not counted because complaint states that Wheaton dropped student coverage	870	870	0
218	Williams v. Burwell, No. 1:13-cv-01699 (D.D.C. Nov. 19, 2013);		3 employees	Complaint	Yes		3	3	
219	Willis Law v. Burwell, No. 1:13-cv-01124-CKK (D.D.C. Aug. 23, 2013);		15 employees	Complaint	Yes		15	15	
220	Yep v. Sobelus, No. 1:12-cv-6756 (N.D. Ill.), Trinite Health Group, Inc. v. Burwell, No. 1:12-cv-06756 (N.D. Ill.); No. 13-1478 (7th Cir.)		4 employees	Website	Yes		4	4	
221	Zubik v. Burwell, No. 2:13-cv-1459 (W.D. Pa.), Nos. 14-1377 (3d Cir.)	Diocese Catholic Charities	140+ full-time employees 115 employees	Complaint Complaint	No No	Diocese self-insured plan Diocese self-insured plan Diocese self-insured plan. Cemeteries was covered by the diocese's previous self-insured plan the Catholic Employers Benefits Plan; the new complaint says that CEBS was converted to the Catholic Benefits Trust, and Cemeteries are omitted as co-plaintiffs.	0 0 0	0 0 0	
223		Catholic Cemeteries	207 employees	Complaint	No		0	0	
224						Total	Total	64,352	46,737 7% of students use university sponsored plans http://www.gao .gov/new_items d08389.pdf
225									
226									
227						Total	Total	64,352 employees in affected plans	3,272 students in affected plans

for DOL

Page 7

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5												
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Eligible Organization Information		Plaintiff in litigation? (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
7	Redacted	8/26/2014	E-mail	Commis-AI Ion Corp and Commis Illinois Inc.	Redacted	Other	No	Plan B Ella Mirena Copper IUDs	Redacted	Other	self-insured	Redacted
8		9/9/2014	E-mail	Loyola University		Non-profit	No	All		Other	Fully insured	
9										Other	Fully insured	
10										Other	Fully insured	
11		9/10/2014	E-mail	Valley Forge Christian College		Non-profit	Yes	Upistal (aka E la) Levocongestrel (aka Plan B Plan B One-Step Next Choice) Intrauterine Devices (of any type) Abortion services except to save the life of the mother		Other	Fully insured	
12						Non-profit	No	All		Other	Fully insured	
13		9/19/2014	E-mail	Continuant		Other	No	Emergency Contraceptives & IUD's		Other	Fully insured	
14		10/ / 2014	E-mail	Sisters of the Order of St. Dominic of Grand Rapids (Dominican Sisters)		Other	No	"All abortifacient coverages such as but not limited to morning after and week after services"		Other	Both	
15										Other	Both self-insured	
16		10/6/2014	E-mail	Holy Ghost Preparatory School		Non-profit	No	All		Other	Fully insured	
17												
18												
19		10/9/2014	Mail	The Catholic Diocese of Memphis in Tennessee		Non-profit				Church Plan	self-insured	
20												
21		10/9/2014	Mail	Bethany University		Non-profit		All		Other	self-insured	
22										Other	self-insured	
23										Other	self-insured	
24		10/10/2014	E-mail	Birgman and Son Lumber Inc. 1195 Creek Mountain Rd Kramer PA 17833		Other		Plan B Ella Mirena Paraguard		Other	Fully insured	
25												

Notifications

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1											
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4											
5	Standard Provider Information										
6	Contact Information for Owner (enter N/A if none)	Name of TPA (enter N/A if none)	Contact Information for TPA (enter N/A if none)	Original Information for TPA (enter N/A if none)	For updated information, enter the effective date of the update	For updated information, enter the effective date of the update	For updated information, enter the effective date of the update	For updated information, enter the effective date of the update	For updated information, enter the effective date of the update	For updated information, enter the effective date of the update	For updated information, enter the effective date of the update
7	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
8	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
9	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
10	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
11	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
12	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
13	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
14	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
15	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
16	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
17	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
18	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
19	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
20	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
21	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
22	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
23	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
24	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
25	Redacted	Redacted	Redacted	Original	N/A	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted

Notifications

Notifications

Notifications

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6. Tracking number	Date notification received	Responsible email address	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (Yes or No) (See instructions in Section 1)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or other?	Name of insurer (See instructions in Section 1)
39	11/26/2014	Email	J.E. Dunn Construction Group Inc.	Redacted	Other		- Plan B (non-coverage) and its generic equivalents - also (injectable version) - Standard (copper IUD) - Mirena and Skyla (non-coverage) remaining (UDs)	Redacted	Other	Self-insured	Redacted
40									Other	Self-insured	
41	12/5/2014	Email	Green in College		Non-profit		Plan B, Ella and a IUDs		Other	self-insured	
42									Other	self-insured	
43	12/9/2014	Email	Convent Presbyterian Church		Non-profit				Other	self-insured	
44											
45	12/17/2014	Email	Trinity Schools, Inc. DB/A Trinity School at River Ridge		Non-profit	No			Other?	Fully insured?	
46	12/17/2014	Email	People of Peace Minnesota, Inc.		Non-profit	No			Other?	Fully insured?	
47							1. If Plan B (non-coverage) and its generic equivalents are not provided, the health plan must provide access to abortion-including products and related counseling services within the week after all contraceptive services, hormonal intrauterine devices, as well as any other drug, device, procedure or mechanism which has the purpose or effect of preventing pregnancy, or which may be used further by inhibiting or terminating its attachment to the uterus.		Other	self-insured	
48	1/9/2015	Ms I	Perisoft LLC		Other		"All contraceptive medications and procedures (barbition abortions, in, contraceptive devices, etc.)"		Other	Fully insured	
49	1/12/2015	Ms I	DMS Companies, Inc.		Other		All		Other	self-insured	
50	1/26/2015	Email	Illinois Baptist Children's Home and Family Services		Non-profit	No					
51	2/1/2015	Ms I	Chert Nearene University		Non-profit	No	"The health Plan will not provide pay for and/or facilitate access to abortion-including products and related counseling services within the week after all contraceptive services, hormonal intrauterine devices, as well as any other drug, device, procedure or mechanism which has the purpose or effect of preventing pregnancy, or which may be used further by inhibiting or terminating its attachment to the uterus." "The health Plan will require a prior authorization for the use of the medications for non-abortifacient purposes." Plan B will be non-covered."		Other	Fully insured	
52											
53	4/15/2015	Ms I	St. Raphael Health Plan - all participating employers (105-4)		Non-profit		All		Church Plan	self-insured	

Notifications

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S	M	N	O	P	Q	R	S	T	U	V	W
Schedule 1 - Provider Information											
6.	Contact information for insurer (enter N/A if not applicable)	Name of PPA (enter N/A if not applicable)	Contact information for PPA (enter N/A if not applicable)	Original information or updated information (enter N/A if not applicable)	For updated information, date the information is updated (enter N/A if not applicable)	For fully insured plans, date letter sent to insurer (enter N/A if not applicable)	For self-insured plans, date letter sent to insurer (enter N/A if not applicable)	For for-profit organizations, date letter sent to organization (enter N/A if not applicable)	For non-profit organizations, date letter sent to organization (enter N/A if not applicable)	Notes	
39	Redacted	Redacted	Redacted	Original	N/A						
40				Original	N/A						
41				Original	N/A						
42				Original	N/A						
43				Original	N/A						
44											
45					N/A						
46					N/A						
47				Updated	12/1/2015						
48				Original	N/A						
49				Original	N/A						
50				Original	N/A						
51				Original	N/A						
52				Original	N/A						
53				Original	N/A						
54				Original	N/A						

Notifications

A	B	C	D	E	F	G	H	I	J	K	L
Tracking number	Date notification received	Received via mail or email?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (If yes, provide instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of insurer (enter N/A if none)
5.1	5/4/2015	Mail	Society of the Precious Blood	Redacted	Non-profit		All	Redacted	Other	Fully insured	Redacted
5.2	5/22/2015	E-mail	Michael James Sales Tax Solutions, LLC	Redacted	Other		"Any and all abortions"	Redacted	Other	Fully insured	Redacted
5.3	07/08/15	Litigation (Zabik v. Burwell)	THE ROMAN CATHOLIC DIOCESE OF PITTSBURGH (* exempt)	Redacted	Non-profit	Yes	All	Redacted	Church Plan	self-insured	Redacted
5.4	07/08/15	Litigation (Zabik v. Burwell)	THE ROMAN CATHOLIC DIOCESE OF ERIE (* exempt)	Redacted	Non-profit	Yes	All	Redacted	Church Plan	self-insured	Redacted
5.5	07/08/15	Litigation (Zabik v. Burwell)	CATHOLIC CHARITIES OF THE DIOCESE OF PITTSBURGH, INC.	Redacted	Non-profit	Yes	All	Redacted	Church Plan	self-insured	Redacted
5.6	07/08/15	Litigation (Zabik v. Burwell)	THE CATHOLIC CEMETERIES ASSOCIATION OF THE DIOCESE OF PITTSBURGH	Redacted	Non-profit	Yes	All	Redacted	Church Plan	self-insured	Redacted
5.7	07/08/15	Litigation (Zabik v. Burwell)	ST. MARTIN CENTER, INC.	Redacted	Non-profit	Yes	All	Redacted	Church Plan	self-insured	Redacted
5.8	07/08/15	Litigation (Zabik v. Burwell)	PRINCE OF PEACE CENTER, INC.	Redacted	Non-profit	Yes	All	Redacted	Church Plan	self-insured	Redacted
5.9	07/08/15	Litigation (Zabik v. Burwell)	ERIE CATHOLIC PREPARATORY SCHOOL	Redacted	Non-profit	Yes	All	Redacted	Church Plan	self-insured	Redacted
6.0	8/1/2015	Mail	Oral Roberts University	Redacted	Non-profit		EC Plan B One-step (the morning after pill); EBA Uteristal Accutane (the week after pill); copper intrauterine devices; device procedure or mechanism which has the purpose or effect of preventing an already fertilized egg from developing further by inhibiting or terminating its attachment to the uterus"	Redacted	Student	Fully insured	Redacted
6.1											
6.2											
6.3											

Notifications

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1	M	N	O	P	Q	R	S	T	U	V	W
2	Service Provider Information								Action Taken		
3	Contact information for issuer (enter N/A if none)	Name of TPA (enter N/A if none)	Contact information for TPA (enter N/A if none)	Original information submitted to the issuer (enter N/A if none)	For updated information, date the information became effective	For updated information, date the information became effective	For insured plans, date the information became effective by PHS	For self-insured plans, date the information became effective by PHS	For for-profit organizations, date letter sent to organization (enter N/A if above)	Notes	
4	Redacted		Redacted	Original	N/A						
5	Redacted		Redacted	Original	N/A						
6	Redacted		Redacted	Original	N/A						
7	Redacted		Redacted	Original	N/A						
8	Redacted		Redacted	Original	N/A						
9	Redacted		Redacted	Original	N/A						
10	Redacted		Redacted	Original	N/A						
11	Redacted		Redacted	Original	N/A						
12	Redacted		Redacted	Original	N/A						
13	Redacted		Redacted	Original	N/A						

5	A	B	C	D	E		F	G	H	I	J	K	L	
					Eligible Organization Information						Plan Information			
						Contact information for eligible organization	Type of organization (Non-profit or other)	Parent litigation? (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)	
6	Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Redacted									Redacted
64		8/2 /2015	E-mail	Cummins-Allison Corp and Cummins Illinois Inc	Redacted									Redacted
65		9/25/2015	E-mail	Wiegartz Supply Co. Inc. & W & P Management LLC	Redacted									Redacted
66		10/14/2015	Ma i	Carolyn's Place Inc.	Redacted									Redacted
67		10/14/2015	Ma i	Dakota Tube Inc	Redacted									Redacted
68		10/28/2015	Ma i	Tyndale House Publishers Inc.	Redacted									Redacted
69		10/29/2015	E-mail	Electrolock Inc. Dunstone Co. Inc. and Stone River Mgmt Co. LLC	Redacted									Redacted
70		11/19/2015	Ma i	Management Analysis and Utilization Inc.	Redacted									Redacted
71		12/17/2015	SWIFT	Conestoga Wood Specialties Corp. Conestoga Transportation Inc. Phone: 717-445-6701	Redacted									Redacted
72		12/2 /2015	E-mail	St. Joseph's Abby (MOA, Chiropractic, Acupuncture) Callican Abby of Spencer	Redacted									Redacted
73		12/2 /2015	Ma i	Dakota Tube Inc.	Redacted									Redacted
74		1/28/2016	Ma i	Community Foundation of Northwest Indiana Inc. St. Mary Medical Center St. Catherine Hospital	Redacted									Redacted
75		2/2 /2016	E-mail	Miller Contracting Services Inc.	Redacted									Redacted
76		3/3/2016	E-mail	Earth Sun Moon Trading company Inc	Redacted									Redacted
77					Redacted									Redacted
78					Redacted									Redacted

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	Service Provider Information		Contact information for TPA (enter N/A if none)	Original information (date the information was received)	For updated information, date the information is effective	For updated information, date the information is effective	For self-insured plans, date the information is effective	For self-insured plans, date the information is effective	Action Taken	Notes	
	Contact information for issuer (enter N/A if none)	Name of TPA (enter N/A if none)									
6	Redacted	Redacted	Redacted	Original	N/A						
61				Original	N/A						
62				Original	N/A						
63				Original	N/A						
64											
65				Original	N/A						
66				Original	N/A						
67											
68				Original	N/A						
69				Original	N/A						
70				Original	N/A						
71				Original	N/A						
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78				Original	N/A						

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Tracking number	Date notification received	Received via mail or email?	Name of eligible organization	Context information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (Instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Other)	Fully insured, self-insured or both?	Name of insurer (enter N/A if none)
6.	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
79.	3/7/2016	E-mail	Lauritsens Sales		Other		All		Other	Fully insured	
80.			Continuum Health Partnerships Inc.								
81.	3/24/2016	E-mail	Continuum Health Management, LLC		Other		Abortion causing drugs, devices and sterilizations, patient education and counseling for all women with reproductive capacity.		Other	self-insured	
82.			Mountain States Health Properties, LLC								
83.	3/25/2016	E-Mail	Fresh Unlimited, Inc.		Other		All		Other	Fully insured	
84.											
85.	4/1/2016	E-mail	Sarkis Tarian, Inc.		Other		All		Other	Fully insured	
86.											
87.	7/19/2016	E-Mail	Mexino Management Company			Yes			Other	self-insured	
88.			Mexino Southwest, LLC								
89.			Mexino Enterprises Inc.								
90.			Mexino Properties Company, LLC								
91.			Mexino Dewatering Inc.								
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Notifications

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6.	Tracking number	Date notification received	Received via mail or email?	Name of eligible organization	Context information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of insurer (enter N/A if none)
105	Redacted	7/26/2016	Utilization: EBU 5th Circuit Court 4:12-cv-3009	East Texas Baptist University (employee)	Redacted		Yes	"abortion-inducing drugs" and related services "NOT" including contraceptives (comp. ¶ 128)	Redacted	Other	self-insured	Redacted
106				Houston Baptist Westminister			Yes				self-insured	
107				Roman Catholic Diocese of Fort Worth* (Exempt)		Non-profit	Yes	"abortion-inducing drugs," sterilization and contraception		Church Plan	self-insured	
108				University of Dallas (employee)			Yes	"abortion-inducing drugs" and sterilization			self-insured	
109		7/26/2016	Utilization: University of Dallas 5th Circuit Court 4:12-cv-314	University of Dallas (student)			Yes	"abortion-inducing drugs," sterilization and contraception (prescribed to treat a medical condition only not to prevent pregnancy)		Student	Fully insured	
110				Catholic Charities of Fort Worth			Yes	abortion-inducing drugs, sterilization and contraception			Fully insured	
111				Agnes College, Nashville								
112				Group Home, Inc.								
113				Catholic Charities of Tennessee			Yes	"abortion-inducing products," sterilization and contraception			Fully insured	
114		7/26/2016	Utilization: Catholic Diocese of Nashville 5th Circuit Court 5:13-cv-01393	The Catholic Diocese of Nashville (Exempt)								
115				Dominican Sisters of St. Cecilia* (Exempt)								
116				Mary Queen of Angels								
117				St. Mary's V.I. Inc.			Yes	contraception and sterilization			self-insured	
118		7/26/2016	McC 6th Circuit Court 1:13-cv-01247	Catholic Family Services (aka Catholic Charities of Kalamazoo)			Yes	"abortion-inducing products," sterilization and contraception			Self-insured	
119				McNigan Catholic Conference* (Exempt)			Yes	"abortion-inducing products," sterilization and contraception			Self-insured	
120				Catholic Charities of Ft. Wayne			Yes	"abortion-inducing products," sterilization and contraception			Both	
121				Diocese of Ft. Wayne* (Exempt)			Yes	"abortion-inducing products," sterilization and contraception			Self-insured	
122				Franciscan Alliance			Yes	"abortion-inducing products," sterilization and contraception			Both	
123			Utilization: Catholic Charities of Ft. Wayne 7th Circuit Court 1:12-cv-00159-JD	Our Sunday Visitor			Yes	"abortion-inducing products," sterilization and contraception			Self-insured	
124		7/26/2016	RBC	Specialty Physicians of Illinois			Yes	"abortion-inducing products," sterilization and contraception			Fully insured	
125				St. Anne Home			Yes	"abortion-inducing products," sterilization and contraception			Self-insured	
126				University of St. Francis			Yes	"abortion-inducing products," sterilization and contraception			Self-insured	
127												

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Tracking number	Date notification received	Received via mail or e-mail?	Name of eligible organization	Eligible Organization Information Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (Instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Other)	Fully insured, self-insured or both?	Name of insurer (enter N/A if none)
128	7/26/2016	litigation: Grace Schools 7/26/2016 3:12-cv-00459-JD-CAN	Biola University (employee)	Redacted		Yes	"abortion-inducing drugs, like ella and Plan B" but not other contraceptives	Redacted		Fully insured	Redacted
129			Biola University (student)			Yes	"abortion-inducing drugs, like ella and Plan B" but not other contraceptives		Student	Fully insured	
130			Grace Schools (employee)			Yes	"abortifacient drugs" but not all contraceptives			Self-insured	
131			Grace Schools (student)			Yes	"abortifacient drugs" but not all contraceptives		Student	Fully insured	
132	7/26/2016	litigation: 8th Circuit Court 2:12-cv-00092	CMS International Ministries (leading company for other insurance providers) Inc. Oak Park Nat'l Life Ins. Co. and N.J.S. Financial Services Inc.)			Yes	Plan B ella Copper IUDs			Self-insured	
133			Heartland Christian Co. Inc.			Yes	Plan B ella Copper IUDs			Self-insured	
134	7/26/2016	litigation: Dorot 8th Circuit Court 5:15-cv-01280	Cornerstone University			Yes	"post-coital" emergency contraceptives" such as "ella Plan B and IUDs"			Fully insured	
135			Dorot College (employee)							Self-insured	
136			Dorot College (student)						Student	Fully insured	
137	7/26/2016	litigation: Little Sisters of the Poor 8th Circuit Court No. 13-1540 (10th Cir) Appeal No. 1:13-CV-02611 (D. Co.)	Little Sisters of the Poor Baltimore, Inc. Little Sisters of the Poor Denver, Colorado ("Little Sisters of Denver")		Non-profit	Yes	"sterilization, contraceptives and drugs that cause abortions," "contraceptives about folic acid, sterilizations, and related education and counseling."			self-insured	
138	7/26/2016	litigation: Reaching Souls	Reaching Souls		Non-profit	Yes	ella Plan B Plan B one-step Next Choice Copper IUDs, W/Regimen		Church Plan	self-insured	
139			Truett-McConnell College								
140			Mid-America Christian				"contraceptives, abortifacients (such as Plan B and e la) and related counseling to their employees and students."			self-insured	
141			Oklahoma Baptist (employee)						Student	Fully insured	
142			Oklahoma Baptist (student)							Fully insured	
143	7/26/2016	litigation: 8th Circuit Court No. 14-6026 (10th Cir) Appeal No. 5:15-cv-01054 (10th Cir)	Oklahoma Wesleyan			Yes	Plan B ella and IUDs			Fully insured	
144			Southern Nazarene University (employee)				"contraceptives, abortifacients (such as Plan B and e la) and related counseling to their employees and students."			Partially self-insured. Insured for claims over \$100,000	
145											

1	M	N	O	P	Q	R	S	T	U	V	W
2	Service Provider Information	Name of TPA (enter N/A if none)	Contact information for TPA (enter N/A if none)	Original information submitted to the TPA (enter N/A if none)	For updated information, date the information became effective	For updated information, date the summary of changes	For is it insured plans, date reflected to user by PHS	For self-insured plans, date notification forwarded to DOL	Action Taken For for-profit organizations, date letter sent to organization (if above)	Notes	
3	Redacted	Redacted	Redacted	Original	N/A	Redacted					
4				Original	N/A						
5				Original	N/A						
6				Original	N/A						
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Tracking number	Date notification received	Received via mail or email?	Name of eligible organization	Eligible Organization Information	Type of organization (Non-profit or other)	Plaintiff in litigation? (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Other)	Fully insured, self-insured or both?	Name of insurer (enter N/A if none)
140	7/26/2016	Litigation: Plaintiff: US 1:13-cv-01261	Southern Nazarene University (student)	Redacted		Yes	"contraception, sterilization, [and] abortifacient"	Redacted	Student	Fully insured	Redacted
141			Priests for Life							Fully insured	
142			Archdiocese of Washington (Plaintiff in litigation with Catholic Archdiocese of Washington, D.C., and the Archdiocese of Washington)* (exempt)							self-insured	
143			Catholic Charities of the Archdiocese of Washington, Inc.								
144			Catholic Information Center, Inc.								
145			The Catholic University of America							Fully insured	
146	7/26/2016	Litigation: Plaintiff: US 1:13-cv-01441	The Catholic University of America (student)			Yes	abortion-inducing products, contraception or sterilization		Student	Fully insured	
147			The Consortium of Catholic Academies of the Archdiocese of Washington, D.C.								
148			Archbishop Carroll High School								
149			Don Bosco Cristo Rey High School								
150			School of the Archdiocese of Washington, D.C.								
151			Mary of Nazareth Roman Catholic Elementary School, Inc.							self-insured	
152			Roman Catholic Archdiocese of Washington								
153			Victory Housing, Inc.								
154			Thomas Aquinas College								
155	7/26/2016	Litigation: Plaintiff: Beckwith Electric Co., Inc. 1:13-cv-01944	Beckwith Electric Co., Inc.		Other	Yes	"emergency contraception," "abortifacient," "any drugs, devices and services capable of ending innocent human life" (specifically lists Plan B, ella, and the IUD as examples of "abortifacients")		Other	self-insured	
156	7/26/2016	Litigation: Plaintiff: Johnson Welded Products, Inc. 1:13-cv-00557	Johnson Welded Products, Inc.		Other	Yes	"all of the contraceptive services required by the contraceptive services mandate"		Other	Not indicated	
157	8/5/2016	Not I	Society of the Precious Blood		Non-profit	No	All		Other	Fully insured	
158	9/17/2016	Litigation: Plaintiff: Catholic Charities of Philadelphia and Circumlocution 2:14-cv-03096-AB	Catholic Charities of the Archdiocese of Philadelphia and Circumlocution 2:14-cv-03096-AB		Non-profit	Yes	"all of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	
159	9/17/2016	Litigation: Plaintiff: Catholic Charities of Philadelphia and Circumlocution 2:14-cv-03096-AB	St. John's Orphan Asylum		Non-profit	Yes	"all of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."		Church Plan	Self-insured	

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Summary of Changes

	N/A if Home/	N/A if Home/	Home/
Redacted	Redacted	Redacted	Redacted

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Tracking number	Date notification received	Received via mail or email?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (If yes, identify instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Health Plan, Other)	Fully insured, self-insured or both?	Name of issuer (Enter N/A if none)
100	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	St. Edmund's Home for Crippled Children	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
101	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Don Guanella Village of the Archdiocese of Philadelphia	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
102	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Delmar Providence Village	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
103	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Philadelphia Protector for Boys of St. Gabriel's System	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
104	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Catholic Community Services Inc.	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
105	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Nutritional Development Services, Inc.	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
106	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Catholic Health Care Services - Supportive Independent Living of St. John Vianney Center	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
107	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	St. John Vianney Center	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
108	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Catholic Clinical Consultants	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
109	9/17/2016	Litigation: Catholic Charities of Philadelphia 3rd Circuit 2:14-cv-03096-AB	Roman Catholic Archdiocese of Philadelphia	Redacted	Non-profit	Yes	"a) of the required contraceptive services with the exception of the prescription and use of contraceptive medications for non-contraceptive medical purposes."	Redacted	Church Plan	Self-insured	Redacted
110	9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	Diocese of Cheyenne	Redacted	Non-profit	Yes	"to providing procuring or facilitating access to abortion-inducing products abortion sterilization or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent of aborting pregnancy or to induce abortion."	Redacted	Church Plan	Self-insured	Redacted
111	9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	Catholic Charities of Wyoming	Redacted	Non-profit	Yes	"to providing procuring or facilitating access to abortion-inducing products abortion sterilization or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent of aborting pregnancy or to induce abortion."	Redacted	Church Plan	Self-insured	Redacted
112	9/15/2015	Litigation: Diocese of Cheyenne 10th Circuit court 14-8040	Saint Joseph's Children's Home	Redacted	Non-profit	Yes	"to providing procuring or facilitating access to abortion-inducing products abortion sterilization or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent of aborting pregnancy or to induce abortion."	Redacted	Church Plan	Self-insured	Redacted

CONCLUSIONS

3	A	B	C	D	E	F	G	H	I	J	K	L
4	Tracking number	Date notification received	Received via mail or email?	Name of eligible organization	Contact information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Other)	Fully insured, self-insured or both?	Name of issuer (enter N/A if none)
5	Redacted	9/15/2015	9/15/2015	St. Anthony Tri-Parish Catholic School 8040	Redacted	Non-profit	Yes	"to providing, procuring, or facilitating access to abortion-inducing products, abortion sterilization, or contraceptives" except when "prescribed with the intent of treating a medical condition not with the intent of inducing pregnancy or to induce abortion."	Redacted	Church Plan	Self-insured	Redacted
178		9/15/2015	9/15/2015	Wynoming Catholic College 8040		Non-profit	Yes	"abortion-inducing products or sterilization" except "contraception, abortion-inducing drugs or devices, or any medical condition not with the intent to prevent pregnancy."		Church Plan	self-insured	
179		9/15/2015	9/15/2015	Colorado Christian University (employee)		Non-profit	Yes	"coverage for a services, drugs, and devices that could terminate human life from the moment of conception including medical abortions, emergency contraceptives like Plan B and Ella, and "other contraceptives."		Other	self-insured	
180		9/15/2015	9/15/2015	Colorado Christian University (student)		Non-profit	Yes	"coverage for abortions and all contraceptives including emergency contraceptives and IUDs."		Student	Fully insured	
181		9/15/2015	9/15/2015	Family Talk		Non-profit	Yes	"abortion-inducing or implantation-preventing drugs, abortion-inducing or implantation-preventing devices, specific family IUDs and "emergency contraception" such as Plan B and Ella" and "any counseling or referrals to promote or refer for ... such abortion-inducing drugs and IUDs."		Other	Partially self-insured with a stop-loss provider and a third-party administrator	
182		9/15/2015	9/15/2015	Association of Christian Schools International (employee)		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion-inducing drugs and devices like Plan B, ella, and IUDs"		Other	self-insured	
183		9/15/2015	9/15/2015	Samarian Ministries International (employee)		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion-inducing drugs and devices like Plan B, ella, and IUDs"		Other	self-insured	
184		9/15/2015	9/15/2015	Taylor University (employee)		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion-inducing drugs and devices like Plan B, ella, and IUDs"		Other	self-insured	
185		9/15/2015	9/15/2015	Indiana Wesleyan University		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion-inducing drugs and devices like Plan B, ella, and IUDs"		Other	self-insured	
186		9/15/2015	9/15/2015	Asbury Theological Seminary		Non-profit	Yes	"the procurement of participation in facilitation of or payment for abortion-inducing drugs and devices like Plan B, ella, and IUDs"		Other	self-insured	
187		9/15/2015	9/15/2015	Alliance Defending Freedom		Non-profit	Yes	"emergency contraceptive medications, hormonal contraceptive medications and devices, and implanted contraceptive devices or related counseling or referrals to promote the use of such items."		Other	self-insured	
188		9/20/2016	9/20/2016	Good Will Publishers, Inc.		Other	Yes	"contraception, abortion-inducing drugs or devices, sterilization and related counseling"		Other	Fully insured	
189		9/20/2016	9/20/2016	Catholic Charities of the Archdiocese of Oklahoma City		Non-profit	Yes	"contraception, abortion-inducing drugs or devices, sterilization and related counseling"		likely church plan, but never alleged	self-insured	
190		9/20/2016	9/20/2016	All Saint's Catholic School		Non-profit	Yes	"contraception, abortion-inducing drugs or devices, sterilization and related counseling"		likely church plan, but never alleged	self-insured	
191												

Notifications

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6	Contact information for issuer (enter N/A if none)	Service Provider Information	Name of TPA (enter N/A if none)	Contact information for TPA (enter N/A if none)	Original information submitted to issuer (enter N/A if none)	For updated information, date the information became effective	For updated information, date the summary of changes	For is it insured plans, date reflected to issuer by PHS	For self-insured plan, date notification forwarded to DOL	Action Taken For for-profit organizations, date letter sent to organization (if above)	Notes		
	Redacted	Redacted	Redacted	Redacted	Original	N/A							
178					Original	N/A							
179					Original	N/A							
180					Original	N/A							
181					Original	N/A							
182					Original	N/A							
183					Original	N/A							
184					Original	N/A							
185					Original	N/A							
186					Original	N/A							
187					Original	N/A							
188					Original	N/A							
189					Original	N/A							
190					Original	N/A							
191					Original	N/A							

A	B	C	D	E	F	G	H	I	J	K	L
Tracking number	Date notification received	Received via mail or email?	Name of eligible organization	Context information for eligible organization	Type of organization (Non-profit or other)	Plaintiff in litigation? (See instruction #2 above)	Contraceptive services not provided	Plan name	Plan type (Student Plan, Church Plan, Other)	Fully insured, self-insured or both?	Name of insurer (enter N/A if none)
Redacted	9/20/2016	Litigation: Catholic Benefits Ass'n LCA v. Burwell 10th Circuit Court No. 14-6159 14-6171	The Catholic Foundation of Atlanta Catholic Review Media	Redacted	Non-profit	Yes	"contraception, abortion-inducing drugs or devices sterilization and related counseling"	Redacted	likely church plan but never alleged	self-insured	Redacted
19	9/20/2016	Litigation: Catholic Benefits Ass'n LCA v. Burwell 10th Circuit Court No. 14-6159 14-6171	Vita St. Francis Catholic Care Center Inc.	Redacted	Non-profit	Yes	"contraception, abortion-inducing drugs or devices sterilization and related counseling"	Redacted	Other	fully-insured	Redacted
19	10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta v. Secretary U.S. Dept of Health & Human Servs et al Nos. 14-12890 14-13242	THE ROMAN CATHOLIC ARCHDIOCESE OF ATLANTA, an association of churches and schools	Redacted	Non-profit	Yes	"abortion-inducing products, contraception, sterilization and related counseling," "unless they are necessary for medically diagnosed conditions unrelated to contraception."	Redacted	Church Plan	self-insured	Redacted
19	10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta v. Secretary U.S. Dept of Health & Human Servs et al Nos. 14-12890 14-13242	THE MOST REVEREND WILTON D GREGORY and his successors Archbishop of Atlanta, Roman Catholic Archdiocese of Atlanta	Redacted	Non-profit	Yes	"abortion-inducing products, contraception, sterilization and related counseling," "unless they are necessary for medically diagnosed conditions unrelated to contraception."	Redacted	Church Plan	self-insured	Redacted
19	10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta v. Secretary U.S. Dept of Health & Human Servs et al Nos. 14-12890 14-13242	CATHOLIC CHARITIES OF THE ARCHDIOCESE OF ATLANTA, INC. a Georgia non-profit corporation	Redacted	Non-profit	Yes	"abortion-inducing products, contraception, sterilization and related counseling," "unless they are necessary for medically diagnosed conditions unrelated to contraception."	Redacted	Church Plan	Self-insured	Redacted
19	10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta v. Secretary U.S. Dept of Health & Human Servs et al Nos. 14-12890 14-13242	Catholic Education of North Georgia Inc. (CENG)	Redacted	Other	Yes	"abortion-inducing products, contraception, sterilization and related counseling," "unless they are necessary for medically diagnosed conditions unrelated to contraception."	Redacted	Church Plan	Self-insured	Redacted
19	10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta v. Secretary U.S. Dept of Health & Human Servs et al Nos. 14-12890 14-13242	THE ROMAN CATHOLIC DIOCESE OF SAVANNAH an ecclesiastical territory	Redacted	Non-profit	Yes	"abortion-inducing products, contraception, sterilization and related counseling," "unless they are necessary for medically diagnosed conditions unrelated to contraception."	Redacted	Church Plan	Self-insured	Redacted
19	10/6/2016	Litigation: Roman Catholic Archdiocese of Atlanta v. Secretary U.S. Dept of Health & Human Servs et al Nos. 14-12890 14-13242	THE MOST REVEREND JOHN HARTMAYER and his successors Bishop of the Roman Catholic Diocese of Savannah et al.	Redacted	Non-profit	Yes	"abortion-inducing products, contraception, sterilization and related counseling," "unless they are necessary for medically diagnosed conditions unrelated to contraception."	Redacted	Church Plan	Self-insured	Redacted
20	10/6/2016	Eternal Word Network v. Burwell No. 14-12696	Eternal Word Television Network Inc.	Redacted	Non-profit	Yes	"artificial contraception, sterilization or abortion or related education and counseling."	Redacted	other	Self-insured	Redacted
20	11/ /2016	Email/mail	Black Group Inc.	Redacted	Other	Yes	"all contraceptive services"	Redacted	Other	Fully-insured	Redacted
20	11/9/2016	Email	The Emergi Lab INC	Redacted	Other	No	All	Redacted	Other	Fully-insured	Redacted
20	11/2 /2016	Email	Marion University	Redacted	Non-profit	No	All	Redacted	Church Plan	self-insured	Redacted

Notifications

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Notifications

Notifications

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Addresses

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Case	Plaintiffs	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number counted towards final total	Total employees (includes H&V/IA and SICPs)	Total students at relevant universities
Am Pulverizer Co. v. U.S. Dept of Health and Human Servs., No. 612-cv-03459, 2012 WL 6951316 (W.D. Mo. Dec. 20, 2012).		175 employees	Complaint	Yes		175	175	
American Family Association v. Scheinus, T-13-cv-00032-S.A-DAS (N.D. Miss. Feb. 20, 2013)		135 employees	Complaint	Yes		135	135	
Amey Med., Inc. v. Burwell, No. 13-1118, 2013 WL 1276025 (8th Cir. Feb. 1, 2013)		18 employees	Complaint	Yes		18	18	
Archdiocese of St. Louis v. Burwell, No. 413-cv-02300 (E.D. MO), No. 14-3016 (8th Cir.)	Archdiocese of St. Louis Catholic Charities of St. Louis	7,800 employees/staff	Complaint	No	Diocese self-insured plan (see Brandt v. Burwell note below)	0	0	
Armstrong v. Burwell, No. 113-cv-00563-RBJ (D. Colo. Sept. 17, 2013), gov't appeal dismissed Sept. 4, 2014 (10th Cir. order).	Louis	1,600 employees	Complaint	No	same	0	0	
Association of Christian Schools International v. Burwell, No. 1:14-cv-2966 (D. Colo.), No. 14-1492 (10th Cir.)	Association of Christian Schools International Samaritan Ministries International	730 employees 140 employees 133 employees	Complaint Complaint Complaint	Yes Yes Yes		730 140 133	730 140 133	
	Taylor University	1,900 Students, 641 Employees	Complaint	Students = no; employees = yes	Complaint does not state that they offer a student health plan, therefore students not counted.	641	641	0
Autocam Corp. v. Burwell, 730 F.3d 618 (6th Cir. Sept. 17, 2013).	Indiana Wesleyan University	15,000 students, 3,565 employees (1,018 FT and 2,547 PT)	Complaint	Students = no; employees = partial	Complaint does not state that they offer a student health plan, therefore students not counted. Complaint states that 890 employees enroll in the plan. Because other entities usually provide the overall number of employees, not the number enrolled in the plan, and in the IFR we estimate 62% of all employees are in plans, this number is updated to 890/62% = 1435	1,435	1,435	0
Ave Maria Foundation v. Burwell, No. 2:13-cv-15198 (E.D. Mich.), Nos. 14-1310 (6th Cir.)	Autocam Autocam Medical The Ave Maria Foundation Ave Maria Communications Dominio's Farms Petting Farm Rhodora J. Donahue Academy, Inc. Thomas More Law Center	478 employees 183 employees 51 employees 19 employees 18 employees 26 employees 14 employees	Complaint Complaint Estimated number based on online information from W-3 filing From W-3 filing From W-3 filing Website From W-3 filing	Yes Yes Yes Yes Yes Yes Yes		478 183 51 19 18 26 14	1,435 478 183 51 19 18 26 14	0
Ave Maria School of Law v. Burwell, No. 2:13-cv-00795 (M.D. Fl.), Nos. 14-15777 (11th Cir.)		68 employees	Complaint	Employees = yes; students = no	Permanent injunction 07/11/2018	0	0	0
Ave Maria University v. Burwell, No. 2:13-cv-00630 (M.D. Fla.), Nos. 14-15780 (11th Cir.)		150 employees	Complaint	Employees = yes; students = no		0	0	0
Barton Indus., Inc. v. Burwell, No. 1:13-cv-01330 (KBJ) (D.D.C. Sept. 25, 2013).		56 employees	Complaint	Yes		56	56	
Beckwith Elite Co. v. Burwell, No. 8:16-cv-1944 (M.D. Fla.)		126 employees	Complaint	Yes		126	126	
Beimont Abbey College v. Scheinus et al., No. 1:11-cv-01989 (D.D.C. Nov. 10, 2011)		1,600 students, 305 employees	Complaint	Yes		1,600 students, 305 employees	1,600	
Bick Holdings, Inc. v. Burwell, No. 4:13-cv-00462 (A.G.F. (E.D. Mo. Apr. 1, 2013).		196 employees	Complaint	Yes		196	196	
Brandt v. Burwell, No. 2:14-cv-00681 (W.D. Pa.), Nos. 14-3663, 14-4087 (3d Cir.)					Diocese self-insured plan.			
	Diocese of Greenburg	3,100 employees, 5,000 other participants in plan (this is a high number- it includes employees from other Dioceses)	Complaint	No	Government argued that these and all similar Catholic diocese-sponsored self-insured plans and entities participating in such plans that are litigants represented by Jones Day likely qualify to be church plans except from ERISA. See, e.g., Doc # 25, 2:14-cv-00681-AJS (W.D. Pa.). We cannot force such plan TPAs to offer contraceptive payments, and it is likely the churches will tell them not to, and the TPAs will not make the offers.	0	0	0
	Catholic Charities	18 employees	Complaint	No	Diocese self-insured plan	0	0	0
	St. John School	13 employees	Complaint	No	Diocese self-insured plan	0	0	0

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Case	Plaintiffs	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number counted towards final total	Total employees (minus H&V/IA and SICPs)	Total students at relevant universities
Briscoe v. Burwell, No. 1:13-cv-00288-WJD-BNB (D. Colo. Sept. 6, 2013). gov't appeal dismissed Sept. 4, 2014 (10th Cir. order); Catholic Benefits Association LCA v. Burwell (CA 11), No. 15-6029, 15-6037, 15-6139, 16-6030, 16-6217 (10th Cir.)	Briscoe owns all plaintiff organizations involved: Continuum Health Partnerships, Inc./ Mountain States Health Properties, LLC/ Continuum Health Management, LLC/ CH-Greely, LLC	200 employees	Complaint	Yes		200	200	
	Catholic Benefits Association	Unknown	N/A	No	Permanent injunction 03/07/2018	0	0	
	Catholic Insurance Company	Unknown	N/A	No	Permanent injunction 03/07/2018	0	0	
	Archdiocese of Baltimore	5,500 participants	Complaint	No	Permanent injunction 03/07/2018	0	0	
	Catholic Review (AKA Cathedral Foundation)	32 employees	Complaint	No	Permanent injunction 03/07/2018	0	0	
	Archdiocese of Oklahoma City- Complaint lists Mount St. Mary, St. Ann, and Office of Catholic Schools as sub-institutes	Unknown (see St. Ann, Mount St. Mary and Office of Catholic Schools below)		No				
	St. Ann	78 employees	From W-3 filing	No	Permanent injunction 03/07/2018	0	0	
	Mount St. Mary	Unknown		No	Permanent injunction 03/07/2018	0	0	
	Office of Catholic Schools- Villis St. Francis Catholic Care Center	100 participants	Complaint	Yes	Permanent injunction 03/07/2018	0	0	
	Goodwill Publishers	140 employees	Complaint	Yes	Permanent injunction 03/07/2018	0	0	
Catholic Charities of the Archdiocese of Philadelphia v. Burwell, No. 2:14-cv-3096 (E.D. Pa.), No. 14-3126 (3d Cir.)	Catholic Charities	103 employees	From W-3 filing	No	Permanent injunction 03/07/2018	0	0	
	Oklahoma City	Unknown		No	Permanent injunction 03/07/2018	0	0	
	All Saints	Unknown		No	Permanent injunction 03/07/2018	0	0	
	Catholic Charities and Family Services, Diocese of Norwich	69 employees	Second Complaint	Yes	Permanent injunction 03/07/2018	0	0	
	Catholic Social Services	626 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. Francis Homes for Boys	227 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. Edmund's Home for Children	226 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	Don Chardella Village	413 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	Divine Providence Village	667 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. Gabriel's System	458 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
Catholic Charities of the Archdiocese of Philadelphia v. Burwell, No. 2:14-cv-3096 (E.D. Pa.), No. 14-3126 (3d Cir.)	Catholic Community Services	92	From W-3 filing	No	Diocese self-insured plan	0	0	
	Nutritional Development Services	64	From W-3 filing	No	Diocese self-insured plan	0	0	
	Villa St. Martha	117 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. Monica Manor	356 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. John Neumann Nursing Home	360 Employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	Immaculate Mary Home	490 Employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. Francis Country House	488 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. Martha Manor	272 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. Mary Manor	339 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	St. John Vianney Center	84 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
Catholic Diocese of Beaumont v. Burwell, No. 1:13-cv-00709 (E.D. Tex.), No. 14-40212 (5th Cir.)	Catholic Clinical Consultants	19	From W-3 filing	No	Diocese self-insured plan	0	0	
	Diocese	950 employees; 232 staff at schools	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust- a self insured church plan	0	0	
	Catholic Charities of Southeast Texas, Inc.	18 employees	Complaint		Offers coverage through Christian Brothers Employee Benefit Trust- a self insured church plan	0	0	
	Diocese of Jackson	900 employees	Complaint	No	Diocese self-insured plan	0	0	
	Catholic Charities	140 employees	Complaint	No	Diocese self-insured plan	0	0	
	Vicksburg	70 employees	Website	No	Diocese self-insured plan	0	0	
	St. Joseph	85 employees	Website	No	Diocese self-insured plan	0	0	
	Diocese of Biloxi	600 employees	Complaint	No	Diocese self-insured plan	0	0	
	De L'epre Deaf Center	5 employees	From W-3 filing	No	Diocese self-insured plan	0	0	
	Catholic Social & Community Services Inc.	20 employees	From W-3 filing	no	Diocese self-insured plan	0	0	
Catholic Diocese of Biloxi v. Burwell, No. 1:14-cv-00146 (S.D. Miss.)	Resurrection Catholic and Sacred Heart	200 employees	Complaint	No	Diocese self-insured plan	0	0	

Draft - For Discussion Purposes

Case	Plaintiffs	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number counted towards final total	Total employees (includes Hobby/IA and SICPs)	Total students at relevant universities
Conlon, Bishop of Catholic Diocese of Joliet v. Sebelius, 1:12-cv-03932 (S.D. Ill. May 21, 2012)	St. Dominic-Jackson Memorial Hospital and affiliated locations and programs	2,200 employees	Complaint	No	Self-insured plan sponsored by Catholic affiliated hospital; grandfathered and already omits contraceptives, so could retain grandfathered status or pursue church plan status to continue omitting.	0	0	
	Diocese of Joliet	At least 1,570 employees	Complaint	No	Diocese self-insured plan	0	0	
	Catholic Charities of Joliet	240 employees	Complaint	No	Diocese self-insured plan	0	0	
	Diocese of Springfield	2585 employees	Complaint	No	Diocese self-insured plan	0	0	
	Catholic Charities of Springfield	200 employees	Complaint	No	Diocese self-insured plan	0	0	
Catholic Diocese of Nashville v. Burwell, No. 3:13-cv-1303 (M.D. Tenn.), No. 13-6640 (6th Cir.)	Catholic Charities of Chicago	2700 employees	Complaint	Yes	Self-funded welfare benefit plan but not sure if church plan	2,700	2,700	
	Diocese of Nashville	1200 employees	Complaint	No	House of Worship, fully insured	0	0	
	Catholic Charities	115 employees	Complaint	Yes	Website/news reports indicate recent drastic downsizing of workforce; students not counted because complaint does not allege a student plan	115	115	
				employees: yes; students: no		16	16	0
Catholic Diocese of Peoria v. Sebelius, 1:12-cv-01276-JES-BQC (C.D. Ill. August 9, 2012)	Aquinas College	16 employees	Website	Yes		16	16	
	Camp Marymount	75 employees	Complaint	Yes		75	75	
	NJOA	85 employees	Complaint	Yes		85	85	
	St. Mary Villa	50 employees	Complaint	Yes		50	50	
Catholic Health Care System v. Burwell, No. 1:12-cv-02542 (E.D.N.Y.), No. 14-427 (2d Cir.), PACER	Dominican Sisters	23 employees	Complaint	No	Religious order	0	0	
		Unknown		No	Diocese self-insured plan (court order, 2013 WL 74240), and grandfathered.	0	0	
				No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp. 2d at 242.	0	0	
	Archdiocese of New York	10,000 employees	Complaint	No	Catholic hospital self-insured plan	0	0	
The Diocese of Rockville Centre	Archdiocese of New York	4,000 employees	Complaint	No	Catholic hospital self-insured plan	0	0	
	Catholic Health Services of Long Island	17,000 employees	Complaint	No	Catholic hospital self-insured plan	0	0	
				No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp. 2d at 242.	0	0	
	2,000 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp. 2d at 242.	0	0		
Christian & Missionary Alliance Foundation, Inc., No. 2:14-cv-00580 (M.D. FL.), Nos. 15-11437, 15-11635 (11th Cir.)	Monsignor Farrel High School	73 employees	Website	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp. 2d at 242.	0	0	
	Cardinal Spellman High School	100 employees	Complaint	No	In the lawsuit the government took the position that this is a self-insured church plan. See, e.g., 987 F. Supp. 2d at 242.	0	0	
	CNA d/b/a Shell Point Retirement Center	1247 employees	Form W-3 filing	Yes		1,247	1,247	
	Alliance Community for Retirement Living	344 employees	Form W-3 filing	Yes		344	344	
Christian Employers Alliance v. Burwell, No. 3:16-cv-309 (D.N.D.)	Alliance Home of Catholic Town and Country Manor	219 employees	Form W-3 filing	Yes		219	219	
	Simpson University	365 employees	Form W-3 filing	Yes		365	365	
		815 employees	Complaint	employees: yes; students: no	Complaint does not seek relief for any student plan	815	815	0
	Crown College	114 employees	https://www.crown.edu/about/quick-facts/ (nearly 1,300 students)	Yes		1,275 students; 114 employees	114	1,275
Colorado Christian Univ. v. Burwell, No. 1:13-cv-02105 (D. Colo.), No. 14-1329 (10th Cir.)	Christian Employers Alliance	Unknown		No	No claim was made for CEA plans, and no list of members beyond TBC and TTC	0	0	
	Trinity Bible College	249 employees	Form W-3 filing	employees: yes; students: no	complaint does not mention student plan	249	249	
	Treasure Island Comm	9 staff	Website	Yes		9	9	
	Colorado Christian University	5,300 students; 680 employees	Complaint	Yes	Permanent injunction 07/11/2018	0	0	0
Conestoga Wood Specialties Corp. v. Burwell (Burwell v. Hobby Lobby Stores, Inc.), No. 13-356 (U.S. June 30, 2014).	Conestoga Wood Specialties Corp. (individual operators of Conestoga Wood Specialties Corporation are the three other named plaintiffs)	950 employees	Complaint	Yes		950	950	

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Case	Plaintiffs	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number counted towards final total	Total employees (includes H&W/VIA at relevant universities)
DeCite v. Azar, No. 4:18-cv-00825-Y (N.D. Tex. Complaint Oct. 6, 2018)	Richard W. DeCite, Yvette DeCite, John Kelley, Alison Kelley, Hope Health & Wellness Center	75 employees	Complaint	Yes		75	
Diocese of Cheyenne v. Burwell, No. 2:14-cv-00021 (D. Wyo.), No. 14-8040 (10th Cir.)	Diocese of Cheyenne	16 employees plus over 100 teachers	Complaint	No	Diocese self-insured plan	0	0
	Catholic Charities	6 employees	Complaint	No	Diocese self-insured plan	0	0
	St. Anthony School	41 employees	Complaint	No	Diocese self-insured plan	0	0
	St. Joseph's Home	130 employees, 62 orphan children	Complaint	No	Diocese self-insured plan	0	0
	JPHCS	20	Complaint	No	Diocese self-insured plan	0	0
Diocese of Fort Wayne-South Bend Inc. v. Burwell, No. 1:12-cv-00159 (N.D. Ind.), No. 14-1431 (7th Cir.)	Wyoming Catholic College	32 employees	Complaint	No	Brother's Employee Benefit Trust - a self insured church plan	0	0
	Diocese of Fort Wayne South Bend	2,741 employees	Complaint	No	Diocese self-insured plan; also grandfathered	0	0
	Catholic Charities	39 employees	Complaint	No	Diocese self-insured plan	0	0
	St. Anne Home	310 employees	Complaint	Yes	Self-insured plan, but not sure if it is a church plan	310	310
	University of St. Francis	2,300 students, 413 employees	Complaint	employees; yes; students no	No student plan discussed. Employee are offered a self-insured health plan, but not sure if it is a church plan, so included	413	413
	Our Sunday Visitor	300 employees	Complaint	Yes	Self-insured plan, but not sure if it is a church plan	300	300
	Specialty Physicians	342 employees	Complaint	Yes	All but 1,733 employees are on a church plan exempt from ERISA. See: https://www.franciscanhealth.org/site/default.htm?cid=2015%20employee%20benefit%20booklet.pdf (Only employees in Illinois are in BCBS plans and there are 1733 of those employees according to complaint)	342	342
	Franciscan Alliance	18,000 employees	Complaint	Partial		1,733	1,733
		32 employees	Complaint	Yes		32	32
		28 employees	Complaint	Yes		28	28
Dordt Coll. v. Burwell, No. 5:13-cv-04100 (N.D. Iowa, Western Division), No. 14-2726 (8th Cir.)		89 employees	Complaint	Yes		89	89
	Dordt College	1,400 students, 280 employees	Complaint	Yes	Permanent injunction 06/14/2018	0	0
		2,923 students, 294 employees	Complaint	employees; yes; students no	Permanent injunction 06/14/2018	0	0
	Cornerstone University	2,589 students, 416 employees	Complaint	No	Self-insured church plan	0	0
	Houston Baptist University	1,290 students, 233 employees	Complaint	Yes	complaint does not mention student plan	1,290 students, 233 employees	1,290
East Texas Baptist Univ. v. Burwell, No. 4:12-cv-03009 (S.D. Tex.), No. 14-20112 (5th Cir.)	Westminster Theological Seminary (Intervenor)	60 FTE, 65 PT employees, 620 students	Complaint in intervention	employees; yes; students no		125	125
		128 employees	Complaint	Yes		128	128
		350 employees	Complaint	Yes		350	350
		450 employees	Complaint	No	Case resolved on basis that plaintiff is integrated auxiliary	0	0
		4 employees	Website	Yes		4	4
Franciscan University v. Scheidus, 2:12-CV-440 (S.D. Ohio)		Unknown	Complaint	No	Sired while grandfathered and then dropped student plan. With no additional sur, no apparent affect from rule	0	0
	Geneva College	1,850 students, 350 employees	Complaint	Yes	Permanent injunction docket # 144	0	0
		22 employees	Complaint	No	Permanent injunction shields from previous rule	0	0
	Freshway Foods	340 employees	Complaint	Yes		340	340
	Freshway Logistics	35 employees	Complaint	Yes		35	35
Grace Schools v. Burwell, No. 3:12-cv-00459 (N.D. Ind.), No. 14-1430 (7th Cir.)	Grace College and Seminary	2,700 students, 457 employees	Complaint	Yes	Permanent injunction 06/14/2018	0	0
		6,222 students, 856 employees	Complaint	Yes	Permanent injunction 06/14/2018	0	0

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Case	Plaintiffs	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number towards final total	Total employees (includes H&V/VIA and SICPs)	Total students at relevant universities
<i>Georgiadis LLC v. Burwell</i> , No. 13-1077 (2013 WL 5566092 (7th Cir. Nov. 8, 2013), cert. denied sub nom. <i>Burwell v. Korte</i> , No. 13-937 (U.S. July 1, 2014).		1,148 employees	Complaint	Yes		1,148	1,148	
<i>Hall v. Burwell</i> , No. 0:13-cv-00295-JRT-LIB (D. Minn. Apr. 2, 2013).		Approximately 50 employees	Complaint and online news reports	Yes		50	50	
<i>Hartenbower v. U.S. Dept of Health and Human Servs.</i> , No. 1:13-cv-02253 (N.D. Ill. Apr. 18, 2013).	Hart Electric	54 employees (including owners)	Complaint	Yes		54	54	
<i>Hastings Christian Center Inc. v. Burwell</i> , No. 0:14-cv-00266-P-AM-JJC (D. Minn. May 28, 2014).	H.I. Hart	7 employees	Complaint	Yes		7	7	
<i>Hobby Lobby Stores Inc. et al. v. Sebelius</i> , et al., No. CV-12-1000-HE (W.D. Okla. Oct. 2, 2012).	Hobby Lobby	60 employees	Complaint	Yes		60	60	
<i>Holland v. U.S. Dept of Health and Human Servs.</i> , No. 13-15487 (S.D. W. Va. July 15, 2014).	Marida	13,240 employees	Complaint	Yes		13,240	13,240	
<i>Infrastructure Alternatives, Inc. v. Burwell</i> , No. 1:13-cv-00031-RJL (W.D. Mich. Sept. 30, 2013).		150 employees	Complaint	Yes		372	372	
<i>Knights for Living Ministries v. Burwell</i> , No. 4:14-cv-675 (E.D. Tex.), No. 15-40031 (5th Cir.)		70 employees	Complaint	Yes		150	150	
<i>Johnson Welded Prods. v. Burwell</i> , No. 1:16-cv-557 (D.D.C.)		108 employees	Form W-3 filing	Yes		70	70	
<i>Korte v. Burwell</i> , No. 12-3881, 2013 WL 5960692 (7th Cir. Nov. 8, 2013), cert. denied No. 13-937 (U.S. July 1, 2014).		421 employees (including L.H. Johnson)	Complaint	Yes		108	108	
<i>Legatus v. Burwell</i> , No. 2:12-cv-12061-RHC-MJH (E.D. Mich. Dec. 20, 2013)	Legatus	90 employees	Complaint	Yes		421	421	
	Wegenart Supply Company W&P Management LLC, and subsidiaries	69 employees	Complaint	Yes	Legatus injunction 12/20/2013, case dismissed 02/02/2018	90	90	
<i>Lindsay v. U.S. Dept of Health and Human Servs.</i> , No. 13-cv-1210 (N.D. Ill. Mar. 20, 2013).		170 employees	Complaint	Yes		0	0	
<i>Little Sisters of the Poor Home for the Aged v. Burwell</i> , No. 1:13-cv-2611 (D. Colo.), No. 13-1540 (10th Cir.)	Christian Brothers Employee Benefit Trust (Little Sisters uses Christian Brothers Employee Benefit Trust, and Christian Brothers Services is the TPA for the Christian Brothers Employee Benefit Trust)	70 employees	Complaint	Yes		170	170	
<i>Louisiana Coll. v. Burwell</i> , No. 1:12-cv-00463 (W.D. La.), No. 14-31167 (5th Cir.)		5,000 employees	Complaint	No	Self-insured church plan, and permanent injunction 05/29/2018	0	0	
<i>March for Life v. Burwell</i> , No. 1:14-cv-1149 (D.D.C.), No. 15-5301 (D.C. Cir.)		1,350 students, 260 employees	Complaint	No	Self-insured church plan	0	0	0
<i>Media Research Center v. Sebelius</i> , No. 1:14-cv-329 (E.D. Virginia)		2 employees covered in plan, less than 10 overall	Complaint	No	All employees must/ do oppose the coverage, therefore not counting as affected by rule.	0	0	0
<i>Messino Mgmt. Co. v. Burwell</i> , No. 13-1594 (6th Cir. July 9, 2014)		114 employees	Complaint	Yes		114	114	
<i>Midwestern Catholic Conf. v. Burwell</i> , No. 1:13-cv-1247 (W.D. Mich.), No. 13-2723 (6th Cir.)	Midwestern Catholic Charities	110 employees	Complaint	Yes		110	110	
<i>Midwest Pastener Corp. v. Burwell</i> , No. 1:13-cv-01337-ESH (D.D.C. Oct. 16, 2013).	Catholic Charities	6,429 employees	Complaint	No	Self-insured church plan	0	0	0
<i>MK Chambers Co. v. Dept of Health and Human Servs.</i> , No. 13-cv-11379 (E.D. Mich. Nov. 21, 2014).		55 employees	Complaint	No	Self-insured church plan	0	0	0
<i>Nagle, Christopher, et al. v. Kathleen Sebelius, et al.</i> , No. 2:13-cv-12056-VAR-DKG (E.D. Mich. May 10, 2013) (AKA "Maken Playcare")		187 employees	Complaint	Yes		187	187	
<i>Newland v. Burwell</i> , 881 F. Supp. 2d 1287 (D. Colo. July 27, 2012), affirmed on appeal, No. 12-1380 (10th Cir. Oct. 3, 2013)		106 employees	Business profile on mha.org	Yes		106	106	
<i>O'Brien v. U.S. Dept of Health & Human Servs.</i> , No. 12-3357 (8th Cir. Nov. 28, 2012)		109 employees	Complaint	Yes		109	109	
<i>Ortega v. Burwell</i> , No. 1:13-cv-3292 (N.D. Ill.), No. 15-3648 (7th Cir.)		265 employees	Dist Ct Brief 4/30/12	No	Permanent injunction	0	0	
<i>Pesisto v. Burwell</i> , No. 1:13-cv-0303 (W.D. Pa.), Nos. 14-1376 (3d Cir.); formerly <i>Moss Reverend Donald W. Trautman, Bishop of the Roman Catholic Diocese of Erie, et al. v. Sebelius</i> , No. 1:12-cv-00123-SPB (W.D. Pa. May 19, 2013) for life, No. 1:13-cv-01261 (D.D.C.), No. 13-5368 (D.C. Cir.)	Diocese of Erie St Martin Center Prince of Peace Center Erie Catholic Preparatory School	87 employees	Complaint	Yes		87	87	
		675+ employees	Complaint	Partial	Only 110 obtain insurance through the plan that would be affected by the exemption. This is updated to 110/62% = 178	178	178	
		1,500 employees	Complaint	No	Diocese self-insured plan	0	0	
		61 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
		20 employees	Form W-3 filing	No	Diocese self-insured plan	0	0	
		80 employees	Complaint	No	Diocese self-insured plan	0	0	
		60 employees	Website	Yes		60	60	

Case	Plaintiffs	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number counted towards final total	Total employees (includes H&V/LA and SICPs)	Total students at relevant universities
Ready Read Auto, Inc. v. Barwell, No. 5:13-cv-6117-SF-028 (W.D. Mo. Dec. 3, 2013).		approximately 179 employees	Complaint	Yes		179	179	
Reaching Souls Int'l, Inc. v. Barwell, No. 5:13-cv-01092 (W.D. Okla.), No. 14-6028 (10th Cir.)		78,000 participants (pastors, employees, and their families)	Complaint	No	Self insured church plan and permanent injunction 03/15/2018	0	0	
Real Alternatives, Inc. v. Barwell, No. 1:15-cv-105 (M.D. Pa.), No. 16-1275 (3d Cir.)		3 employees	Complaint	No	All employees must/do oppose the coverage; therefore not counting as affected by rule.	0	0	
Right to Life of Michigan v. Kathleen Sebelius, No. 1:13-cv-01202 (W.D. Mich. Nov. 22, 2013)		43 employees	Complaint	No	All employees must/do oppose the coverage; therefore not counting as affected by rule.	0	0	
Roman Catholic Archdiocese of Washington v. Barwell, No. 1:13-cv-01441 (D.D.C.), Nos. 13-5371, 14-5021 (D.C. Cir.)	Catholic University	7,000 students, 1,766 employees	Complain	Yes		7,000 students, 1,766 employees	1,766	7,000
	Archdiocese of Washington	2,100 eligible employees						
	teachers/employees at schools	1,200						
	Archdiocese of Washington	370 students, 78 eligible employees	Complaint	No	Diocese self-insured plan	0	0	
	Thomas Aquinas College		Complaint	No	Church plan and complaint does not state that it offers student insurance	0	0	
	Consortium of Catholic Academies	119 employees	Complaint	No	Diocese self-insured plan	0	0	
	Archdiocese Carroll	70 employees	Complaint	No	Diocese self-insured plan	0	0	
	Don Bosco	51 employees	Complaint	No	Diocese self-insured plan	0	0	
	Catholic Information Center	9 employees	Complaint	No	Diocese self-insured plan	0	0	
	Mary of Nazareth	44 employees	Complaint	No	Diocese self-insured plan	0	0	
	Catholic Charities	890 employees	Complaint	No	Diocese self-insured plan	0	0	
	Victory Housing	184 employees	Complaint	No	Diocese self-insured plan	0	0	
Roman Catholic Archdiocese of Atlanta v. Barwell, No. 1:12-cv-03489 (N.D. Ga. Nos. 14-12890, 14-13239 (11th Cir.)	Roman Catholic Archdiocese of Atlanta	9,800 students, 4,200 employees	Complaint	No	Diocese self-insured plan	0	0	
	Catholic Charities	75 employees	Complaint	No	Diocese self-insured plan	0	0	
	CEMS	200 employees	Complaint	No	Diocese self-insured plan	0	0	
	Diocese of Savannah	5,000 students, hundreds of employees	Complaint	No	Diocese self-insured plan	0	0	
Roman Catholic Diocese of Dallas v. Sebelius, No. 3:12-cv-01589-B (N.D. Tex.)		900 teachers/staff, 100+ employees	Complaint	No	Diocese self-insured plan	0	0	
School of the Ozarks v. Rightchoice Managed Care, Inc. No. 6:13-cv-03157 (W.D. Mo.), No. 15-1330 (8th Cir.)		1,442 students, 601 employees	Students - online employees Form W-3 Filing	Employees only	Complaint does not say they offer a student plan	601	601	
Shupe Holdings, Inc. v. Barwell, No. 2:12-cv-92 (E.D. Mo.) and CNS Int'l Ministries, No. 14-1507 (8th Cir.)	Shupe	50 employees	2dan complaint and linked in	Yes		50	50	
	Ozark	51 employees	2dan complaint and linked in	Yes		51	51	
	CNS International Ministries	204 employees	Form W-3 Filing	Yes		204	204	
	NIS Financial	49 employees	2dan Complaint	Yes		49	49	
	CNS Corp	49 employees	2dan Complaint	Yes		49	49	
	Heartland Christian College	12 employees	Form W-3 Filing	Employees only	Complaint does not say they offer a student plan	12	12	0
Shaw Chief Mfg. Co. v. Barwell, No. 13-0036-CV-W-CDS (W.D. Mo. Feb. 28, 2013).		370 employees	Complaint	Yes		370	370	
SKA, LLC v. Barwell, No. 0:13-cv-01375-ADM-LTB (D. Minn. July 8, 2013).	Southern Nazarene University	35 employees	Complaint	Yes	Permanent injunction 05/15/2018	35	35	
Southern Nazarene Univ. v. Barwell, No. 5:13-cv-1015 (W.D. Okla.), No. 14-6026 (10th Cir.)	OK Wesleyan University	2,100 students, 505 employees	Complaint	Yes	Permanent injunction 05/15/2018	0	0	
	OK Wesleyan University	1,220 students, 557 employees	Complaint	Employees only	Permanent injunction 05/15/2018	0	0	
	OK Baptist University	1,900 students, 328 employees	Complaint	Yes	Permanent injunction 05/15/2018	0	0	
	Mid America Christian University	1,447 students, 298 employees	Complaint	No	Permanent injunction 05/15/2018	0	0	
Stewart v. Barwell, No. 1:13-cv-01879 (D.D.C. Apr. 3, 2014).	Entompress Develop. Design & Construct, LLC	43 employees	Complaint	Yes		43	43	
Stinson Electric, Inc. v. Barwell, No. 14-00830-PJS-JUG (D. Minn. April 30, 2014).		19 employees	Business profile on munda.org	Yes		19	19	
The CWZ Zumbido Co. v. Barwell, No. 1:13-cv-01611 (D.D.C. Nov. 27, 2013).		350 employees	Complaint	Yes		350	350	
The Chiswell College v. Sebelius, No. 3:12-cv-04404-N (N.D. Tex.)		322 students, 50 employees	Complaint	Employees only	Complaint does not say they offer a student plan	50	50	
The QC Gap, Inc. v. Barwell, No. 0:13-cv-01726-JRT-SBK (D. Minn. Sept. 11, 2013).		62 employees	Complaint	Yes		62	62	

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Case	Plaintiffs	Number of Employees/Students	Document employee number located within	Are students/employees counted in final total?	If not counted, explanation why	Number counted towards final total
Thomas G. Waskel v. Kathleen Sebelius, No. 12-cv-23820-Graham/Goodman (S.D. Fla. Nov. 7, 2012)	Archdiocese of Miami	Unknown		No	House of worship	0
	Catholic Health Services	2,000 employees	Complaint	Yes		2,000
	Catholic Hospice	610 employees	Form W-3 Filing	Yes	Lawsuit mentions St. Thomas University but asserts no claims for its health plans	610
	St. Thomas University	Unknown		No		0
Tom & Hank Constr. v. Barwell, No. 112-cv-00322		60 employees	Complaint	Yes		60
Trifolion, Inc. v. Barwell, No. 113-cv-1207 (D.D.C.)		469 employees	Complaint	Yes		469
Lyndale House Publishers, Inc. v. Barwell, 904 F. Supp. 2d 106 (D.D.C. Nov. 16, 2012);		260 employees	Complaint	Yes		260
Union University v. Barwell, No. 1:14-cv-1079 (W.D. Tenn.)		2,829 students, 1,116 employees	Students - online; employees Form w3 Filing	Employees only	Complaint does not say they offer a student plan	1,116 employees
Univ. of Dallas v. Barwell, No. 4:12-cv-00314 (N.D. Tex.).	Roman Catholic Diocese of Fort Worth	6,500 students, 2,000 employees	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust - a self insured church plan	0
No. 14-10241 (5th Cir.), Nos. 14-10661 (5th Cir.)	University of Dallas	2,600 students, 725 employees	Complaint	Yes		725
	Catholic Charities	332 employees	Complaint	Yes		332
	Our Lady Of Victory Catholic School	23 employees	Complaint	No	Offers coverage through Christian Brothers Employee Benefit Trust - a self insured church plan	0
Univ. of Notre Dame v. Barwell, No. 3:13-cv-1276 (N.D. Ind.), No. 13-3853 (7th Cir.)		11,500 students, 5,000 employees	Complaint	yes		11,500 students, 5,000 employees
Valley Forge Christian College of the Assnibles of God v. Barwell, No. 14-4622 (E.D. Pa. Aug. 14, 2014)		Unknown	Complaint	No	Plaintiff voluntarily dismissed suit; our understanding is they were satisfied with previous	0
Wenganz Supply Co. v. Barwell, No. 2:12-cv-12061 (E.D. Mich.).		170 employees	DC Ruling	Yes		170
No. 14-1183		870 Employees	Complaint	Yes	Permanent injunction 02/22/2018	0
Wheaton College v. Barwell, No. 1:13-cv-08910 (N.D. Ill.), No. 14-2396 (7th Cir.)		3 employees	Complaint	Yes		3
Williams v. Barwell, No. 13-3-cv-01699 (D.D.C. Nov. 19, 2013);		15 employees	Complaint	Yes		15
Willis Law v. Barwell, No. 1:13-cv-01124-CKK (D.D.C. Aug. 23, 2013);		4 employees	Website	Yes		4
Yep v. Seblins, No. 1:12-cv-6756 (N.D. Ill.), Truine Health Group, Inc. v. Barwell, No. 1:12-cv-06756 (N.D. Ill.), No. 13-1478 (7th Cir.)		140+ full-time employees	Complaint	No	Diocese self-insured plan	0
Zulke v. Barwell, No. 2:13-cv-4159 (W.D. Pa.), Nos. 14-1377 (3d Cir.)	Diocese	115 employees	Complaint	No	Diocese self-insured plan	0
	Catholic Charities		Complaint		Diocese self-insured plan. Catholics was covered by the diocese's previous self-insured plan the Catholic Employees Benefits Plan. The new complaint says that CEBS was converted to the Catholic Benefits Trust, and Centers are omitted as ~~co-plaintiffs~~	0
	Catholic Cemeteries	207 employees	Complaint	No		0
Total						

estimated 2,100,000 students were covered by plans of four-year granting institutions of higher education, and there were a total of 20,207,000 students in degree-granting postsecondary institutions other than 2-year degree programs, see at [https://www.archdiocese.org/documents/Networks/Collisions/Why_Shiny_Mart et al.pdf](https://www.archdiocese.org/documents/Networks/Collisions/Why_Shiny_Mart_et_al.pdf) and https://nces.ed.gov/ipeds/data/ipeds/data/d16/tabs/d16_105.20.aspx?current=yes.

Total employees in affected plans 48,654

Total students in affected plans 2,626

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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA : CIVIL ACTION NUMBER
VS. 17-4540

DONALD J. TRUMP, ET AL.

THURSDAY, DECEMBER 14, 2017
COURTROOM 3B
PHILADELPHIA, PA 19106

BEFORE THE HONORABLE WENDY BEETLESTONE, ESQUIRE, J.

PRELIMINARY INJUNCTION HEARING

SUZANNE R. WHITE, RPR, FCRR, CM
OFFICIAL COURT REPORTER
FIRST FLOOR U. S. COURTHOUSE
601 MARKET STREET
PHILADELPHIA, PA 19106
(215) 627-1882

PROCEEDINGS RECORDED BY STENOGRAPHY-COMPUTER,
TRANSCRIPT PRODUCED BY COMPUTER-AIDED TRANSCRIPTION

1 **APPEARANCES:**

2 **OFFICE OF THE ATTORNEY GENERAL**
3 **JONATHAN SCOTT GOLDMAN, ESQUIRE**
4 **NICOLE J. BOLAND, ESQUIRE**
5 **STRAWBERRY SQUARE, 16TH FLOOR**
6 **HARRISBURG, PA 17120**

7 **AND**

8 **MICHAEL J. FISCHER, ESQUIRE**
9 **NICOLE BROCK, ESQUIRE**
10 **21 S. 12TH STREET, 3RD FLOOR**
11 **PHILADELPHIA, PA. 19107**

12 **COUNSEL FOR THE COMMONWEALTH OF PENNSYLVANIA**

13 **UNITED STATES DEPARTMENT OF JUSTICE**
14 **CIVIL DIVISION**
15 **ETHAN PRICE DAVIS, ESQUIRE**
16 **950 PENNSYLVANIA AVENUE, NW**
17 **ROOM 3133**
18 **WASHINGTON, DC 20530**

19 **AND**

20 **U.S. DEPARTMENT OF JUSTICE**
21 **ELIZABETH L. KADE, ESQUIRE**
22 **JUSTIN MICHAEL SANDBERG, ESQUIRE**
23 **REBECCA M. KOPPLIN, ESQUIRE**
24 **BRIAN STIMSON, ESQUIRE**
25 **CHRISTOPHER HEALY, ESQUIRE**
26 **20 MASSACHUSETTS AVENUE, NW**
27 **WASHINGTON, DC 20530**

28 **COUNSEL FOR DONALD TRUMP, ET AL.**

1 (THE CLERK OPENS COURT.)

2 THE COURT: WE ARE HERE IN THE MATTER OF
3 COMMONWEALTH OF PENNSYLVANIA VERSUS DONALD TRUMP; DONALD
4 WRIGHT, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN
5 SERVICES; STEVE MNUCHIN, UNITED STATES DEPARTMENT OF THE
6 TREASURY, RENE ALEXANDER ACOSTA, UNITED STATES
7 DEPARTMENT OF LABOR. THIS IS CASE NUMBER 17-4540.

8 TODAY WE HAVE A HEARING ON THE
9 COMMONWEALTH'S MOTION FOR A PRELIMINARY INJUNCTION.

10 LET ME TELL -- MOSTLY FOR THE FOLKS IN
11 THE COURTROOM, I HAVE ALREADY DETERMINED HOW THIS WILL
12 PROCEED. WE WILL BE WORKING FROM NOW UNTIL 6. IF THE
13 PARTIES FINISH BEFORE 6, THEN WE WILL FINISH BEFORE 6.

14 THE PARTIES HAVE REQUESTED OPENING
15 STATEMENTS. I HAVE ALLOWED THEM 15 MINUTES EACH FOR
16 OPENING STATEMENTS. THE PARTIES HAVE ALSO ASKED FOR
17 CLOSING STATEMENTS AND I HAVE ALLOWED THEM 15 MINUTES
18 EACH FOR CLOSING STATEMENTS.

19 IN THE INTERIM, IT IS MY VIEW THAT THIS
20 IS THE PLAINTIFF'S HEARING. I AM NOT GOING TO IMPOSE
21 ANY PARTICULAR RULES. I'M GOING TO ALLOW THEM TO DO
22 WHAT THEY THINK THEY NEED TO DO IN ORDER TO PROCEED.

23 WITH THAT, PLEASE CAN WE HAVE THE
24 INTRODUCTIONS ON THE PLAINTIFFS' SIDE, MOVING TO THE
25 DEFENSE SIDE.

1 MR. GOLDMAN: YOUR HONOR, MY NAME IS
2 JONATHAN GOLDMAN, THE EXECUTIVE DEPUTY ATTORNEY GENERAL
3 FOR THE COMMONWEALTH OF PENNSYLVANIA IN CHARGE OF THE
4 CIVIL LAW DIVISION.

5 MS. BOLAND: GOOD MORNING, YOUR HONOR.
6 MY NAME IS NICOLE BOLAND. I'M THE DEPUTY ATTORNEY
7 GENERAL WITH THE OFFICE OF ATTORNEY GENERAL.

8 MR. FISCHER: GOOD MORNING, YOUR HONOR.
9 MY NAME IS MICHAEL FISCHER, DEPUTY ATTORNEY GENERAL WITH
10 THE OFFICE OF ATTORNEY GENERAL.

11 THE COURT: AND NICOLE BROCK, IS SHE
12 HERE?

13 MS. BROCK: YES, YOUR HONOR. I'M NICOLE
14 BROCK, DEPUTY ATTORNEY GENERAL FROM THE OFFICE OF
15 ATTORNEY GENERAL.

16 MR. DAVIS: GOOD MORNING, YOUR HONOR. I
17 AM ETHAN DAVIS. I'M A DEPUTY ASSISTANT ATTORNEY GENERAL
18 WITH THE U.S. DEPARTMENT OF JUSTICE.

19 MS. KADE: GOOD MORNING, YOUR HONOR. MY
20 NAME IS ELIZABETH KADE. I'M A TRIAL ATTORNEY WITH THE
21 DEPARTMENT OF JUSTICE.

22 MR. SANDBERG: GOOD MORNING, YOUR HONOR.
23 I'M JUSTIN SANDBERG. I'M A CHIEF TRIAL COUNSEL WITH THE
24 DEPARTMENT OF JUSTICE.

25 MR. HEALY: GOOD MORNING, YOUR HONOR. MY

1 NAME IS CHRISTOPHER HEALY. I'M A TRIAL ATTORNEY FOR THE
2 U.S. DEPARTMENT OF JUSTICE.

3 MS. KOPPLIN: GOOD MORNING, YOUR HONOR.
4 MY NAME IS REBECCA KOPPLIN. I'M ALSO A TRIAL ATTORNEY
5 WITH THE DEPARTMENT OF JUSTICE.

6 THE COURT: MR. GOLDMAN.

7 MR. GOLDMAN: MAY I APPROACH, YOUR HONOR?

8 THE COURT: YOU MAY.

9 MR. GOLDMAN: BEFORE I BEGIN, YOUR HONOR,
10 IF WE CAN CLARIFY ONE THING. I BELIEVE WE HAD SPOKEN
11 ABOUT ON THE PHONE IN CONFERENCE THAT WE WOULD EACH HAVE
12 A HALF-HOUR FOR OPENINGS AND A HALF-HOUR FOR CLOSINGS.

13 THE COURT: I DID NOT RECALL IT THAT WAY,
14 BUT IF THAT IS HOW YOU WANT TO USE YOUR TIME, THAT IS
15 FINE. YOU SHOULD OF COURSE ASSUME THAT I HAVE READ ALL
16 THE BRIEFS AND THAT I'M VERY FAMILIAR WITH THE ARGUMENTS
17 THAT YOU MADE IN YOUR BRIEFS AND ALSO THE ATTACHMENTS
18 THERETO. SO TO THE EXTENT THAT IT'S POSSIBLE THAT YOU
19 NOT REPEAT WHAT IS IN THOSE DOCUMENTS, THAT WOULD
20 PROBABLY BE A GOOD THING.

21 GO AHEAD.

22 MR. GOLDMAN: THANK YOU, YOUR HONOR. AS
23 I SAID, MY NAME IS JONATHAN GOLDMAN. I'M HERE FOR THE
24 COMMONWEALTH OF PENNSYLVANIA.

25 IF I MAY ASK THE COURT'S INDULGENCE,

1 FOLLOWING OUR CONFERENCE ON TUESDAY EVENING AT WHICH
2 YOUR HONOR URGED THE PARTIES NOT TO BRING LIVE WITNESSES
3 TO REPEAT THE ALLEGATIONS ALREADY MADE UNDER OATH IN
4 THEIR DECLARATIONS, THERE ARE OTHER FACTS THAT ARE
5 ALREADY IN THE RECORD, WE SIGNIFICANTLY RESTRUCTURED OUR
6 CASE. AND SEEKING TO FOLLOWING YOUR HONOR'S GUIDANCE,
7 WE REDUCED THE NUMBER OF WITNESSES FROM SIX TO LIKELY
8 THREE, AND WE SCALED BACK THE TESTIMONY OF THOSE
9 WITNESSES.

10 THE LAWYERS BESIDE ME AT COUNSEL TABLE
11 AND ALSO BACK THERE ARE MEMBERS OF THE TEAM. WE HAVE
12 ALL WORKED TOGETHER, AND HAD WE HAD ALL SIX WITNESSES
13 HERE, EVERYBODY WOULD HAVE HAD A WITNESS, A SPEAKING
14 ROLE HERE. SOME MEMBERS OF COUNSEL MAY NOT, BUT I JUST
15 WANTED TO ACKNOWLEDGE THEIR HARD WORK FOR THE COURT.

16 THIS CASE IS ABOUT TWO NEW REGULATIONS
17 PROMULGATED BY THE DEFENDANTS, THE RELIGIOUS EXEMPTION
18 RULE AND THE MORAL EXEMPTION RULE. THESE ARE EXEMPTIONS
19 TO THE CONTRACEPTIVE MANDATE UNDER THE AFFORDABLE CARE
20 ACT, WHICH IS THE LAW OF THE LAND. AND THEY ARE
21 INCREDIBLY BROAD. THEY ARE THE EXCEPTIONS THAT SWALLOW
22 THE RULE. THEY WERE PROMULGATED OUTSIDE THE CONSTRAINTS
23 OF THE ADMINISTRATIVE PROCEDURE ACT AND ON TOP OF
24 ALREADY EXISTING EXCEPTIONS, A RELIGIOUS EXCEPTION AND
25 ACCOMMODATION, WHICH WERE MUCH NARROWER IN SCOPE. THEY

1 REQUIRE MORE ACCOUNTABILITY. AND IN THE CASE OF THE
2 ACCOMMODATION, THEY REQUIRE AN EMPLOYER'S INSURER TO
3 STEP IN AND PROVIDE CONTRACEPTIVE CONFERENCE FOR WOMEN
4 IF THE EMPLOYER OPTS OUT. THESE NEW RULES DO NOT DO
5 THAT.

6 AS A RESULT OF THESE NEW RULES, WOMEN IN
7 PENNSYLVANIA AND ACROSS THE COUNTRY TOO WILL LOSE THEIR
8 INSURANCE COVERAGE FOR CONTRACEPTIVE CARE. THIS WILL
9 COST THE COMMONWEALTH TO SUFFER ECONOMIC DAMAGES AS IT'S
10 FORCED TO STEP INTO THE BREACH, AND -- UNDER THE CURRENT
11 LAWS, AND COVER THE COST OF ADDITIONAL CONTRACEPTIVE
12 CARE FOR THE ADDITIONAL WOMEN WHO WILL NEED IT. AND
13 WHERE WOMEN ARE NOT ABLE TO GET CONTRACEPTIVE COVERAGE
14 THROUGH THE COMMONWEALTH OR ELSEWHERE, THERE WILL BE AN
15 INCREASE IN UNINTENDED PREGNANCIES, WHICH WILL CAUSE THE
16 COMMONWEALTH FURTHER ECONOMIC HARM.

17 IN ADDITION TO THESE ECONOMIC HARMS, THE
18 NEW RULES WILL CAUSE WOMEN IN THIS COMMONWEALTH AND
19 BEYOND TO SUFFER ECONOMIC HARM AND MEDICAL HARM, WHICH
20 FOR SOME WOMEN MAY BE CATASTROPHIC.

21 ON TOP OF THIS, THE RULES PLAINLY VIOLATE
22 THE LAW, AS WE HAVE LAID OUT IN OUR MOTION. THE
23 COMMONWEALTH TODAY ASKS ONLY THAT THE COURT ENFORCE THE
24 LAW AND ISSUE A PRELIMINARY INJUNCTION TO MAINTAIN THE
25 STATUS QUO UNTIL WE CAN HAVE A FULL TRIAL.

1 THE COURT: MR. GOLDMAN, GIVEN THE
2 ADMONITION THAT A COURT SHOULD NOT REACH CONSTITUTIONAL
3 ISSUES WHEN IT CAN RESOLVE A MATTER ON STATUTORY CLAIMS,
4 ARE YOU, IN THE CONTEXT OF THIS PRELIMINARY INJUNCTION,
5 PURSUING THE CONSTITUTIONAL CLAIMS OR ARE YOU FOCUSING
6 YOUR EFFORTS ON THE APA PROCEDURAL AND SUBSTANTIVE
7 CLAIMS?

8 MR. GOLDMAN: WE ARE, AS WE DID ON OUR
9 BRIEF, YOUR HONOR, WE'RE FOCUSING ON ALL OF THE CLAIMS.
10 THE REASON WHY IS THIS -- AND TO BE VERY CLEAR, THE
11 PROCEDURAL APA CLAIMS ARE VALID AND THE DEFENDANTS
12 VIOLATED THE PROCEDURAL APA. IF YOU WERE TO ENJOIN THE
13 RULES BASED ON THAT, PRESUMABLY IT WOULD NOT BE VERY
14 EFFICIENT. PRESUMABLY THE DEFENDANTS WOULD GO BACK,
15 TAKE THE SAME RULES, PUT THEM UP FOR NOTICE AND COMMENT
16 FOR 30 DAYS, AND THEN WE WOULD BE RIGHT BACK HERE BEFORE
17 YOUR HONOR ON THE MORE SUBSTANTIVE CLAIMS.

18 THE COURT: WELL, YOU HAVE TWO APA
19 CLAIMS. ONE IS A PROCEDURAL CLAIM AND ONE IS A
20 SUBSTANTIVE CLAIM UNDER THE APA. I THINK WHAT YOU SAID
21 WOULD OCCUR IF I DETERMINED IT ONLY UNDER THE PROCEDURAL
22 PRONG. BUT IF I ALSO DECIDED IT UNDER THE SUBSTANTIVE
23 PRONG, WOULD THAT SAME ISSUE OCCUR?

24 MR. GOLDMAN: NO, YOUR HONOR. IF YOU
25 DECIDED IT UNDER THE SUBSTANTIVE APA CLAIM, YOU COULD

1 ACTUALLY GET TO ALL OF THE CONSTITUTIONAL ISSUES THROUGH
2 THE APA CLAIM BECAUSE IT WOULD SHOW THAT THE LAW -- THE
3 APA WAS SUBSTANTIVELY VIOLATED BECAUSE THE RULES VIOLATE
4 THE LAW ON THE CONSTITUTIONAL GROUNDS, NOT THE GROUNDS
5 WE LAID OUT.

6 THE COURT: OKAY. GO AHEAD.

7 MR. GOLDMAN: SO TO YOUR POINT, YOUR
8 HONOR, WE DO HAVE FIVE CLAIMS HERE AND WE ARE URGING
9 YOUR HONOR TO CONSIDER ALL FIVE OF THEM: EQUAL
10 PROTECTION, TITLE VII UNDER THE CIVIL RIGHTS ACT; AND
11 THE PREGNANCY DISCRIMINATION ACT ESTABLISHMENT CLAUSE;
12 AND THEN THE PROCEDURAL AND SUBSTANTIVE APA CLAIMS.

13 I KNOW YOU ARE WELL AWARE OF THE STANDARD
14 FOR AN INJUNCTION. IT'S LAID OUT ON PAGE 17 OF OUR
15 MOTION. AND WE BELIEVE, YOUR HONOR, THAT WE HAVE SOME
16 WITNESSES TODAY TO ADD PRIMARILY ADDITIONAL TESTIMONY
17 AND COLOR AND NUANCE. WE BELIEVE THAT YOUR HONOR IS IN
18 GOOD STEAD TO ISSUE AN INJUNCTION ALREADY, BASED ON THE
19 FINDINGS OF FACT AND THE FACTS THAT ARE IN OUR MOTION
20 AND OUR PAPERS.

21 AND IF I MAY, I WOULD LIKE TO LIST THOSE
22 OUT, SINCE THEY ARE ALREADY IN THE RECORD, UNLESS YOUR
23 HONOR WOULD PREFER ME TO MOVE ON.

24 THE COURT: GO AHEAD.

25 MR. GOLDMAN: IN THE RECORD, THE FACTS

1 INCLUDE THE FOLLOWING. UNINTENDED PREGNANCY IS
2 PREVALENT IN THE UNITED STATES. THAT IS IN THE WEISMAN
3 DECLARATION AT PARAGRAPHS 22 THROUGH 23.

4 PREVENTING UNINTENDED PREGNANCY RESULTS
5 IN FINANCIAL SAVINGS FOR WOMEN. THAT IS IN THE WEISMAN
6 DECLARATION AT PARAGRAPHS 49 THROUGH 50 AND THE
7 STEINBERG DECLARATION AT PARAGRAPH 30.

8 UNINTENDED PREGNANCY IS A PREVENTABLE
9 HEALTH CONDITION FOR WOMEN, IN THE WEISMAN DECLARATION,
10 PARAGRAPHS 19 THROUGH 20, AND THE CHUANG DECLARATION AT
11 PARAGRAPHS 15 AND 41.

12 CONTRACEPTIVES ARE ALSO EFFECTIVE IN
13 PREVENTING UNINTENDED PREGNANCY. NOT ONLY IS THAT ON
14 TABLE 5-3 ON PAGE 106 OF THE COMMITTEE'S REPORT ITSELF,
15 IT'S ALSO IN THE WEISMAN DECLARATION AT PARAGRAPH 30,
16 THE CHUANG DECLARATION AT PARAGRAPHS 41 THROUGH 43, AND
17 THE STEINBERG DECLARATION AT PARAGRAPHS 30 AND THE BUTTS
18 DECLARATION AT PARAGRAPH 36.

19 WOMEN WHO FOREGO CONTRACEPTION OR USE
20 LESS EFFECTIVE CONTRACEPTION ARE AT RISK OF UNINTENDED
21 PREGNANCY. THAT IS ALREADY IN THE RECORD AT WEISMAN
22 DECLARATION, PARAGRAPH 48, CHUANG DECLARATION PARAGRAPH
23 39, STEINBERG DECLARATION PARAGRAPH 30, AND THE BUTTS
24 DECLARATION AT PARAGRAPH 58.

25 THE COURT: THERE IS NO NEED TO REFER TO

1 THE RECORD. I KNOW THE RECORD. JUST SAY WHAT YOU NEED
2 TO SAY, AND I WILL BELIEVE YOU THAT IT'S IN THE RECORD.

3 MR. GOLDMAN: THANK YOU.

4 THE COURT: UNLESS OPPOSING COUNSEL SAYS
5 IT'S NOT IN THE RECORD, AND THEN WE WILL HAVE A LITTLE
6 FIGHT ON IT.

7 MR. GOLDMAN: FAIR ENOUGH.

8 COST IS A BARRIER TO ASSESSING
9 CONTRACEPTION CARE. BEFORE THE ACA'S CONTRACEPTION
10 MANDATE, PATIENTS WOULD NOT FILL THEIR CONTRACEPTIVE
11 PRESCRIPTIONS, OPTING INSTEAD TO ASK THEIR PHYSICIANS
12 FOR LESS EFFECTIVE BUT CHEAPER METHODS OF CONTRACEPTION
13 AT LEAST UP FRONT, ULTIMATELY NOT CHEAPER IN THE LONG
14 RUN. BEFORE THAT CONTRACEPTIVE MANDATE, PATIENTS WOULD
15 NOT FILL THEIR CONTRACEPTIVE PRESCRIPTIONS, OPTING
16 INSTEAD TO FAIL TO USE CONTRACEPTION SOMETIMES
17 ALTOGETHER BECAUSE OF THE COST. BEFORE THE ACA
18 CONTRACEPTIVE MANDATE, IUDS WERE ONE OF THE MOST
19 EXPENSIVE FORMS OF CONTRACEPTIVES FOR PATIENTS IN TERMS
20 OF THE INITIAL COST WHICH HAS TO BE PAID UP FRONT. AND
21 YET IUDS ARE A MUCH MORE EFFECTIVE METHOD OF
22 CONTRACEPTIVE CARE THAN ARE BIRTH CONTROL PILLS AND
23 OBVIOUSLY THAN ARE NOTHING.

24 THE CONTRACEPTION MANDATE HAS RESULTED IN
25 MORE WOMEN USING CONTRACEPTIVES GENERALLY AND MORE

1 EFFECTIVE METHODS OF CONTRACEPTIVES SPECIFICALLY. MORE
2 WOMEN ARE USING IUDS, FOR EXAMPLE, THAN ORAL BIRTH
3 CONTROL PILLS OR NO METHOD OF CONTRACEPTION AT ALL, SUCH
4 THAT AFTER THE CONTRACEPTIVE MANDATE PATIENTS WERE FREE
5 TO MAKE CONTRACEPTIVE CHOICES PURELY ON THE BASIS OF
6 MEDICAL NEEDS, LISTENING TO THE RECOMMENDATIONS OF THEIR
7 DOCTORS, WITHOUT HAVING TO WEIGH THE COST OF CARE, WHICH
8 IS EXACTLY WHAT THE AFFORDABLE CARE ACT INTENDED. AND
9 AS A RESULT, AFTER THE CONTRACEPTIVE MANDATE, PATIENTS
10 HAD MADE MORE MEDICALLY INFORMED CONTRACEPTIVE CHOICES,
11 WHICH HAVE BEEN BETTER FOR THE HEALTH OF THEM AND THEIR
12 FAMILIES.

13 THE PENNSYLVANIA DEPARTMENT OF HEALTH AND
14 HUMAN SERVICES HAS ENCOURAGED THE USE OF LARCS,
15 LONG-ACTING CONTRACEPTION, AS POST PARTUM CONTRACEPTION
16 TO REDUCE THE RATE OF UNINTENDED PREGNANCIES BY CHANGING
17 ITS FEE FOR SERVICE PAYMENT POLICIES FOR HOSPITAL
18 PROVIDERS, A POLICY OF THE COMMONWEALTH.

19 MORE THAN 2.5 MILLION WOMEN IN
20 PENNSYLVANIA COULD BENEFIT FROM THE CONTRACEPTIVE CARE
21 MANDATE AND OVER 700,000 PENNSYLVANIANS HAVE ENROLLED IN
22 MEDICAID AS A RESULT OF THE EXPANSION UNDER THE
23 CONTRACEPTIVE CARE MANDATE.

24 THE DEPARTMENT OF INSURANCE ESTIMATES
25 THAT THE WOMEN IN PENNSYLVANIA WHO HAVE BENEFITED FROM

1 THE CONTRACEPTIVE CARE MANDATE HAVE SAVED OVER
2 \$250 MILLION ANNUALLY, AND THOSE ARE JUST THE DOLLARS.
3 THAT IS NOT THE HEALTH BENEFITS.

4 HOWEVER, YOUR HONOR, PENNSYLVANIA HAS NO
5 STATUTE OR REGULATION REQUIRING EMPLOYERS OFFERING PLANS
6 REGULATED BY THE PENNSYLVANIA DEPARTMENT OF INSURANCE
7 THAT OPT OUT OF THE CONTRACEPTIVE CARE MANDATE TO
8 PROVIDE CONTRACEPTIVE COVERAGE TO ITS EMPLOYEES OR
9 BENEFICIARIES. OTHER STATES MAY HAVE A LAW LIKE THAT.
10 THIS ONE DOESN'T. AND SIMILARLY, PENNSYLVANIA HAS NO
11 STATUTE OR REGULATION REQUIRING EMPLOYERS OFFERING PLANS
12 REGULATED BY ERISA THAT OPT OUT TO PROVIDE CONTRACEPTIVE
13 COVERAGE TO ITS EMPLOYEES OR BENEFICIARIES.

14 THEREFORE, DUE TO THE NEW RULES AND
15 REGULATIONS, THESE EXEMPTIONS, WOMEN WILL LOSE
16 CONTRACEPTIVE COVERAGE WHEN THEIR EMPLOYERS OPT OUT OF
17 PROVIDING IT, OR IN SOME CASES THE EMPLOYERS OF THEIR
18 SPOUSES THROUGH WHOM THEY HAVE COVERAGE. AS A RESULT
19 SOME OF THESE WOMEN WILL FAIL TO USE CONTRACEPTIVES OR
20 WILL USE LESS EFFECTIVE CONTRACEPTIVE METHODS DUE TO THE
21 COST. WE HAVE SEEN THIS ALREADY.

22 MANY WOMEN WHOSE EMPLOYERS REFUSE TO
23 PROVIDE COVERAGE FOR THEIR CONTRACEPTIVE COSTS WILL SEEK
24 FINANCIAL ASSISTANCE THROUGH STATE GOVERNMENT PROGRAMS.
25 THIS GETS TO THE ISSUE OF STATE HARM. THE AMOUNT OF

1 MONEY THE COMMONWEALTH SPENDS ON MEDICAID AND THE FAMILY
2 PLANNING SERVICES PROGRAM IS CONTINGENT UPON ENROLLMENT
3 SO THAT THE MORE PEOPLE HAVE TO HERE ENROLL IN THESE
4 STATE PROGRAMS, THE MORE MONEY THE COMMONWEALTH MUST
5 SPEND ON THEM. THE NEW RULES WILL IMPOSE ADDITIONAL
6 ECONOMIC AND OTHER BURDENS ON FAMILY PLANNING CLINICS
7 AROUND PENNSYLVANIA, AND THE COMMONWEALTH OF
8 PENNSYLVANIA WILL BEAR MUCH OF THAT BURDEN. LOW INCOME
9 WOMEN WHO ARE NOT ELIGIBLE FOR FUNDING THROUGH STATE
10 GOVERNMENT PROGRAMS WILL BE FORCED TO CHOOSE BETWEEN
11 PAYING OUT OF POCKET, IF THEY CAN, OR GOING WITHOUT
12 CONTRACEPTION ALTOGETHER. WOMEN WHO STOP USING
13 CONTRACEPTION ARE MORE LIKELY TO HAVE UNPLANNED
14 PREGNANCIES AND TO REQUIRE ADDITIONAL MEDICAL ATTENTION.
15 THESE THINGS ARE IN MANY WAYS TRUISMS.

16 BECAUSE PATIENTS WILL LOSE CONTRACEPTIVE
17 COVERAGE UNDER THE NEW RULES, THEY WILL THEN MAKE LESS
18 MEDICALLY SOUND CONTRACEPTIVE CHOICES AND THEREFORE THEY
19 WILL BE HARMED.

20 MANY WOMEN WHO NO LONGER RECEIVE
21 CONTRACEPTIVE COVERAGE WILL NOT ONLY FACE FINANCIAL HARM
22 BUT WILL ALSO FACE MEDICAL HARM. AND AGAIN, SOME CASES
23 YOU WILL HEAR AND IT'S ALREADY IN THE RECORD, THAT CAN
24 BE CATASTROPHIC, EVEN FATAL HARM.

25 IN SUM, THE NEW RULES WILL HAVE A

1 NEGATIVE EFFECT ON THE HEALTH OF PENNSYLVANIA WOMEN.
2 THAT IS IN ADDITION TO THE ECONOMIC HARM AND OTHER HARM
3 TO THE COMMONWEALTH AS A WHOLE.

4 THE COURT: MR. GOLDMAN, I JUST NEED
5 TO -- I NEED TO ROLL YOU BACK TO THE VERY BEGINNING, AND
6 THAT ISSUE IS STANDING. I THINK SOME OF THE BRIEFING IS
7 ABOUT STANDING. AND THE QUESTION IS, DOES THE
8 COMMONWEALTH HAVE STANDING TO CHALLENGE AN AFFIRMATIVE
9 ACTION OF AN AGENCY, AND IF SO, WHAT IS YOUR SUPPORT FOR
10 THAT POSITION?

11 MR. GOLDMAN: THE COMMONWEALTH ABSOLUTELY
12 DOES HAVE THAT STANDING. IT IS STANDING BOTH IN TERMS
13 OF REAL ECONOMIC HARM. IT HAS SUFFERED HARM AND WILL
14 SUFFER HARM. AND THEN ALSO UNDER THE PARENS PATRIAE
15 DOCTRINE WHERE IT IS ABLE TO ASSERT STANDING ON BEHALF
16 OF ITS CITIZENS IN A MORE GLOBAL SENSE.

17 THE COURT: WHICH CASE ARE YOU RELYING ON
18 OR WHICH SET OF CASES?

19 MR. GOLDMAN: FORGIVE ME, JUDGE. THE
20 CASES ARE IN OUR BRIEF.

21 THE COURT: WHO IS THE STANDING ATTORNEY
22 WHO DID THE ANALYSIS FOR THAT? WHY DON'T YOU COME UP
23 AND TELL ME ABOUT THAT.

24 MR. FISCHER: THANK YOU, YOUR HONOR.

25 MR. GOLDMAN: MAY I STAND HERE, YOUR

1 HONOR?

2 THE COURT: YOU MAY.

3 MR. FISCHER: GOOD MORNING, YOUR HONOR.

4 MICHAEL FISCHER FOR THE COMMONWEALTH.

5 AS MR. GOLDMAN SAID, THE COMMONWEALTH
6 DOES HAVE STANDING, BOTH DIRECT STANDING AS A RESULT OF
7 THE FINANCIAL HARM, AS WELL AS PARENS PATRIAE STANDING
8 TO ASSERT ITS INTEREST IN PROTECTING THE HEALTH AND
9 WELFARE OF ITS RESIDENTS. AS WE DISCUSSED IN OUR BRIEF,
10 WE THINK MASSACHUSETTS VERSUS EPA IS A TEXTBOOK EXAMPLE
11 OF WHEN A STATE CAN ASSERT STANDING BASED BOTH ON A
12 DIRECT INJURY AS WELL AS A PARENS PATRIAE THEORY.

13 THE COURT: WASN'T MASSACHUSETTS A CASE
14 INVOLVING INACTION RATHER THAN AFFIRMATIVE ACTION?

15 MR. FISCHER: IT WAS AN INACTION CASE,
16 YOU ARE RIGHT. TEXAS VERSUS UNITED STATES IS AN ACTION
17 CASE. NOW AS THE COURT INDICATED IN THE DIRECTION WE
18 WERE SENT, THAT CASE WAS AFFIRMED BY AN EVENLY DIVIDED
19 SUPREME COURT. SO IT IS NOT -- THE COURT'S DECISION IS
20 NOT BINDING ON YOUR HONOR.

21 HOWEVER, THE FIFTH CIRCUIT'S DECISION WE
22 THINK IS INSTRUCTIVE. THE FIFTH CIRCUIT LOOKED AT THE
23 GOVERNMENT'S POLICY, THE DAPA PROGRAM IN THAT CASE THAT
24 HAD BEEN IMPLEMENTED, DECIDED IT WOULD CAUSE THE STATE
25 OF TEXAS AND OTHER STATES DIRECT FINANCIAL HARM, FOUND

1 THAT THAT WAS SUFFICIENT TO ESTABLISH STATE STANDING.
2 THAT DECISION AGAIN WAS AFFIRMED BY AN EVENLY DIVIDED
3 COURT. SO AT LEAST FOUR JUSTICES OF THE COURT AT THE
4 TIME WERE CONVINCED THAT THE STATE DID HAVE STANDING.

5 WE THINK THIS IS REALLY NO DIFFERENT FROM
6 ANY OTHER STANDING ANALYSIS INVOLVING OTHER -- INVOLVING
7 PRIVATE PLAINTIFFS, INVOLVING OTHER GOVERNMENT
8 PLAINTIFFS. THE COMMONWEALTH HERE ALLEGES A DIRECT
9 FINANCIAL HARM. THAT IS INJURY IN FACT. THAT IS
10 TEXTBOOK INJURY IN FACT. IT IS CLEARLY TRACEABLE TO THE
11 DEFENDANT'S ACTIONS. IT IS CLEARLY REDRESSABLE THROUGH
12 RELIEF IN THIS COURT. SO WE BELIEVE IT'S FAIRLY CLEAR
13 THAT WE SATISFY THE ELEMENTS OF STANDING UNDER A DIRECT
14 THEORY.

15 AND IN ADDITION, UNDER PARENS PATRIAE
16 THEORY, THERE IS SOME, I WILL ADMIT, SOMEWHAT CONFUSING
17 CASE LAW ON PARENS PATRIAE THEORY. BUT ONE THEME THAT
18 EMERGES, AND THIS IS ACTUALLY DISCUSSED AT LENGTH IN THE
19 DISTRICT COURT DECISION IN TEXAS VERSUS UNITED STATES,
20 IS THAT WHERE A STATE IS ASSERTING ITS QUASI SOVEREIGN
21 INTEREST IN PROTECTING THE HEALTH AND WELFARE OF ITS
22 CITIZENS, IT MAY DO SO IN CHALLENGING FEDERAL AGENCY
23 ACTION THAT IT ALLEGES IS IN VIOLATION OF A FEDERAL
24 STATUTE. THAT IS WHAT WE ARE ALLEGING HERE.

25 THERE ARE CASES GOING BACK TO I BELIEVE

1 MASSACHUSETTS VERSUS MELLON THAT SAY A STATE CANNOT
2 ASSERT PARENS PATRIAE STANDING AGAINST THE FEDERAL
3 GOVERNMENT IN CHALLENGING A FEDERAL STATUTE.

4 THE COURT: WELL, IS THIS -- THIS CONCEPT
5 CALLED SPECIAL SOLICITUDE?

6 MR. FISCHER: YES.

7 THE COURT: AND I HAVE TO SAY THAT THE
8 CONCEPT OF SPECIAL SOLICITUDE IS, SHALL WE SAY, NOT AS
9 CRYSTAL CLEAR AS IT COULD BE IN THE JURISPRUDENCE.

10 MR. FISCHER: ABSOLUTELY.

11 THE COURT: TELL ME, HOW DOES IT APPLY,
12 WHEN DOES IT APPLY, HOW DO I USE IT?

13 MR. FISCHER: IT APPLIES -- AND THE
14 SPECIAL SOLICITUDE IS DISCUSSED IN MASSACHUSETTS VS.
15 EPA, ALTHOUGH ACTUALLY, THE PHRASE APPEARS FIRST IN, I
16 BELIEVE, THE D.C. CIRCUIT DECISION THAT WE CITED -- I
17 APOLOGIZE, I FORGET THE NAME -- BUT AUTHORED BY THEN
18 JUDGE SCALIA, WHERE HE TALKED AT LENGTH ABOUT PARENS
19 PATRIAE STANDING AND QUASI-SOVEREIGN STANDING.

20 THE ESSENCE OF SPECIAL SOLICITUDE, WE
21 BELIEVE, IS THAT A STATE HAS -- THAT THE COURT SHOULD
22 GIVE ADDITIONAL DEFERENCE TO STATES IN ANALYZING THE
23 EXTENT OF ANY INJURY THAT IS SUFFERED TO WHETHER OR NOT
24 THAT INJURY CONFERS STANDING.

25 NOW, HERE -- FRANKLY, WE -- AS I SAID

1 EARLIER, I DON'T THINK IT'S NECESSARY TO EVEN RELY ON
2 SPECIAL SOLICITUDE, BUT IN MASSACHUSETTS VERSUS EPA, THE
3 COURT ESSENTIALLY SAID THE STATE OF MASSACHUSETTS,
4 COMMONWEALTH OF MASSACHUSETTS, CAN ASSERT ITS INTEREST
5 IN PROTECTING ITS CITIZENS FROM ENVIRONMENTAL HARM.
6 THAT RESPONSIBILITY WAS ACTUALLY DELEGATED TO EPA.

7 EPA, UNDER THE SUPREMACY CLAUSE, COULD
8 PROHIBIT MASSACHUSETTS FROM ACTING. SO SINCE EPA HAD
9 THAT RESPONSIBILITY, MASSACHUSETTS, BECAUSE IT SIMILARLY
10 HAD A DUTY TO PROTECT ITS CITIZENS, COULD CHALLENGE
11 EPA'S INACTION IN THAT CASE UNDER THIS THEORY THAT AS A
12 SOVEREIGN STATE, IT COULD INITIATE LITIGATION TO PROTECT
13 THE -- IN THAT CASE, THE INTEREST OF ITS CITIZENS, A
14 CLEAN ENVIRONMENT AND PROTECTION FROM THE HARMFUL
15 EFFECTS OF CLIMATE CHANGE.

16 WE BELIEVE THAT DOES -- THAT EXPLAINS THE
17 CONCEPT OF SPECIAL SOLICITUDE, THAT THERE IS ADDITIONAL
18 DEFERENCE GIVEN TO A STATE WHEN IT'S ASSERTING AN
19 INTEREST IN PROTECTING BOTH ITS OWN SOVEREIGN
20 PREROGATIVES. THERE YOU HAD COASTLINE THAT
21 MASSACHUSETTS ARGUED WAS BEING ERODED, AS WELL AS THE
22 INTEREST OF ITS STATE -- INTEREST OF ITS RESIDENTS.

23 THE COURT: SO IS THE SPECIAL SOLICITUDE,
24 IS IT, FOR WANT OF A BETTER TERM, A GLOSS OVER THE
25 STANDING INQUIRY THAT I MUST UNDERTAKE OR DOES IT IMPACT

1 ON ANY OF THE PRONGS OF THE STANDING ANALYSIS IN
2 PARTICULAR?

3 MR. FISCHER: YOUR HONOR, I BELIEVE -- I
4 WOULD SAY THAT IT'S BOTH TO SOME EXTENT. IT IS A GLOSS,
5 BUT I THINK IT IS PARTICULARLY DIRECTED TO THE INJURY
6 PRONG. IT IS LESS RELEVANT TO I THINK THE CAUSATION AND
7 REDRESSABILITY PRONGS, BUT IT DOES ALLOW THE
8 COMMONWEALTH OR STATE TO ASSERT INJURIES THAT MAY BE IN
9 SOME CASES, FOR A PRIVATE LITIGANT, WOULD NOT BE
10 SUFFICIENT.

11 IT'S HARD TO THINK OF AN ANALOGOUS
12 SITUATION INVOLVING A PRIVATE LITIGANT TO MASSACHUSETTS
13 VERSUS EPA, BUT IT SEEMS LIKE THE COURT IS SAYING THAT
14 TO THE EXTENT THERE IS ANY AMBIGUITY OR DOUBT HERE ABOUT
15 WHETHER THIS IS A SUFFICIENT INJURY, WE ARE GOING TO
16 RECOGNIZE THE STATE'S SOVEREIGN PREROGATIVE AND
17 QUASI-SOVEREIGN INTEREST IN PROTECTING ITS CITIZENS AND
18 FIND THAT THERE IS SUFFICIENT INTEREST HERE.

19 THE COURT: OKAY. THANK YOU,
20 MR. FISCHER.

21 MR. FISCHER: THANK YOU, YOUR HONOR.

22 THE COURT: MR. GOLDMAN, YOU HAVE MORE
23 TIME IF YOU WANT TO.

24 MR. GOLDMAN: IF I MAY ASK MR. FISCHER TO
25 STAY HERE FOR ONE MOMENT, BECAUSE I WOULD LIKE TO TRY TO

1 MARRY UP A LITTLE BIT MASSACHUSETTS V EPA WITH THE CASE
2 HERE.

3 THE COURT: OKAY.

4 MR. GOLDMAN: AND THAT IS MASSACHUSETTS
5 VERSUS EPA, THERE WAS A LAW PROTECTING THE ENVIRONMENT
6 WHICH ALSO PROTECTED THE CITIZENS OF MASSACHUSETTS. THE
7 AGENCIES FAILED TO ENFORCE THAT LAW IN A WAY THAT HARMED
8 MASSACHUSETTS. MASSACHUSETTS THEREFORE HAD STANDING.

9 SIMILARLY HERE, THERE IS A LAW THAT
10 PROTECTS WOMEN AND PEOPLE AROUND THE COUNTRY; THAT'S THE
11 AFFORDABLE CARE ACT AND THE CONTRACEPTIVE CARE MANDATE.
12 THAT ALSO PROTECTS THE CITIZENS OF PENNSYLVANIA, MEN AND
13 WOMEN, AND HERE, THE AGENCIES ARE NOT ENFORCING THE
14 CONTRACEPTIVE CARE ACT. AND IN FACT, THE REGULATIONS AT
15 ISSUE HERE HAVE UNDERMINED THE ACT, AND THAT IS -- IT'S
16 VERY MUCH ON PAR AND IT REINFORCES THE STANDING THAT THE
17 COMMONWEALTH HAS HERE.

18 THE COURT: OKAY, THANK YOU. PROCEED.

19 MR. GOLDMAN: SO ALL OF THAT IS ALREADY
20 IN THE RECORD, YOUR HONOR. AND AGAIN, WE BELIEVE YOUR
21 HONOR CAN SAFELY ISSUE AN INJUNCTION RIGHT NOW, AND IF
22 YOU ARE INCLINED TO DO THAT, WE WOULD SIT DOWN, BUT I
23 ASSUME WE WILL KEEP ARGUING OUR CASE.

24 ON TOP OF THAT, YOUR HONOR, WE ARE POISED
25 TO BRING THREE WITNESSES TO THE COURT TODAY. THE FIRST

1 IS DR. CAROL WEISMAN. SHE WILL ADD -- THERE'S A
2 DECLARATION IN THE RECORD, AS YOU WELL KNOW. SHE WILL
3 ADD ADDITIONAL PERSPECTIVE TODAY AS ONE OF ONLY 16
4 MEMBERS OF THE INSTITUTE OF MEDICINES COMMITTEE ON
5 PREVENTATIVE SERVICES FOR WOMEN THAT WAS CONVENED BY THE
6 HEALTH RESOURCES SERVICES ADMINISTRATION, THE HRSA, IN
7 CONNECTION WITH THE AFFORDABLE CARE ACT.

8 SHE WILL ALSO SPEAK ABOUT HER ROLE IN A
9 STUDY PERFORMED SINCE THE ACA HAS GONE INTO EFFECT THAT
10 DEMONSTRATES THAT THE CONTRACEPTIVE MANDATE HAS IN FACT
11 RESULTED IN WOMEN MAKING BETTER, SAFER, MORE EFFECTIVE
12 AND MORE COST-EFFECTIVE HEALTH CHOICES.

13 THE COURT: IN PENNSYLVANIA?

14 MR. GOLDMAN: YES, YOUR HONOR.

15 DR. SAMANTHA BUTTS WILL ALSO SPEAK TODAY,
16 YOUR HONOR. SHE HAS, AS YOU KNOW, HAS A DECLARATION IN
17 THIS CASE AS WELL. SHE IS GOING TO ADD ADDITIONAL
18 PERSPECTIVE AS A MEDICAL DOCTOR, TEACHER AND RESEARCHER
19 WHO USES A VARIETY OF CONTRACEPTIVES TO TREAT PATIENTS
20 AS PART OF HER PRACTICE, WHICH INCLUDES INFERTILITY,
21 HELPING WOMEN CONCEIVE.

22 AND YES, YOU WILL HEAR HOW SHE IS USING
23 CONTRACEPTIVES AS PART OF HER PRACTICE AT THE UNIVERSITY
24 OF PENNSYLVANIA SCHOOL OF MEDICINE IN WEST PHILADELPHIA.
25 AND SHE WILL ALSO PROVIDE TESTIMONY ABOUT HOW

1 HER ABILITY TO PRESCRIBE THE BEST CONTRACEPTIVE
2 PRESCRIPTIONS FOR PATIENTS CHANGED PRE AND POST
3 CONTRACEPTIVE CARE MANDATE AND WHAT THAT WILL MEAN THEN
4 FOR HOW WOMEN WILL BE HARMED UNDER THE NEW RULES AS
5 THEIR EMPLOYERS OPT OUT OF PROVIDING COVERAGE.

6 AND LAST, DR. CYNTHIA CHUANG WILL ALSO
7 TESTIFY TODAY.

8 THE COURT: CHUANG, T-U-O-N-G?

9 MR. GOLDMAN: I'M SORRY, IT'S
10 C-H-U-A-N-G.

11 THE COURT: OKAY.

12 MR. GOLDMAN: AND IT'S PRONOUNCED CHUANG.
13 SHE WILL ADD ADDITIONAL PERSPECTIVE AS A MEDICAL DOCTOR,
14 TEACHER AND RESEARCHER WHO TREATS PATIENTS AT THE
15 HERSHEY MEDICAL CENTER IN HERSHEY, PENNSYLVANIA.

16 SHE WILL ALSO PROVIDE SOME TESTIMONY
17 ABOUT SOME OF HER OWN RESEARCH THAT HAS DEMONSTRATED
18 THAT SINCE THE ACA'S CONTRACEPTIVE MANDATE HAS GONE INTO
19 EFFECT IT ALSO HAS IN FACT RESULTED IN WOMEN MAKING
20 BETTER, SAFER, MORE EFFECTIVE AND MORE COST-EFFECTIVE
21 HEALTH CHOICES.

22 WE WILL DO OUR BEST AS WE RAISE THEM TO
23 NOT BE DUPLICATIVE OF WHAT IS IN THE RECORD, AND YOU
24 HAVE MADE VERY CLEAR, YOUR HONOR, YOUR COUNSEL TO DO
25 THAT. WE HAVE RESTRUCTURED OUR WITNESS OUTLINES. WE DO

1 HAVE SOME LAYING OF FOUNDATION. IF AT ANY POINT YOU
2 FEEL LIKE YOU HAVE ALREADY HEARD THAT, BY ALL MEANS,
3 SHEPHERD US ALONG, AND WE WILL DO OUR BEST TO DO THAT TO
4 OURSELVES SO YOU DON'T HAVE TO.

5 THE COURT: I'M ASSUMING THAT THE
6 DEFENDANTS WILL NOT PUT YOU THROUGH THE PROCESS OF
7 SETTING FORTH A DEEP FOUNDATION FOR EVERYTHING THAT IS
8 TO BE ELICITED.

9 MS. KADE: YOUR HONOR, WE HAVE STIPULATED
10 TO THE ADMISSIBILITY OF EVERYTHING EXCEPT FOR THE
11 DEMONSTRATIVE EXHIBITS.

12 THE COURT: THANK YOU. OKAY.

13 MR. GOLDMAN: IN CONCLUSION, YOUR HONOR,
14 WE BELIEVE THAT YOU CAN ISSUE THIS INJUNCTION NOW. WE
15 HOPE THAT YOU WILL DO SO AS SOON AS YOUR HONOR IS READY,
16 AND WILL DO SO CONSIDERING ALL OF THE DIFFERENT CLAIMS
17 TO KEEP THE STATUS QUO IN PLACE AND PROTECT THE CITIZENS
18 OF THE COMMONWEALTH.

19 THE COURT: SO I UNDERSTAND THERE IS A
20 DATE BY WHICH PENNSYLVANIA THINKS IT WOULD BE USEFUL FOR
21 ME TO HAVE DECIDED THIS MATTER.

22 MR. GOLDMAN: THERE IS, YOUR HONOR. I
23 WOULD SAY BEYOND USEFUL, I WOULD SAY EVEN NECESSARY.
24 THAT DATE IS JANUARY 1ST, 2018. THE REASON WHY THAT
25 DATE IS IMPORTANT IS BECAUSE MANY ERISA HEALTHCARE PLANS

1 HAVE AN OPEN ENROLLMENT WHERE THE NEW PLANS START ON THE
2 FIRST OF THE YEAR. NOT ALL OF THEM, BUT MANY. SO THAT
3 WILL BE A -- WE BELIEVE A LARGE WINDOW WHERE POLICIES
4 WILL CHANGE, EMPLOYERS WILL START TAKING ADVANTAGE OF
5 THESE NEW RULES.

6 THE COURT: OKAY. SO YOU ARE SAYING THAT
7 BECAUSE THE EXEMPTIONS WERE PUT IN PLACE EFFECTIVE
8 IMMEDIATELY THAT WHILE THERE MAY BE NO CHANGE IN PLANS
9 RIGHT NOW, AS OF JANUARY THE 1ST, BECAUSE THERE IS THIS
10 OPEN ENROLLMENT PERIOD, IT IS LIKELY THAT THE PLANS WILL
11 CHANGE AT THAT POINT?

12 MR. GOLDMAN: CORRECT, YOUR HONOR. AND
13 BY THE WAY, IT IS CERTAINLY POSSIBLE THAT PLANS HAVE
14 ALREADY CHANGED IF APPROPRIATE NOTICE HAS BEEN GIVEN.
15 WE JUST DON'T KNOW THAT YET. WE HAVE NOT SEEN THAT YET.

16 THE COURT: OKAY. THANK YOU VERY MUCH.

17 MR. GOLDMAN: THANK YOU, YOUR HONOR.

18 THE COURT: DEFENSE.

19 MR. DAVIS: MAY I APPROACH, YOUR HONOR?

20 THE COURT: YOU MAY.

21 MR. DAVIS: GOOD MORNING, YOUR HONOR.

22 ETHAN DAVIS FOR THE UNITED STATES.

23 IF THERE IS ONE THEME WE WOULD ASK YOUR
24 HONOR TO KEEP IN MIND TODAY AS WE HEAR FROM THE
25 WITNESSES, IT IS THAT THIS COURT IS NOT WRITING ON A

1 BLANK SLATE. OVER THE PAST SIX YEARS, DOZENS OF
2 ENTITIES WITH RELIGIOUS AND MORAL OBJECTIONS HAVE SUED
3 OVER THE CONTRACEPTIVE COVERAGE REQUIREMENT.

4 THOSE LAWSUITS PRODUCED A PATCHWORK OF
5 PRELIMINARY AND PERMANENT INJUNCTIONS THROUGHOUT THE
6 UNITED STATES, MANY OF WHICH ARE STILL IN EFFECT TODAY.
7 THE SUPREME COURT ALSO WEIGHED IN ON THESE ISSUES FOUR
8 TIMES, FIRST IN HOBBY LOBBY, THEN IN LITTLE SISTERS,
9 THEN IN WHEATON COLLEGE, AND FINALLY IN ZUBIK.

10 AND THE FEDERAL GOVERNMENT HAS CHANGED
11 THE RULES GOVERNING CONTRACEPTIVE COVERAGE MULTIPLE
12 TIMES SINCE 2011. THERE IS A LOT OF WATER UNDER THE
13 BRIDGE AND THIS POINT MATTERS TO VIRTUALLY ALL OF THE
14 ISSUES IN THIS CASE.

15 FIRST ON STANDING. THE COMMONWEALTH'S
16 PAPERS GIVE THE IMPRESSION THAT THE NEW RULES ARE GOING
17 TO WITHDRAW CONTRACEPTIVE COVERAGE FROM MILLIONS OF
18 WOMEN WHO ARE CURRENTLY RECEIVING COVERAGE AND THAT THEY
19 ARE THE EXCEPTION THAT WILL SWALLOW THE RULE, BUT IT
20 SHOULD NOT ESCAPE YOUR NOTICE, YOUR HONOR, THAT NONE OF
21 THOSE MILLIONS OF WOMEN WHO WILL SUPPOSEDLY BE AFFECTED
22 BY THESE RULES IS A PLAINTIFF IN THIS CASE, NOR DID ANY
23 OF THEM SUBMIT A DECLARATION EXPLAINING THAT AN EMPLOYER
24 IS ABOUT TO DROP CONTRACEPTIVE COVERAGE.

25 AND WHY DON'T WE SEE ANY INDIVIDUALS IN

1 THIS CASE, YOUR HONOR? IT'S BECAUSE YOUR HONOR IS NOT
2 WRITING ON A BLANK SLATE. MANY AND MAYBE ALL OF THE
3 RELIGIOUS EMPLOYERS WHO OBJECT TO PROVIDING
4 CONTRACEPTIVE COVERAGE HAVE ALREADY SUED. MANY ARE
5 ALREADY PROTECTED BY INJUNCTIONS. SO EMPLOYEES WHO WORK
6 FOR THOSE RELIGIOUS ORGANIZATIONS HAVE NOT BEEN
7 RECEIVING CONTRACEPTIVE COVERAGE FOR YEARS.

8 TAKE THE LITTLE SISTERS AS AN EXAMPLE.
9 AS YOUR HONOR RECOGNIZED IN DENYING THE LITTLE SISTERS
10 MOTION TO INTERVENE, GRANTING AN INJUNCTION IN THIS CASE
11 WOULD NOT CHANGE THE FACT THAT THE LITTLE SISTERS ARE
12 NOT CURRENTLY PROVIDING CONTRACEPTIVE COVERAGE TO THEIR
13 EMPLOYEES.

14 THE COURT: WELL, I AGREE WITH YOU WITH
15 RESPECT TO THE RELIGIOUS EXEMPTION. QUITE CLEARLY THERE
16 HAS BEEN A LOT OF LITIGATION ABOUT THIS, BUT THE MORAL
17 EXEMPTION IS SOMETHING NEW, ISN'T IT?

18 MR. DAVIS: THE MORAL EXEMPTION IS NEW,
19 YOUR HONOR, BUT THERE'S ALSO BEEN LITIGATION OVER THAT.
20 THERE WAS A CASE HERE IN PENNSYLVANIA, THE REAL
21 ALTERNATIVES CASE, AND THERE WAS ALSO A CASE IN D.C.
22 CALLED MARCH FOR LIFE. SO I DON'T THINK THE LITIGATION
23 OVER THAT IS NEW.

24 THE COURT: WELL, BUT IN THE CONTEXT OF
25 THE AFFORDABLE CARE ACT, IT IS NEW, BECAUSE THE MORAL

1 EXEMPTION WAS ONLY ISSUED A FEW WEEKS AGO. SO THERE HAS
2 BEEN NO LITIGATION IN THE CONTEXT OF THE MORAL EXEMPTION
3 OR A MORAL EXEMPTION AS IT APPLIES TO THE ACA, CORRECT?

4 MR. DAVIS: I AGREE WITH THAT, YOUR
5 HONOR. THERE HAS BEEN DISCUSSIONS OF CONSCIENCE ISSUES
6 DURING THE RULEMAKINGS, BUT THERE HAS NOT BEEN
7 LITIGATION OVER THIS MORAL EXEMPTION RULE, THIS ONE THAT
8 WAS JUST PASSED IN 2017, UNTIL NOW.

9 THE COURT: SO I'M A LITTLE PUZZLED BY
10 WHAT THE MORAL EXEMPTION MEANS. HOW DOES ONE
11 DETERMINE -- WELL, A COUPLE OF QUESTIONS. HOW DOES AN
12 ENTITY DETERMINE THAT IT HAS A MORAL CONVICTION? HOW IS
13 THAT CONVICTION INSTANTIATED THROUGHOUT THE ENTIRE
14 ORGANIZATION? WHO MAKES -- IN OTHER WORDS, WHO MAKES
15 THE DETERMINATION? AND HOW DOES ONE DECIDE WHAT IS
16 MORAL AND WHAT IS NOT MORAL?

17 I UNDERSTAND IN THE CONTEXT OF RELIGION
18 THAT THERE ARE QUITE CLEAR MORAL PRECEPTS, BUT WE ARE A
19 COUNTRY WHERE, RIGHTLY OR WRONGLY, WHETHER YOU AGREE
20 WITH IT OR NOT, PEOPLE HAVE VERY DIFFERENT VIEWS ABOUT
21 WHAT MORALITY IS. SO HELP ME UNDERSTAND THE MORALITY
22 EXEMPTION IN THE CONTEXT OF THOSE QUESTIONS.

23 MR. DAVIS: SURE. YOUR HONOR, THE FIRST
24 THING I SAY ABOUT THAT IS THAT THE MORAL EXEMPTION RULE
25 DOES NOT APPLY TO PUBLICLY TRADED COMPANIES, UNLIKE THE

1 RELIGIOUS EXEMPTION RULE, SO WE ARE TALKING ONLY ABOUT
2 CLOSELY-HELD ENTITIES. SO IN TERMS OF DECIDING WHO CAN
3 ASSERT THE MORAL CLAIM, I THINK IT WOULD JUST BE THE
4 OWNERS OF A CLOSELY-HELD ORGANIZATION OR A NONPROFIT.

5 THE COURT: ARE YOU POSITIVE OF THAT?

6 MR. DAVIS: YES, YOUR HONOR.

7 THE COURT: OKAY.

8 MR. DAVIS: THAT'S NOT TRUE FOR
9 RELIGIOUS.

10 THE COURT: I'LL HAVE TO REREAD THE MORAL
11 EXEMPTION, BECAUSE I THOUGHT IT SAID SOMETHING CONTRARY
12 TO THAT.

13 MR. DAVIS: IT DOES NOT, YOUR HONOR.

14 THE COURT: I WILL TAKE A LOOK AT IT.

15 MR. DAVIS: SO THE ONLY QUESTION IS WHO
16 CAN ASSERT IT. I THINK THAT WOULD BE JUST THE SAME
17 PEOPLE WHO CAN ASSERT THE CLAIM IN A CONTEXT OF THE
18 RELIGIOUS EXEMPTION, WHICH WOULD BE THE OWNERS OF THE
19 CLOSELY HELD COMPANY OF WHOEVER RUNS A NONPROFIT. SO
20 THAT'S THAT QUESTION.

21 AS TO YOUR OTHER QUESTION ABOUT WHAT DOES
22 IT LOOK LIKE TO ASSERT THIS KIND OF CLAIM, I THINK IT
23 LOOKS VERY SIMILAR TO WHAT HAPPENS WITH A RELIGIOUS
24 EXEMPTION. I MEAN, THE EMPLOYER WILL JUST ASSERT A
25 SINCERELY-HELD MORAL CONVICTION, AND THEN THAT EMPLOYER

1 IS EXEMPT.

2 I WILL SAY I DOUBT THAT THIS WILL BE
3 WIDELY USED, BECAUSE AS THE RULES POINT OUT, PROVIDING
4 CONTRACEPTIVE COVERAGE IS COST NEUTRAL. SO THERE REALLY
5 WOULDN'T BE A REASON TO ASSERT THIS UNLESS AN EMPLOYER
6 ACTUALLY DID HAVE A SINCERE --

7 THE COURT: WELL, WHAT IF A -- WHAT IF
8 THE CEO OF THE COMPANY HAD A SINCERELY-HELD MORAL
9 CONVICTION THAT WOMEN SHOULD REMAIN AT HOME AND THAT --
10 AND MADE A DETERMINATION, THEREFORE, NOT TO PROVIDE
11 CONTRACEPTIVE SERVICES IN THE INSURANCE PLAN OF THE
12 COMPANY IN ORDER TO IMPOSE HIS NORMATIVE CONSTRUCT ON
13 HIS WORKFORCE, BUT THE BOARD OF DIRECTORS DOES NOT AGREE
14 WITH THAT. IN FACT, THEY BELIEVE THAT THERE IS A MORAL
15 IMPERATIVE THAT WOMEN BE ALLOWED TO MAKE THEIR OWN
16 CHOICES. HOW DO YOU DETERMINE, ONE, WHAT IS AN
17 APPROPRIATE MORAL CONVICTION, AND TWO, WHO PREVAILS IN
18 THAT CONTEXT?

19 MR. DAVIS: WELL, A COUPLE OF ANSWERS TO
20 THAT, YOUR HONOR. THE FIRST IS THAT I THINK GENERAL
21 PRINCIPLES OF CORPORATE LAW WOULD ANSWER THE QUESTION
22 ABOUT WHO IS ENTITLED TO ADVANCE THAT KIND OF OBJECTION
23 ON BEHALF OF THE COMPANY. BUT IF YOUR HONOR'S
24 HYPOTHETICAL POSES A SITUATION WHERE THE EMPLOYER
25 ACTUALLY DOES NOT HAVE A SINCERE OBJECTION, IT'S REALLY

1 A PRETEXT FOR COVERING --

2 THE COURT: NO, I'M NOT SUGGESTING IT'S A
3 PRETEXT. THE CEO REALLY DOES BELIEVE, AS A MORAL
4 MATTER, THAT WOMEN SHOULD STAY AT HOME.

5 MR. DAVIS: BUT THE CEO DOES NOT HAVE A
6 MORAL OBJECTION TO PROVIDING CONTRACEPTIVE COVERAGE.
7 THE REAL OBJECTION IS TO -- THE REAL --

8 THE COURT: HE HAS A MORAL OBJECTION TO
9 PROVIDING COVERAGE BECAUSE HE THINKS THAT WOMEN SHOULD
10 STAY AT HOME AND HE BELIEVES THAT WOMEN SHOULD STAY AT
11 HOME -- IF THEY ARE PREGNANT ALL THE TIME, THEY ARE
12 GOING TO STAY AT HOME.

13 MR. DAVIS: YOUR HONOR, AGAIN, I THINK --

14 THE COURT: DON'T BUCK THE HYPOTHETICAL.
15 JUST ANSWER THE QUESTION.

16 MR. DAVIS: UNDER THAT HYPOTHETICAL, YOUR
17 HONOR, I ASSUME THAT EMPLOYEES WOULD COMPLAIN ABOUT IT
18 TO IRS OR TREASURY OR LABOR, AND THE LABOR DEPARTMENT
19 DOES HAVE A ROLE IN POLICING THE SINCERITY OF
20 RELIGIOUS -- OR NOT -- NOT THE SINCERITY.

21 THE COURT: SO THE DEPARTMENT OF LABOR
22 WOULD BE POLICING THE MORAL CONVICTIONS OF AN ENTITY?

23 MR. DAVIS: NO. THE DEPARTMENT OF LABOR
24 COULD CONCEIVABLY, IN THAT CIRCUMSTANCE, ASK WHETHER A
25 PARTICULAR -- POLICE THAT KIND OF SITUATION TO A DEGREE.

1 IT PROBABLY WOULDN'T --

2 THE COURT: SO WHO WOULD BE POLICING
3 WHETHER A MORAL CONVICTION IS APPROPRIATELY HELD?

4 MR. DAVIS: I THINK, AGAIN, IT WOULD
5 DEPEND ON THE CIRCUMSTANCES. IF AN EMPLOYEE WERE TO SAY
6 TO THE GOVERNMENT THAT THERE IS NOT IN FACT A SINCERE
7 MORAL OBJECTION TO PROVIDING CONTRACEPTIVE COVERAGE,
8 THAT IN FACT, WHAT IS GOING ON HERE IS IT'S
9 DISCRIMINATION AGAINST WOMEN, AND THAT IS -- THEN I
10 THINK THAT THE LABOR DEPARTMENT COULD INVESTIGATE THAT.

11 THE COURT: SO THE LABOR DEPARTMENT WOULD
12 HAVE TO BE DETERMINING WHAT A MORAL CONVICTION --
13 WHETHER A MORAL CONVICTION IS APPROPRIATE OR NOT?

14 MR. DAVIS: I WOULD NOT PUT IT THAT
15 BROADLY, YOUR HONOR. I WOULD SAY IF THERE IS A -- AS
16 LONG AS THERE IS A SINCERE MORAL OBJECTION TO PROVIDE
17 CONTRACEPTIVE COVERAGE, THEN THAT EMPLOYER IS EXEMPT,
18 PERIOD. AND ONLY IF THAT --

19 THE COURT: WELL, YOU ARE STILL BUCKING
20 THE HYPOTHETICAL. IF THERE IS A MORAL CONVICTION RULE
21 OUT THERE, SOMEONE IS GOING TO HAVE TO DETERMINE WHETHER
22 IT IS AN APPROPRIATE MORAL CONVICTION OR NOT, CORRECT?

23 MR. DAVIS: NO, I DON'T AGREE WITH THAT,
24 YOUR HONOR.

25 THE COURT: SO IS IT JUST SORT OF A

1 FREE-FLOATING CONCEPT THAT EVERYBODY DECIDES THEMSELVES
2 AND NOBODY POLICES IT?

3 MR. DAVIS: YOUR HONOR, I WOULDN'T CALL
4 IT A FREE-FLOATING CONCEPT THAT IS TOTALLY UNPOLICED. I
5 WOULD SAY THAT, LIKE THE RELIGIOUS EXEMPTION, THE ONLY
6 QUESTION THAT IS ASKED IS WHETHER AN EMPLOYER HAS A
7 SINCERE RELIGIOUS OR MORAL OBJECTION TO PROVIDING
8 CONTRACEPTIVE COVERAGE, AND IF THAT IS TRUE, THEN THAT
9 EMPLOYER IS EXEMPT.

10 THE COURT: OKAY. SO WHAT YOU'RE TELLING
11 ME IS IF THE CEO SAYS I HAVE A SINCERE MORAL CONVICTION
12 TO NOT PROVIDE CONTRACEPTIVES TO WOMEN BECAUSE I WANT
13 THEM TO STAY AT HOME, THAT IS FINE?

14 MR. DAVIS: I WOULD NOT SAY THAT IS FINE,
15 YOUR HONOR. I WOULD SAY THAT IN THAT CIRCUMSTANCE,
16 AGAIN, AN EMPLOYEE MIGHT COMPLAIN TO THE LABOR
17 DEPARTMENT AND THERE IS SOME ROLE FOR THE LABOR
18 DEPARTMENT --

19 THE COURT: THE LABOR DEPARTMENT, OKAY.

20 MR. DAVIS: WE CAN FOLLOW UP ON THAT.

21 THE COURT: MOVE ON.

22 MR. DAVIS: I WOULD SAY, RETURNING TO
23 STANDING, YOUR HONOR, BECAUSE THE LITTLE SISTERS ARE
24 PROTECTED BY THE ZUBIK INJUNCTION WHICH PROHIBITS THE
25 FEDERAL GOVERNMENT FROM ENFORCING THE MANDATE AGAINST

1 THEM. THE SAME IS TRUE OF MANY OTHER RELIGIOUS
2 ORGANIZATIONS. AND THAT IS WHY THE ONLY SPECIFIC
3 EXAMPLE OF AN EMPLOYER WHO'S GOING TO DROP COVERAGE THAT
4 PENNSYLVANIA WAS ABLE TO GIVE WAS THE UNIVERSITY OF
5 NOTRE DAME, BUT AS THE COURT KNOWS, NOTRE DAME LATER
6 ANNOUNCED THAT ITS THIRD-PARTY ADMINISTRATOR WOULD
7 CONTINUE TO OFFER NO COST CONTRACEPTIVE COVERAGE.

8 I'M NOT SAYING THAT IT'S IMPOSSIBLE THAT
9 ANYONE WOULD EVER HAVE STANDING TO CHALLENGE THESE
10 RULES, YOUR HONOR. WHAT I'M SAYING IS THAT IT'S
11 PENNSYLVANIA'S BURDEN TO SHOW YOUR HONOR SOMEONE WHO IS
12 GOING TO LOSE COVERAGE, AND THEY HAVEN'T BEEN ABLE TO DO
13 THAT, EVEN AFTER CLAIMING THAT MILLIONS OF WOMEN COULD
14 BE AFFECTED BY THIS.

15 I SUSPECT YOU WILL HEAR TODAY FROM THE
16 COMMONWEALTH'S WITNESS ABOUT THEIR CONCERNS ABOUT THE
17 IMPACT THAT THE NEW RULES WILL HAVE ON WOMEN'S ACCESS TO
18 CONTRACEPTION. WE HAVE NOT DEPOSED THESE WITNESSES. WE
19 DON'T KNOW WHAT THEY ARE GOING TO SAY, BUT I URGE YOUR
20 HONOR TO LISTEN TO WHETHER ANY OF THEM CAN POINT TO A
21 SINGLE PENNSYLVANIA EMPLOYER OR ANY EMPLOYER OR A SINGLE
22 EMPLOYEE WHO IS GOING TO LOSE COVERAGE AS OF
23 JANUARY 1ST.

24 I WOULD ALSO LIKE TO TALK A LITTLE ABOUT
25 THE PARENS PATRIAE THEORY THAT CAME UP EARLIER. YOUR

1 HONOR, IT HAS BEEN WELL SETTLED SINCE MASSACHUSETTS
2 VERSUS MELLON, 1923, THAT A STATE CANNOT REPRESENT ITS
3 CITIZENS PARENS PATRIAE AGAINST THE FEDERAL GOVERNMENT.
4 AS MELLON EXPLAINED IT, IT HAS NO POWER -- IT IS NO PART
5 OF ITS DUTY OR POWER TO ENFORCE THEIR RIGHTS IN RESPECT
6 OF THEIR RELATIONS WITH THE FEDERAL GOVERNMENT. AND
7 THAT FIELD IS THE UNITED STATES AND NOT THE STATE WHICH
8 REPRESENTS THEM AS PARENS PATRIAE. THERE IS NO
9 EXCEPTION TO THAT RULE IN MELLON FOR CASES WHERE THE
10 STATE IS CHALLENGING A FEDERAL AGENCY ACTION INSTEAD OF
11 A STATUTE.

12 AND MASSACHUSETTS VERSUS EPA, YOUR HONOR,
13 THE SPECIAL SOLICITUDE DISCUSSION THAT WE HAD EARLIER, I
14 THINK THE BEST WAY TO UNDERSTAND THE SPECIAL SOLICITUDE
15 POINT IS THAT IT APPLIES WHEN THE STATE IS ABLE TO SHOW
16 AN INJURY TO ITS CONCRETE SOVEREIGN INTEREST. AND IN
17 MASSACHUSETTS VERSUS EPA, THAT WAS AN INJURY TO THE
18 TERRITORY OF THE STATE ITSELF. AND THAT IS WHAT THIS
19 CASE SAYS. I HAVE IT HERE. IT SAYS: GIVEN
20 MASSACHUSETTS STATE IN PROTECTING ITS QUASI SOVEREIGN
21 INTEREST, THE COMMONWEALTH IS ENTITLED TO SPECIAL
22 SOLICITUDE IN ITS STANDING ANALYSIS. I DON'T THINK WE
23 HAVE ANYTHING LIKE THAT HERE. WE DON'T HAVE ANY DAMAGE
24 TO THE STATE'S TERRITORY. ALL WE HAVE IS SPECULATION
25 THAT SOME EMPLOYERS WILL ULTIMATELY SHIFT FROM CURRENTLY

1 PROVIDING COVERAGE TO NOT PROVIDING COVERAGE.

2 THE COURT: LET ME TALK TO YOU ABOUT THE
3 TEXAS VERSUS UNITED STATES CASE IN THE CONTEXT OF
4 STANDING. SO IN THAT CASE THE SUPREME COURT CERTIFIED A
5 NUMBER OF ISSUES, INCLUDING WHETHER OR NOT TEXAS HAD
6 STANDING. AND THEN IT AFFIRMED BY AN EQUALLY DIVIDED
7 COURT WITHOUT OPINION.

8 NOW ONE OF THE QUESTIONS THAT I ASKED YOU
9 TO LOOK AT IS, GIVEN SILLIMAN VERSUS HUDSON RIVER BRIDGE
10 COMPANY, WHICH I KNOW IS AN OLD CASE, 1861. DON'T TELL
11 ME IT'S OLD SO THEREFORE IT DOES NOT APPLY. WHAT IS THE
12 IMPACT IN YOUR VIEW OF SILLIMAN ON TEXAS VERSUS THE
13 UNITED STATES, PARTICULARLY THE STANDING ANALYSIS THAT
14 THE COURT IN TEXAS VERSUS UNITED STATES IN THE 5TH
15 CIRCUIT DID.

16 MR. DAVIS: YOUR HONOR, I THINK THAT
17 SINCE HUDSON BRIDGE, THE COURT HAS SAID REPEATEDLY THAT
18 AN AFFIRMANCE BY AN EQUALLY DIVIDED COURT IS NOT
19 ENTITLED TO PRECEDENTIAL WEIGHT.

20 THE COURT: WELL, EXCEPT SILLIMAN TALKED
21 ABOUT THE JURISDICTIONAL CONTEXT, WHICH IS WHY IT IS
22 DIFFERENT.

23 MR. DAVIS: I DON'T SEE ANY CASE SINCE
24 SILLIMAN THAT SAYS THAT THE JURISDICTIONAL CONTEXT WOULD
25 BE DIFFERENT, THAT SOMEHOW BECAUSE IT'S A JURISDICTIONAL

1 DECISION THAT THE COURT'S AFFIRMANCE WOULD BE ENTITLED
2 TO --

3 THE COURT: NO. I THINK THE POINT IS
4 THAT SILLIMAN WAS A JURISDICTIONAL DECISION. AND AS FAR
5 AS WE CAN FIND, THE ONLY ISSUE WHEN THERE WAS AN EQUALLY
6 DIVIDED COURT THAT CONCERNED A JURISDICTIONAL ANALYSIS.
7 SO EVEN THOUGH SUBSEQUENT CASES HAVE SAID GENERALLY
8 EQUALLY DIVIDED COURTS ARE NOT BINDING PRECEDENT,
9 SILLIMAN SUGGESTS THAT THERE IS THIS CARVEOUT IN THE
10 CONTEXT OF STANDING.

11 AND SO MY QUESTION TO YOU IS, DO I JUST
12 IGNORE SILLIMAN OR DO I SAY THAT IT IS TOO OLD OR DO I
13 SAY THAT SOMEHOW IT HAS BEEN MOOTED AT THIS POINT?

14 MR. DAVIS: YOUR HONOR, I WOULD SAY YOU
15 SHOULD READ SILLIMAN IN LIGHT OF THE CASES THAT CAME
16 LATER. AND THE CASES THAT CAME LATER SAID FLATLY,
17 WITHOUT CARVING OUT JURISDICTION OR ANYTHING ELSE, THOSE
18 CASES SAID AN AFFIRMANCE BY AN EQUALLY DIVIDED COURT IS
19 NOT ENTITLED TO PRECEDENTIAL EFFECT. I'M NOT AWARE -- I
20 HAVE NOT EXHAUSTIVELY LOOKED AT EVERY CASE SINCE 1861,
21 BUT I'M NOT AWARE OF ANY CASE SINCE THEN THAT HAS HELD
22 THAT A JURISDICTIONAL DECISION -- THAT AFFIRMANCE BY AN
23 EQUALLY DIVIDED COURT OF A JURISDICTIONAL DECISION IS
24 ENTITLED TO PRECEDENTIAL FORCE, OF THE SUPREME COURT.

25 THE CASES I WOULD CITE TO YOUR HONOR,

1 NEIL VERSUS BIGGERS, THAT'S N-E-I-L VERSUS
2 B-I-G-G-E-R-S, 409 U.S. 188 AT 192. THAT IS A 1972
3 SUPREME COURT DECISION.

4 AND ARKANSAS WRITERS' PROJECT VERSUS
5 RAGLAND, 481 U.S. 221. THAT'S A 1987 SUPREME COURT
6 DECISION THAT HELD: OF COURSE, AN AFFIRMANCE BY AN
7 EQUALLY DIVIDED COURT IS NOT ENTITLED TO ANY
8 PRECEDENTIAL WEIGHT.

9 THE COURT: I WILL TAKE A LOOK AT THOSE
10 CASES.

11 MOVE ON.

12 MR. DAVIS: I WOULD LIKE TO TALK A LITTLE
13 ABOUT THE PROCEDURAL APA ISSUE, YOUR HONOR.

14 HERE AGAIN, YOUR HONOR IS NOT WRITING ON
15 A BLANK SLATE. LIKE THE LAST ADMINISTRATION DID THREE
16 TIMES IN 2010, 2011 AND 2014, THE AGENCIES ISSUED THE
17 NEW RULES AS INTERIM FINAL RULES. LIKE THOSE PRIOR
18 IFRS, THREE SEPARATE LAWS PROVIDE STATUTORY AUTHORITY:
19 26 U.S.C. 9833; 29 U.S.C. --

20 THE COURT: ARE YOU TALKING ABOUT --
21 YOU'RE CONNECTING WITH THE ORIGINAL RELIGIOUS EXEMPTION,
22 THE SECOND RELIGIOUS EXEMPTION? IS THAT WHAT WE ARE
23 TALKING ABOUT HERE?

24 MR. DAVIS: NO, YOUR HONOR. WE ARE
25 TALKING ABOUT JUST THE BASIS OF STATUTORY AUTHORITY TO

1 DO THIS AS AN IFR INSTEAD OF THROUGH NOTICE AND COMMENT.
2 I THINK EVEN APART FROM THE APA, THERE ARE THREE
3 SEPARATE STATUTES THAT GIVE THE AGENCIES INDEPENDENT
4 AUTHORITY TO DO THIS.

5 THE COURT: OKAY.

6 MR. DAVIS: AND THOSE STATUTES SAY THAT
7 THE SECRETARY MAY PROMULGATE ANY INTERIM FINAL RULES AS
8 THE SECRETARY DETERMINES ARE APPROPRIATE. THAT IS THE
9 SAME AUTHORITY THAT THE PRIOR ADMINISTRATION RELIED ON
10 TO DO THESE AS INTERIM FINAL RULES, AND WE ARE RELYING
11 ON IT AS WELL.

12 IF YOUR HONOR DID NOT THINK THAT WAS
13 SUFFICIENT, THERE WAS ALSO GOOD CAUSE DIRECTLY UNDER THE
14 APA, AND THE D.C. CIRCUIT EXPRESSLY UPHELD ONE OF THE
15 LAST ADMINISTRATION'S CONTRACEPTIVE COVERAGE IFRS IN THE
16 PRIESTS FOR LIFE DECISION. AND THERE, LIKE HERE, THE
17 AGENCY MADE A GOOD CAUSE FINDING IN THE RULE THAT IT
18 ISSUED. THERE, LIKE HERE, THE IFR WAS MODIFYING
19 REGULATIONS THAT HAD RECENTLY BEEN ENACTED UNDER NOTICE
20 AND COMMENT RULE MAKING. THERE, LIKE HERE, THE ISSUES
21 THE IFR HAD ADDRESSED HAD ALREADY BEEN SUBJECTED TO
22 THOUSANDS AND THOUSANDS OF COMMENTS. THERE, LIKE HERE,
23 HHS EXPOSED ITS INTERIM FINAL RULE TO COMMENTS BEFORE
24 PERMANENT IMPLEMENTATION. AND THERE, LIKE HERE, THE
25 GOVERNMENT WAS -- THERE THE GOVERNMENT WAS RESPONDING TO

1 THE SUPREME COURT'S DECISION IN WHEATON COLLEGE. HERE
2 THE GOVERNMENT WAS RESPONDING TO THE SUPREME COURT'S
3 DECISION IN ZUBIK. THERE DELAY AND IMPLEMENTATION OF
4 THE RULE WOULD DELAY THE IMPLEMENTATION OF THE
5 ALTERNATIVE OPT-OUT FOR RELIGIOUS OBJECTORS. AND HERE
6 DELAY WOULD INTERFERE WITH THE IMPLEMENTATION OF THE
7 RELIGIOUS AND MORAL EXEMPTIONS. SO I THINK IF THERE WAS
8 GOOD CAUSE IN PRIESTS FOR LIFE, I THINK THERE IS GOOD
9 CAUSE HERE.

10 THE COURT: WELL, IN PRIESTS FOR LIFE,
11 THE NEW IFRS WERE PRETTY MUCH IDENTICAL TO PRIOR
12 REGULATIONS, WEREN'T THEY?

13 MR. DAVIS: I DON'T THINK THEY WERE
14 VIRTUALLY IDENTICAL, YOUR HONOR. THE IFR EXPANDED THE
15 WAY THE ACCOMMODATION COULD BE INVOKED.

16 THE COURT: WELL, BUT THEY DIDN'T MAKE
17 SIGNIFICANT CHANGES IN THE LAW, DID THEY?

18 MR. DAVIS: WELL, I DON'T KNOW IF I WOULD
19 EVEN DESCRIBE THIS AS A MORE SIGNIFICANT CHANGE THAN THE
20 ONE AT ISSUE, PRIESTS FOR LIFE, YOUR HONOR.

21 THE COURT: SO YOU WOULD SAY THAT THE
22 RELIGIOUS EXEMPTION AND THE MORAL EXEMPTIONS ARE NOT
23 SIGNIFICANT CHANGES.

24 MR. DAVIS: I WOULD NOT SAY IT THAT WAY,
25 YOUR HONOR. I WOULD SAY THEY ARE ARGUABLY NOT MORE

1 SIGNIFICANT THAN THE CHANGE AT ISSUE IN THE IFR THAT WAS
2 RESPONDING TO WHEATON COLLEGE. THAT IS BECAUSE, LIKE I
3 HAVE DISCUSSED, THERE IS NO INDICATION HERE THAT ANYONE
4 IS GOING TO LOSE CONTRACEPTIVE COVERAGE AS A RESULT OF
5 THESE NEW RULES. BACK THEN IT WAS A -- THERE WAS A
6 RELATIVELY SIGNIFICANT CHANGE TO THE RULES TO EXPAND THE
7 WAY THAT THE ENTITIES COULD INVOKE THE ACCOMMODATION.

8 BUT I WOULD SAY EVEN IF YOUR HONOR DOES
9 NOT SEE IT THAT WAY AND THINKS THAT THIS CHANGE IS MORE
10 SIGNIFICANT THAN THE ONE BACK IN 2014, THAT IS ONLY ONE
11 OF THE FACTORS IN THE PRIESTS FOR LIFE DECISION.

12 THE COURT: WELL, THE OTHER ONE WAS GOOD
13 CAUSE. BUT IN PRIESTS FOR LIFE I THINK THE COURT MADE A
14 DETERMINATION THAT THERE WAS GOOD CAUSE AND THUS SAID --
15 PUTTING ASIDE WHETHER THERE WAS -- THEY WERE IDENTICAL
16 OR WHETHER THERE WAS A SIGNIFICANT CHANGE, THEN SAID IT
17 WAS APPROPRIATE. BUT IN THIS CASE I HAVE TO -- ARE
18 YOU -- DO YOU AGREE THAT I HAVE TO MAKE A THRESHOLD
19 DETERMINATION OF GOOD CAUSE BEFORE I CAN GET INTO THE
20 SAME SPACE THAT PRIESTS FOR LIFE -- THE PRIESTS FOR LIFE
21 COURT WAS OR IS IT YOUR VIEW THAT I DON'T HAVE TO MAKE
22 THAT DETERMINATION OF GOOD CAUSE BEFORE GOING ALONG WITH
23 THE HOLDING IN THAT CASE?

24 MR. DAVIS: YOUR HONOR, IF I UNDERSTAND
25 THE QUESTION CORRECTLY, I THINK THAT ALL OF THOSE --

1 THESE FACTORS WE HAVE BEEN DISCUSSING GO TO WHETHER OR
2 NOT THERE WAS GOOD CAUSE TO DO THE IFR IN THAT CASE AS
3 AN IFR INSTEAD OF THROUGH NOTICE AND COMMENT. I THINK
4 THE SIGNIFICANCE OF THE CHANGE IS ALL UNDER THAT HEADING
5 OF WHETHER OR NOT THERE IS GOOD CAUSE. I WOULD SAY YOU
6 DON'T EVEN HAVE TO REACH THE GOOD CAUSE ISSUE AT ALL IN
7 OUR VIEW BECAUSE OF THE SEPARATE BASES OF STATUTORY
8 AUTHORITY. BUT IN THE EVENT YOU WERE TO REACH THE GOOD
9 CAUSE ISSUE, I THINK IF YOU READ THAT PART OF THAT -- OF
10 THE D.C. CIRCUIT'S DECISION, I THINK WE ARE ALMOST ON
11 ALL FOURS WITH IT HERE.

12 THE COURT: GO AHEAD.

13 MR. DAVIS: I WOULD LIKE TO MOVE TO THE
14 STATUTORY AUTHORITY FOR THE EXEMPTIONS.

15 THE COURT: GO AHEAD.

16 MR. DAVIS: YOUR HONOR, IN OUR VIEW WE
17 HAVE THREE SEPARATE BASES OF STATUTORY AUTHORITY.

18 THE FIRST IS THE AFFORDABLE CARE ACT
19 ITSELF. HERE AGAIN, YOUR HONOR IS NOT WRITING ON A
20 BLANK SLATE. THIS IS THE SOURCE OF AUTHORITY THAT THE
21 LAST ADMINISTRATION USED TO CRAFT THE ORIGINAL RELIGIOUS
22 EMPLOYER EXEMPTION. THE STATUTE IS A BROADLY WORDED
23 DELEGATION OF AUTHORITY TO THE AGENCIES. IT PROVIDES
24 THAT COVERED GROUP HEALTH PLANS SHALL PROVIDE -- OR
25 SHALL COVER WHATEVER HRSA SPECIFIES IN ITS GUIDELINES.

1 THE BREADTH OF THE STATUTE IS APPARENT
2 WHEN COMPARED TO THE OTHER THREE SUBSECTIONS OF THAT
3 STATUTE. THOSE SUBSECTIONS ADDRESS EVIDENCE BASED ITEMS
4 OF SERVICES, IMMUNIZATIONS AND SERVICES FOR CHILDREN,
5 ADDRESS GUIDELINES THAT WERE ALREADY IN EXISTENCE AT THE
6 TIME THE AFFORDABLE CARE ACT WAS ENACTED. AND
7 SUBSECTION (A) (4) WAS A GRANT OF AUTHORITY TO DEVELOP
8 GUIDELINES THAT DID NOT ALREADY EXIST.

9 AND ON PAGE 23 OF ITS BRIEF, PENNSYLVANIA
10 ARGUES THAT NOTHING IN THE LANGUAGE OF THE ACA OR ITS
11 LEGISLATIVE HISTORY SUGGESTS THAT CONGRESS INTENDED TO
12 GIVE DEFENDANTS OR ANY AGENCY BLANKET AUTHORITY TO
13 PERMIT EMPLOYEES TO OPT-OUT. IF THAT IS TRUE, THE
14 ORIGINAL EXEMPTION FOR CHURCHES HAS TO FALL AS WELL,
15 WHICH WOULD EXPOSES CHURCHES AND HOUSES OF WORSHIP TO
16 THE MANDATE FOR THE FIRST TIME. AND THAT RESULT WOULD
17 IMPERIL THE MANDATE ITSELF BECAUSE WE KNOW FROM HOBBY
18 LOBBY THAT IT IMPOSES A SUBSTANTIAL BURDEN.

19 SO PENNSYLVANIA ALSO ARGUES THAT THE
20 RULES CONFLICT WITH THE PURPOSE OF THE STATUTE, WHICH IS
21 TO INCREASE COVERAGE FOR PREVENTIVE SERVICES. AND THAT
22 ARGUMENT WOULD ALSO WIPE AWAY THE ORIGINAL CHURCH
23 EXEMPTION. IT'S ALSO INCONSISTENT WITH THE BEST
24 EVIDENCE OF A STATUTE'S PURPOSE, WHICH IS ITS TEXT. AND
25 THE ACA DOES NOT REQUIRE GROUP HEALTH PLANS TO COVER

1 CONTRACEPTION. IT DOES NOT MENTION CONTRACEPTION.
2 INSTEAD IT DELEGATES AUTHORITY TO THE AGENCIES TO DECIDE
3 WHAT KINDS OF PREVENTIVE SERVICES SHOULD BE COVERED.

4 THE COURT: WELL, THE CONTRACEPTIVE
5 MANDATE WAS ADOPTED. WELL, THE HRSA ADOPTED THE
6 INSTITUTE'S RECOMMENDATION IN AUGUST OF 2011. AND THE
7 CONTRACEPTIVE MANDATE WAS ENACTED OR PROMULGATED UNDER
8 THE AUTHORITY GIVEN BY THE ACA TO THE AGENCY. SO IN
9 THIS CASE DOES THE -- DO THE EXEMPTIONS, THE MORAL AND
10 RELIGIOUS EXEMPTIONS, IMPACT ON THE CONTRACEPTIVE
11 MANDATE? DON'T THEY CARVE OUT EXCEPTIONS TO THE
12 CONTRACEPTIVE MANDATE? SO YOU HAVE AN AGENCY CARVING
13 OUT EXCEPTIONS TO AN AGENCY'S RULES.

14 MR. DAVIS: THAT'S CORRECT.

15 THE COURT: THAT IS CORRECT.

16 MR. DAVIS: YES.

17 THE COURT: WHAT AUTHORITY IS THERE FOR
18 AN AGENCY TO CARVE OUT AN EXCEPTION TO AN AGENCY'S
19 PREVIOUSLY PROMULGATED RULES?

20 MR. DAVIS: YOUR HONOR, I THINK IT IS
21 JUST GENERAL REGULATORY AUTHORITY THAT ALL AGENCIES HAVE
22 TO CHANGE THEIR RULES, CARVE OUT EXEMPTIONS TO THEM. I
23 THINK THE STATUTES THAT I MENTIONED EARLIER PROVIDE THAT
24 AUTHORITY. I THINK IT'S JUST INHERENT IN THE APA THAT
25 AGENCIES HAVE THAT ABILITY. AND I THINK IF THE QUESTION

1 IS WHETHER THERE IS STATUTORY AUTHORITY FOR AGENCIES TO
2 DO THAT, I WOULD JUST POINT YOUR HONOR AGAIN TO THE ACA,
3 42 U.S.C. 300 GG-13(A)(4), WHICH PROVIDES DISCRETION, A
4 BROAD GRANT OF DISCRETION FOR THE AGENCIES TO DEVELOP
5 RULES GOVERNING WHAT TYPES OF PREVENTIVE SERVICES WILL
6 BE COVERED AND WHO WILL BE COVERED BY THEM. THERE IS
7 NOTHING IN THAT STATUTE THAT PROHIBITS THE AGENCY FROM
8 DOING THAT.

9 AND HERE I WOULD LIKE TO ADDRESS ANOTHER
10 ONE OF YOUR HONOR'S QUESTIONS, WHICH IS WHETHER THE
11 AGENCIES ARE ENTITLED TO DEFERENCE IN INTERPRETING THE
12 AFFORDABLE CARE ACT. THE ANSWER TO THAT QUESTION IS
13 YES. IT'S CLEAR THAT CONGRESS HAS DELEGATED TO THE
14 AGENCIES THE AUTHORITY TO MAKE RULES CARRYING THE FORCE
15 OF LAW IN THIS CONTEXT AND THE AGENCIES WERE EXERCISING
16 THAT AUTHORITY IN CRAFTING THESE RULES.

17 THE COURT: BUT IF THE INTERPRETATION
18 CONFLICTS WITH THE STATUTE'S PLAIN LANGUAGE, IT IS NOT
19 ENTITLED TO JUDICIAL DEFERENCE, CORRECT?

20 MR. DAVIS: THAT'S CORRECT. BUT HERE I
21 DON'T THINK THAT IS TRUE HERE, TO BE CLEAR, YOUR HONOR.
22 I THINK THE STATUTE IS A BROAD GRANT OF AUTHORITY.
23 THERE IS NOTHING IN IT THAT PROHIBITS THE AGENCIES FROM
24 DOING THIS.

25 THE COURT: I UNDERSTAND.

1 MR. DAVIS: THE SECOND BASIS OF STATUTORY
2 AUTHORITY FOR THESE EXEMPTIONS, YOUR HONOR, IS RFRA.

3 THE COURT: BEFORE YOU GO INTO THAT, AS I
4 UNDERSTAND IT, YOU ARE NOT MAKING AN ARGUMENT WITH
5 RESPECT TO THE MORAL EXEMPTION UNDER RFRA. YOUR RFRA
6 ARGUMENT IS FOCUSED SOLELY ON THE RELIGIOUS EXEMPTION.

7 MR. DAVIS: THAT'S CORRECT, YOUR HONOR.
8 AND THE SOURCE OF STATUTORY AUTHORITY FOR THE MORAL
9 EXEMPTION IS THE ACA.

10 AS I SAID, THE SECOND BASIS OF STATUTORY
11 AUTHORITY FOR THE EXEMPTIONS IS RFRA. HERE YOU DON'T
12 HAVE TO INCLUDE THAT RFRA ACTUALLY REQUIRES THE
13 EXEMPTIONS. BECAUSE EVEN IF RFRA DOES NOT REQUIRE THEM,
14 RFRA AUTHORIZES THE RELIGIOUS EXEMPTION. AND AGAIN ON
15 THIS POINT, YOUR HONOR, YOU ARE NOT WRITING ON A BLANK
16 SLATE. WE KNOW FROM HOBBY LOBBY AND YEARS OF LITIGATION
17 THAT THE UNADORNED MANDATE IMPOSES A SUBSTANTIAL BURDEN.
18 THE AGENCIES HAVE DISCRETION IN DETERMINING HOW TO
19 ALLEVIATE THAT BURDEN, AND IN EXERCISING THAT
20 DISCRETION, THE AGENCIES REASONABLY DECIDED TO RESPOND
21 WITH AN EXEMPTION RATHER THAN AN ACCOMMODATION.

22 THE COURT: WELL, LET ME ASK YOU A
23 QUESTION. DOES ANY OF THE AGENCIES HERE HAVE ANY
24 SPECIFIC EXPERTISE WITH RESPECT TO RFRA?

25 MR. DAVIS: YOUR HONOR, WE ARE NOT

1 ARGUING THAT THE AGENCIES ARE ENTITLED TO CHEVRON
2 DEFERENCE UNDER RFRA WRIT LARGE. WE DO THINK THAT THE
3 AGENCIES ARE ENTITLED TO DEFERENCE ON SOME OF THE
4 SUBSIDIARY QUESTIONS THAT TRIGGER THEIR EXPERTISE, SUCH
5 AS WHETHER THERE IS A COMPELLING INTEREST UNDER RFRA. A
6 LOT OF THOSE ISSUES ACTUALLY INVOLVE INTERPRETATIONS OF
7 THE AFFORDABLE CARE ACT AND THEY FALL SQUARELY WITHIN
8 THE AGENCY'S TECHNICAL EXPERTISE. BUT RFRA IS A
9 GENERALLY APPLICABLE STATUTE LIKE THE FREEDOM OF
10 INFORMATION ACT OR OTHERS THAT ARE NOT GENERALLY
11 CONSIDERED TO CONFER CHEVRON DEFERENCE.

12 AND BACK TO MY POINT ABOUT RFRA
13 AUTHORIZING THE AGENCIES TO DO THIS, THE SUPREME COURT
14 HAS RECOGNIZED THAT AN ENTITY FACED WITH CONFLICTING
15 LEGAL OBLIGATIONS SHOULD BE AFFORDED SOME LEEWAY. SO IN
16 THE RICCI VERSUS DESTEFANO CASE IN THE SUPREME COURT,
17 THE CITY OF NEW HAVEN ADMINISTERED AN EXAM FOR
18 FIREFIGHTERS. THE EXAM PRODUCED RACIALLY DISPARATE
19 RESULTS. THE MINORITY FIREFIGHTERS TOLD THE CITY THAT
20 IF IT CERTIFIED THE RESULTS, THEY WOULD SUE THE CITY FOR
21 VIOLATING TITLE VII'S DISPARATE IMPACT PROVISION. AND
22 THE WHITE FIREFIGHTERS TOLD THE CITY THAT IF IT DID NOT
23 CERTIFY THE RESULTS, THEY WOULD SUE THE CITY FOR
24 VIOLATING TITLE VII'S DISPARATE TREATMENT PROVISION. SO
25 THE CITY WAS CAUGHT BETWEEN THE DISPARATE IMPACT

1 PROVISION ON THE ONE HAND AND THE DISPARATE TREATMENT
2 PROVISION ON THE OTHER HAND. INSTEAD OF REQUIRING THE
3 CITY TO HIT A PERFECT BULLSEYE IN BETWEEN THOSE TWO
4 STATUTES, THE SUPREME COURT GAVE SOME LEEWAY. IT HELD
5 THAT AN EMPLOYER MAY ENGAGE IN INTENTIONAL
6 DISCRIMINATION FOR THE ASSERTED PURPOSE OF AVOIDING OR
7 REMEDYING AN UNINTENTIONAL DISPARATE IMPACT IF THE
8 EMPLOYER HAS A STRONG BASIS IN EVIDENCE TO BELIEVE THAT
9 IT WILL BE SUBJECT TO DISPARATE IMPACT LIABILITY IF IT
10 FAILS TO TAKE THE RISK CONSCIOUS DISCRIMINATORY ACTION.
11 SO THE SAME IS TRUE HERE.

12 THE COURT: SO YOU ARE TAKING -- YOU ARE
13 BORROWING LAW FROM THE DISCRIMINATORY -- DISCRIMINATION
14 JURISPRUDENCE THAT PERTAINS TO A MUNICIPALITY AND
15 APPLYING IT TO -- WHICH IS A STATE ENTITY, AND APPLYING
16 IT TO A FEDERAL AGENCY THAT FALLS UNDER THE EXECUTIVE
17 FUNCTION, IS THAT CORRECT?

18 MR. DAVIS: I WOULD NOT PUT IT LIKE THAT.
19 AGAIN, YOUR HONOR --

20 THE COURT: WELL, THAT IS WHAT YOU ARE
21 DOING, WHETHER YOU PUT IT LIKE THAT OR NOT. SO THE
22 QUESTION IS WHY WOULD YOU TAKE -- WHY WOULD YOU BORROW
23 FROM ONE LINE OF JURISPRUDENCE WHICH HAS NOTHING TO DO
24 WITH WHAT WE ARE TALKING ABOUT HERE. AND IF YOU ARE
25 GOING TO DO THAT, YOU HAVE TO PROVIDE ME WITH SOME

1 PRETTY STRONG RATIONALE BACKED UP BY APPLICABLE
2 PRECEDENT, SO THAT MEANS THIRD CIRCUIT OR SUPREME COURT
3 PRECEDENT, TO TELL ME THAT THAT IS APPROPRIATE.

4 MR. DAVIS: YOUR HONOR, I THINK IF YOU
5 LOOK AT THE REASONING OF THIS CASE --

6 THE COURT: NO, I -- NO, NO. YOU CAN
7 TAKE ANY KIND OF LOGICAL SYLLOGISM IN PRETTY MUCH ANY
8 CASE IN THE LAW AND JUST SAY WELL, IT APPLIES HERE. BUT
9 THAT IS NOT WHAT WE DO WHEN WE ANALYZE CASE LAW. WHAT
10 WE DO IS TAKE A LOOK AT THE JURISPRUDENCE AND DETERMINE
11 WHETHER IT IS APPROPRIATE TO APPLY A PARTICULAR SET OF
12 JURISPRUDENCE IN ONE CONTEXT WHEN IT HAS BEEN DEVELOPED
13 IN ANOTHER CONTEXT.

14 SO WHAT I NEED IF YOU WANT TO MAKE THAT
15 COMPARISON IS TO DRAW A JURISPRUDENTIAL LINE BETWEEN THE
16 CASE -- THE NEW HAVEN CASE THAT YOU MENTIONED, WHICH
17 CONCERNS DISCRIMINATION, AND THE CASE HERE --
18 DISCRIMINATION IN THE CONTEXT OF A STATE ENTITY TO HERE,
19 WHICH CONCERNS AN AGENCY'S DETERMINATION AS TO WHETHER
20 IT CAN OR CANNOT ENACT A PARTICULAR REGULATION. IF YOU
21 CAN DRAW -- IF YOU CAN DRAW THAT CONNECTION, FINE, I'M
22 HAPPY TO CONSIDER IT. BUT YOU CAN'T JUST SAY IT.

23 MR. DAVIS: YOUR HONOR, I RESPECTFULLY
24 DISAGREE WITH HOW YOU CHARACTERIZE THAT. I THINK IT IS
25 APPROPRIATE IN REASONING ON THE BASIS OF CASES NOT TO

1 USE CASES IN THE EXACT SAME CONTEXT BUT INSTEAD TO USE
2 REASON BY ANALOGY TO CASES THAT MAY INVOLVE A DIFFERENT
3 CONTEXT, IN THAT CASE, THE MUNICIPALITY INSTEAD OF THE
4 FEDERAL GOVERNMENT. BUT STILL THE GENERAL LEGAL
5 PRINCIPLE THAT THAT CASE RECOGNIZES, THAT AN ENTITY
6 FACED WITH CONFLICTING LEGAL OBLIGATIONS SHOULD BE
7 AFFORDED SOME LEEWAY. AND THAT PRINCIPLE FROM THAT CASE
8 APPLIES EQUALLY HERE. EVEN THOUGH IT IS IN A DIFFERENT
9 CONTEXT IN THAT CASE, IT'S THE SAME THING HERE.

10 THE EXEMPTION RECOGNIZES THE REALITY THAT
11 THE AGENCIES WOULD LIKELY BE SUBJECT TO UNDER RFRA.
12 WELL, IT COULD BE SUBJECT TO LIABILITY UNDER RFRA THAT
13 THE AGENCIES CHOSE THE ACCOMMODATIONS THAT -- BUT EVEN
14 IF YOUR HONOR IS NOT PERSUADED BY THAT POSITION, WHICH I
15 --

16 THE COURT: I CAN TELL YOU I'M NOT
17 PERSUADED BY THAT.

18 MR. DAVIS: I UNDERSTAND, YOUR HONOR.
19 THE OTHER BASIS FOR STATUTORY AUTHORITY HERE IS THAT
20 RFRA DOES REQUIRE THE RELIGIOUS RULE, EVEN IF YOU THINK
21 IT DOES NOT AUTHORIZE IT. AND HERE THE AGENCIES HAVE
22 CONCLUDED THAT REQUIRING OBJECTING ENTITIES TO CHOOSE
23 BETWEEN THE MANDATE, THE ACCOMMODATION, OR PENALTIES FOR
24 NONCOMPLIANCE IMPOSES A SUBSTANTIAL BURDEN IN THE
25 AGENCY'S VIEW THE ACCOMMODATION, THE PREVIOUS

1 ACCOMMODATION WAS NOT ENOUGH TO ALLEVIATE THAT
2 SUBSTANTIAL BURDEN BECAUSE MANY ENTITIES OBJECTED TO THE
3 ACT OF SUBMITTING A SELF-CERTIFICATION FORM. THOSE
4 ENTITIES SINCERELY BELIEVE THAT SUBMITTING THE FORM MADE
5 THEM COMPLICIT IN PROVIDING CONTRACEPTIVE COVERAGE.
6 EVEN IF A COURT WERE TO DISAGREE WITH THAT BELIEF, HOBBY
7 LOBBY PROHIBITS QUESTIONING IT, AND AS THE SUPREME COURT
8 EXPLAINED, I BELIEVE, IMPLICATES A DIFFICULT AND
9 IMPORTANT QUESTION OF RELIGION AND MORAL PHILOSOPHY THAT
10 COURTS SHOULD NOT BE WADING INTO.

11 ON COMPELLING INTEREST, THE AGENCIES HAVE
12 NOW TAKEN THE POSITION THAT THE MANDATE DOES NOT SERVE A
13 COMPELLING GOVERNMENT INTEREST. AND THIS GOES TO THE
14 LAST OF YOUR HONOR'S QUESTIONS, WHICH I PREVIOUSLY
15 ADDRESSED. EVEN THOUGH THE AGENCIES DON'T GET CHEVRON
16 DEFERENCE UNDER RFRA, ON THE SUBSIDIARY QUESTIONS UNDER
17 RFRA, I THINK THEY DO ON THE COMPELLING INTEREST ISSUE,
18 AND THAT IS BECAUSE THE COMPELLING INTEREST ISSUE IS
19 TIED IN PART TO THE AGENCY'S INTERPRETATION OF THE
20 AFFORDABLE CARE ACT AND IT GOES RIGHT TO THE AREAS WHERE
21 THE AGENCIES HAVE DEFERENCE.

22 AND BEFORE I GO FURTHER, YOUR HONOR, I
23 JUST WANT TO MAKE SURE I'M NOT GOING OVER TIME.

24 THE COURT: NO, I THINK YOU ARE
25 ACTUALLY -- YOU STARTED ABOUT EIGHT MINUTES PAST AND IT

1 IS NOW 20 MINUTES TO, SO YOU ARE EXACTLY ON TIME. I
2 THINK I DID GIVE THE OTHER SIDE A LITTLE BIT MORE. SO
3 IF YOU HAVE ANYTHING ELSE YOU NEED TO SAY, FEEL FREE.

4 MR. DAVIS: I'LL JUST SAY THAT ON THE
5 COMPELLING INTEREST ISSUE, THE AGENCIES MADE A VARIETY
6 OF DIFFERENT CONCLUSIONS IN A WELL-REASONED PART OF THE
7 RULE THAT SPANS SEVERAL PAGES. AND FIRST CONGRESS DID
8 NOT MANDATE THAT CONTRACEPTION BE COVERED AT ALL. AS AN
9 INTERPRETATION OF THE AFFORDABLE CARE ACT, THAT IS
10 ENTITLED TO DEFERENCE. SECOND, CONGRESS EXPRESSLY
11 DECIDED NOT TO APPLY THE PREVENTIVE SERVICES REQUIREMENT
12 TO GRANDFATHER PLANS COVERING TENS OF MILLIONS OF
13 EMPLOYEES.

14 THE COURT: LET ME TALK TO YOU ABOUT
15 THOSE GRANDFATHERED HEALTH PLANS. I THINK ONE OF THE
16 REASONS THAT WERE GIVEN IN THE IFRS FOR BYPASSING THE
17 NOTICE AND COMMENT RULE MAKING WAS, I THINK IT WAS:
18 DELAYING AVAILABILITY OF THE EXEMPTION WOULD ALSO
19 INCREASE THE COST OF HEALTH INSURANCE BECAUSE GROUPS
20 WITH GRANDFATHERED HEALTH PLANS WISH TO MAKE CHANGES TO
21 THEIR HEALTH PLANS THAT WILL REDUCE THE COST OF
22 INSURANCE COVERAGE FOR THEIR BENEFICIARIES OR POLICY
23 HOLDERS BUT WHICH COULD CAUSE THE PLANS TO LOSE
24 GRANDFATHERED STATUS.

25 DO YOU RECALL THAT --

1 MR. DAVIS: YES, YOUR HONOR.

2 THE COURT: -- RATIONALE?

3 SO THERE WERE 54,000 COMMENTS, AND I
4 THINK YOU PROVIDED THEM TO US. WE HAVE THEM IN THE
5 RECORD. SO IN ORDER TO MAKE SURE THAT THAT WAS BACKED
6 UP BY THE RECORD, BECAUSE IT WAS JUST A BOLD STATEMENT,
7 IT WAS A CONCLUSION, WE SEARCHED ALL THOSE 54,000
8 COMMENTS, AND WE COULD NOT LOCATE A SINGLE COMMENT THAT
9 REFERENCED A GRANDFATHERED HEALTH PLAN. SO WE WONDER IS
10 THERE ANY WAY THAT THEY COULD POSSIBLY BE IN THE
11 COMMENTS UNDER A DIFFERENT TERMINOLOGY THAN
12 GRANDFATHERED HEALTH PLAN.

13 MR. DAVIS: IF YOUR HONOR DOES NOT MIND,
14 WE WILL GET BACK TO YOU ON THAT QUESTION.

15 THE COURT: WELL, IF YOU COULD, I
16 THINK -- I'M SURE YOU HAVE SOMEONE THAT CAN DO IT NOW,
17 BUT IF YOU COULD GET BACK TO ME BEFORE THE END OF THE
18 DAY. WHAT I WOULD LIKE YOU TO DO IS TO SEARCH THE
19 54,000 COMMENTS AND TELL ME -- AND PROVIDE ME A LIST OF
20 THE CASE -- OF THE INSTANCES IN WHICH THERE WAS SOME
21 COMMENTARY FROM A GRANDFATHERED HEALTH PLAN WHICH
22 SUGGESTED THAT THEY WISH TO MAKE CHANGES TO THEIR HEALTH
23 PLANS IN A FASTER FASHION THAN WOULD OTHERWISE BE THE
24 CASE. I THINK YOU CAN DO THAT OVER LUNCH AND GET BACK
25 TO ME.

1 MR. DAVIS: YES.

2 THE COURT: OKAY. ANYTHING ELSE?

3 MR. DAVIS: I WILL STOP THERE, YOUR
4 HONOR.

5 THE COURT: OKAY. SO WHAT WE ARE GOING
6 TO DO NOW -- ARE YOU NOW READY TO GO TO YOUR WITNESSES?

7 MR. GOLDMAN: I AM, YOUR HONOR.

8 THE COURT: WELL, I THINK WE SHOULD TAKE
9 A QUICK BREAK IN ORDER TO GET EVERYONE SORTED. WE WILL
10 BE BACK HERE IN TEN MINUTES, SO THAT IS JUST ABOUT EIGHT
11 MINUTES TO.

12 THE CLERK: ALL RISE.

13 (BREAK TAKEN.)

14 THE COURT: ARE YOU READY TO GO?

15 MR. GOLDMAN: YES, YOUR HONOR. MAY I
16 APPROACH?

17 THE COURT: YOU MAY APPROACH. AND THE
18 WITNESS MAY TAKE THE WITNESS STAND.

19 (CAROL WEISMAN, COMMONWEALTH'S WITNESS,
20 SWORN.)

21 THE CLERK: STATE AND SPELL YOUR FULL
22 NAME FOR THE RECORD, PLEASE.

23 THE WITNESS: CAROL WEISMAN, C-A-R-O-L
24 W-E-I-S-M-A-N.

25 DIRECT EXAMINATION

1 BY MR. GOLDMAN:

2 Q. WHERE ARE YOU FROM, DR. WEISMAN?

3 A. ORIGINALLY FROM PITTSBURGH, PENNSYLVANIA.

4 Q. AND WHAT DO YOU DO FOR A LIVING?

5 A. I'M A PROFESSOR AT THE PENN STATE COLLEGE OF
6 MEDICINE.

7 Q. AND IF I MAY, YOU HAVE AN EXHIBIT BINDER BEFORE
8 YOU.

9 MR. DAVIS: AND, YOUR HONOR, IF I
10 UNDERSTAND YOUR RULES, YOU WOULD LIKE THE EXHIBITS MOVED
11 INTO EVIDENCE BEFORE THE WITNESS IS QUESTIONED?

12 THE COURT: IT DOES NOT REALLY MATTER
13 BECAUSE WE DON'T HAVE A JURY, SO JUST DO IT -- IT WOULD
14 BE BETTER IF YOU DID NOT QUESTION HER.

15 BUT HAVE YOU STIPULATED TO EVERYTHING?

16 MS. KADE: EVERYTHING EXCEPT FOR
17 DEMONSTRATIVE.

18 THE COURT: OKAY. SO CAN WE JUST
19 STIPULATE THAT EXHIBITS 1 THROUGH -- WHICH ONE IS THE
20 DEMONSTRATIVE?

21 MS. KADE: IT IS 18, YOUR HONOR.

22 THE COURT: CAN WE JUST STIPULATE AT THIS
23 POINT THAT EVERYTHING EXCEPT EXHIBIT 18 IS ADMITTED?

24 MR. GOLDMAN: YES, YOUR HONOR.

25 MS. KADE: YES, YOUR HONOR.

1 THE COURT: THEY ARE ALL ADMITTED, AND
2 THEREFORE YOU DO NOT HAVE TO LAY A FOUNDATION OR
3 AUTHENTICATION.

4 (GOVERNMENT EXHIBIT 18 ADMITTED INTO
5 EVIDENCE.)

6 BY MR. GOLDMAN:

7 Q. IF YOU WOULD TURN, DR. WEISMAN, TO TAB 4, WHICH
8 WOULD BE EXHIBIT 4.

9 DO YOU KNOW WHAT THAT DOCUMENT IS?

10 A. YES. THAT IS MY CV.

11 Q. AND IF YOU WOULD JUST FLIP THROUGH IT BRIEFLY.
12 CAN YOU CONFIRM THAT THE CONTENTS OF THAT ARE ACCURATE?

13 A. YES.

14 Q. AND EXHIBIT 3 OF THE TAB, IF YOU CAN FLIP
15 THROUGH THAT.

16 A. YES.

17 Q. ARE YOU FAMILIAR WITH THAT DOCUMENT?

18 A. YES. THAT IS MY DECLARATION.

19 Q. AND IF YOU COULD REVIEW THAT BRIEFLY AND IF YOU
20 CAN CONFIRM IF YOU ARE COMFORTABLE WITH THE STATEMENTS
21 CONTAINED THERE?

22 A. YES, I AM.

23 Q. I WOULD LIKE TO ASK YOU BRIEFLY ABOUT YOUR
24 EDUCATION. WHERE DID YOU GO TO COLLEGE -- AND BY THE
25 WAY, YOUR HONOR, IF YOU WOULD PREFER US NOT TO GO

1 THROUGH THIS, WE CAN STIPULATE OVER IT.

2 THE COURT: I DON'T NEED IT.

3 DO YOU NEED IT?

4 MS. KADE: NO, YOUR HONOR.

5 THE COURT: WE DON'T NEED IT.

6 BY MR. GOLDMAN:

7 Q. I MAY ASK SOME TARGETED QUESTIONS IN THERE, IF I
8 MAY. WHAT WAS THE FOCUS OF YOUR ACADEMIC WORK AT
9 WELLESLEY AND THEN JOHNS HOPKINS UNIVERSITY?

10 A. I STUDIED SOCIOLOGY.

11 Q. AND WAS THERE A FOCUS WITHIN THAT?

12 A. AT THE UNDERGRADUATE LEVEL, NOT REALLY AT THE
13 GRADUATE LEVEL, I BECAME INTERESTED IN GENDER RELATED
14 ISSUES.

15 Q. AND DID THAT INCLUDE HEALTHCARE AT THAT TIME?

16 A. YES.

17 Q. YOU ARE NOT A MEDICAL DOCTOR, ARE YOU?

18 A. I AM NOT.

19 MR. DAVIS: YOUR HONOR, MAY I HAVE
20 PERMISSION TO LEAD FOR SOME OF THESE FOUNDATIONAL
21 QUESTIONS.

22 THE COURT: ARE YOU OKAY WITH THAT?

23 MS. KADE: UNTIL I SEE WHAT THE QUESTIONS
24 ARE, YOUR HONOR, I'M NOT SURE, BUT AT THIS POINT, YES.

25 THE COURT: OKAY. PERMISSION TO LEAD FOR

1 THE MOMENT -- I'M SORRY, WHAT IS YOUR NAME?

2 MS. KADE: ELIZABETH, YOUR HONOR.

3 THE COURT: ELIZABETH WHAT?

4 MS. KADE: KADE.

5 THE COURT: THE MOMENT MS. KADE OBJECTS,
6 THEN WE MAY HAVE TO CHANGE TASKS.

7 BY MR. GOLDMAN:

8 Q. AM I CORRECT THAT YOU -- AFTER YOU GOT YOUR
9 PH.D. FROM JOHNS HOPKINS, YOU WORKED AS AN ASSOCIATE
10 RESEARCH SCIENTIST THERE?

11 A. YES.

12 Q. AND WHY DID YOU CHOOSE TO WORK AT JOHNS HOPKINS
13 UNIVERSITY?

14 A. I WAS OFFERED A FACULTY POSITION IN WHICH I
15 COULD CONDUCT RESEARCH AS WELL AS TEACH AT THE GRADUATE
16 LEVEL.

17 Q. AND DID THEY HAVE A PRETTY GOOD PROGRAM?

18 A. OH, THEY HAVE THE TOP PROGRAM IN PUBLIC HEALTH
19 IN THE COUNTRY.

20 Q. DID YOU WORK IN THE -- YOU WORKED IN RESEARCH
21 HEALTH SERVICES. AT THE TIME YOU JOINED JOHNS HOPKINS
22 UNIVERSITY, DID THAT INCLUDE THE FIELD OF WOMEN'S
23 HEALTHCARE?

24 A. THE FIELD OF HEALTH SERVICES RESEARCH WAS JUST
25 BEING ESTABLISHED AT THAT TIME. IT'S AN

1 INTERDISCIPLINARY FIELD, PEOPLE FROM DIFFERENT TRAINING
2 BACKGROUNDS STUDYING HOW HEALTHCARE IS DELIVERED, THE
3 COST OF CARE, THE QUALITY OF CARE. AND I BECAME
4 INVOLVED WITH THOSE RESEARCHERS SPECIFICALLY TO LOOK AT
5 WOMEN'S HEALTHCARE.

6 Q. IS IT FAIR TO SAY THAT YOU PLAYED A PART IN THE
7 CREATION OF WOMEN'S HEALTHCARE AS A FIELD WITHIN
8 RESEARCH HEALTH SERVICES?

9 A. YES.

10 Q. AND YOU WORKED AT JOHNS HOPKINS UNIVERSITY FOR
11 24 YEARS?

12 A. YES.

13 Q. AND I'M NOT GOING TO ASK YOU ABOUT YOUR
14 PROMOTIONS DURING THAT TIME, BUT GENERALLY SPEAKING, CAN
15 YOU DESCRIBE THE WORK THAT YOU DID WHILE AT JOHNS
16 HOPKINS UNIVERSITY?

17 A. I DESIGNED AND LED A NUMBER OF RESEARCH PROJECTS
18 ON DIFFERENT TOPICS. I TAUGHT MASTERS LEVEL STUDENTS.
19 I SUPERVISED DOCTORAL STUDENTS, ESPECIALLY IN THEIR
20 DISSERTATION PROJECTS, AND I CO-LED A COUPLE OF ACADEMIC
21 PROGRAMS.

22 Q. AND IS ALL THAT TEACHING WORK? DID YOU ALSO DO
23 RESEARCH DURING THAT TIME?

24 A. YES, RESEARCH WAS A GREAT PART OF MY
25 RESPONSIBILITIES.

1 Q. AND DID YOU ALSO GIVE PRESENTATIONS AND MAKE
2 PUBLICATIONS AS WELL?

3 A. YES.

4 Q. SO AFTER JOHNS HOPKINS UNIVERSITY YOU WENT TO
5 UNIVERSITY OF MICHIGAN AFTER 24 YEARS?

6 A. CORRECT.

7 Q. AND THEN YOU WENT TO PENN STATE COLLEGE OF
8 MEDICINE, CORRECT?

9 A. CORRECT.

10 Q. AND WHEN DID YOU GO TO PENN STATE COLLEGE OF
11 MEDICINE?

12 A. IN 2003, SO I HAVE BEEN THERE 15 YEARS.

13 Q. AND IS THAT YOUR CURRENT JOB?

14 A. YES.

15 Q. WHAT IS YOUR POSITION THERE?

16 A. A DISTINGUISHED PROFESSOR OF PUBLIC HEALTH
17 SCIENCES AND OBSTETRICS AND GYNECOLOGY IN THE COLLEGE OF
18 MEDICINE.

19 Q. AND YOU ARE NOT A DOCTOR?

20 A. I AM NOT.

21 Q. A MEDICAL DOCTOR.

22 A. NOT A PHYSICIAN.

23 Q. ARE THERE MANY NON-DOCTORS WHO ARE DISTINGUISHED
24 PROFESSORS IN THAT PROGRAM WITHIN THE MEDICAL SCHOOL?

25 A. YES. MEDICAL SCHOOLS TYPICALLY HAVE M.D.'S AND

1 PH.D.'S ON FACULTY.

2 Q. WHAT IS THE FOCUS OF YOUR WORK AT PENN STATE?

3 A. AGAIN, THE FOCUS OF MY WORK IS CONDUCTING
4 RESEARCH ON WOMEN'S HEALTHCARE TOPICS. I ALSO TEACH
5 MASTERS LEVEL STUDENTS, PARTICULARLY IN THE MPH PROGRAM,
6 AND DOCTORAL STUDENTS IN THE DOCTOR OF PUBLIC HEALTH
7 PROGRAM.

8 I ALSO SPEND PART OF MY TIME AS ASSOCIATE
9 DEAN FOR FACULTY AFFAIRS.

10 Q. DO YOU, IN ADDITION TO TEACHING AND RESEARCHING,
11 DO YOU PUBLISH ARTICLES?

12 A. YES.

13 Q. AND GIVE PRESENTATIONS?

14 A. YES.

15 Q. IN THE CONTEXT OF YOUR RESEARCH, ARE THOSE
16 CLINICAL INVESTIGATIONS?

17 A. SOMETIMES THEY ARE CLINICAL INVESTIGATIONS,
18 SOMETIMES THEY ARE POPULATION-BASED STUDIES. SO IT'S A
19 VARIETY OF DIFFERENT KINDS OF STUDIES.

20 Q. AND WHEN IT IS A CLINICAL INVESTIGATION, DO YOU
21 EVER SERVE AS WHAT'S CALLED AN INVESTIGATOR IN THOSE
22 STUDIES?

23 A. YES.

24 Q. WHAT IS AN INVESTIGATOR? WHAT METHODS DOES AN
25 INVESTIGATOR USE?

1 A. AN INVESTIGATOR IS RESPONSIBLE FOR OVERSEEING
2 THE CONDUCT OF A RESEARCH PROJECT. THE METHODS THAT WE
3 USE CAN BE QUITE DIVERSE. THE RESEARCH I DO SOMETIMES
4 INVOLVES SURVEY RESEARCH, IN WHICH WE ASK PEOPLE
5 QUESTIONS IN A SYSTEMATIC WAY. SOMETIMES IT INVOLVES
6 ANALYSIS OF HEALTH CLAIMS DATA TO LOOK AT COST OF CARE.
7 SOMETIMES WE TEST INTERVENTIONS TO SEE IF THEY WORK WITH
8 PATIENTS OR OTHERS.

9 Q. IS IT FAIR TO SAY THAT WHEN DO YOU THAT KIND OF
10 WORK, THE WORK YOU DO IS BASED ON SCIENCE AND EVIDENCE?

11 A. YES.

12 Q. HAVE ANY OF THE INVESTIGATIONS THROUGHOUT YOUR
13 CAREER BEEN RELATED TO CONTRACEPTIVE USE?

14 A. YES.

15 Q. YOU DON'T HAVE TO COUNT. I KNOW YOUR RÉSUMÉ IS
16 VERY EXTENSIVE, BUT CAN YOU ESTIMATE ROUGHLY HOW MANY
17 INVESTIGATIONS HAVE INVOLVED CONTRACEPTIVE USE?

18 A. WELL, I ESTIMATE I HAVE DONE OVER 40 PROJECTS IN
19 MY CAREER, AND I WOULD SAY A THIRD TO A HALF OF THEM
20 HAVE TO DO WITH WOMEN'S REPRODUCTIVE HEALTH GENERALLY.

21 Q. AND HAVE YOU AUTHORED ANY PUBLICATIONS
22 SPECIFICALLY RELATING TO ACCESS TO CONTRACEPTIVE CARE?

23 A. YES.

24 Q. CAN YOU GIVE SOME EXAMPLES OF SPECIFIC AREAS IN
25 WHICH YOU HAVE PUBLISHED ARTICLES RELATED TO

1 CONTRACEPTIVE CARE?

2 A. YES. SO I'VE CONDUCTED STUDIES OF ADOLESCENTS'
3 CONTRACEPTIVE DECISION-MAKING. I HAVE CONDUCTED WORK ON
4 WOMEN'S RECEIPT OF CONTRACEPTIVE COUNSELING IN THE
5 CONTEXT OF MANAGED CARE PLANS. I HAVE CONDUCTED STUDIES
6 IN INTEGRATION OF REPRODUCTIVE HEALTH SERVICES INTO
7 WOMEN'S PRIMARY CARE SETTINGS, AND I HAVE CONDUCTED
8 STUDIES OF WOMEN'S PRECONCEPTION HEALTHCARE, WHICH
9 INCLUDES CONTRACEPTIVE USE BUT NOT EXCLUSIVELY.

10 AND THEN MORE RECENTLY I HAVE BEEN
11 INVOLVED IN SOME STUDIES LOOKING AT WOMEN'S
12 CONTRACEPTIVE BEHAVIOR FOLLOWING THE AFFORDABLE CARE
13 ACT.

14 Q. SO IS IT FAIR TO SAY THAT YOU ARE FAMILIAR WITH
15 THE AFFORDABLE CARE ACT?

16 A. YES.

17 Q. AND HAVE YOU TAUGHT, RESEARCHED, WRITTEN AND
18 GIVEN PRESENTATIONS ON IT?

19 A. I HAVE.

20 Q. AND ARE YOU ALSO FAMILIAR WITH THE CONTRACEPTIVE
21 MANDATE CONTAINED IN THE AFFORDABLE CARE ACT?

22 A. YES.

23 Q. AND HAVE YOU TAUGHT, RESEARCHED, WRITTEN AND
24 GIVEN PRESENTATIONS ABOUT THAT AS WELL?

25 A. YES.

1 Q. HAS ANY OF THE SCHOLARLY WORK YOU HAVE DONE ON
2 THIS TOPIC RELATED TO PEOPLE IN PENNSYLVANIA?

3 A. YES.

4 Q. AND HAS ANY OF THE SCHOLARLY WORK YOU'VE
5 PERFORMED ON THIS TOPIC ALSO RELATED TO PEOPLE OUTSIDE
6 OF PENNSYLVANIA AS WELL?

7 A. YES, BOTH NATIONAL STUDIES AND SOME STUDIES IN
8 PENNSYLVANIA.

9 Q. AM I CORRECT THAT YOU WERE CHOSEN AS ONE OF ONLY
10 16 MEMBERS OF THE INSTITUTE OF MEDICINE'S COMMITTEE ON
11 PREVENTATIVE SERVICES FOR WOMEN THAT WAS CONVENED BY THE
12 HEALTH RESOURCES SERVICES ADMINISTRATION IN CONNECTION
13 WITH THE AFFORDABLE CARE ACT?

14 A. YES.

15 MR. GOLDMAN: YOUR HONOR, IF I MAY AT
16 THIS TIME, I WOULD LIKE TO PROFFER THIS WITNESS, DR.
17 CAROL WEISMAN, BASED ON HER KNOWLEDGE, EDUCATION,
18 EXPERIENCE AND TRAINING, AS AN EXPERT IN THE AREA OF
19 PREVENTATIVE MEDICAL CARE FOR WOMEN, INCLUDING
20 CONTRACEPTIVE CARE.

21 THE COURT: ANY OBJECTIONS?

22 MS. KADE: YOUR HONOR, WE OBJECT UNDER
23 FEDERAL RULE 26(A) REQUIRES DISCLOSURE OF EXPERT
24 TESTIMONY UNDER FEDERAL RULE 702, 703, AND 705. THE
25 PLAINTIFF HAS NOT PROVIDED US WITH THE REQUIRED

1 DISCLOSURE OF THIS PERSON AS AN EXPERT OR THE SUBJECT
2 MATTER ON WHICH THE WITNESS IS EXPECTED TO PRESENT
3 EXPERT TESTIMONY.

4 MR. GOLDMAN: OBVIOUSLY, YOUR HONOR, THIS
5 IS THE CONTEXT OF AN INJUNCTION PROCEEDING. THERE HAVE
6 NOT BEEN ANY DEPOSITIONS, THERE'S NO TIME FOR THAT. AND
7 IN FACT, MUCH OF DR. WEISMAN'S CONTENT OF HER TESTIMONY
8 HAS BEEN DISCLOSED IN THE FORM OF HER DECLARATION WHICH
9 IS ATTACHED TO OUR MOTION OVER A MONTH AGO.

10 MS. KADE: YOUR HONOR, THEY WERE NOT
11 DISCLOSED AS AN EXPERT TESTIMONY.

12 THE COURT: OKAY. I OVERRULE YOUR
13 OBJECTION. SHE IS ADMITTED AS AN EXPERT IN PREVENTATIVE
14 MEDICAL CARE INCLUDING CONTRACEPTION. IS THAT WHAT YOU
15 WANTED?

16 MR. GOLDMAN: YES, YOUR HONOR. AND JUST
17 FOR THE RECORD, COUNSEL HAD OBJECTED TO DR. WEISMAN AS
18 AN EXPERT, SO IT SEEMS THAT THEY MUST HAVE KNOWN FROM
19 THE DECLARATION THAT SHE WAS BEING OFFERED AS AN EXPERT.

20 THE COURT: YOU JUST WON, YOU DIDN'T HAVE
21 TO MAKE AN ARGUMENT.

22 MR. GOLDMAN: I'M SORRY?

23 THE COURT: YOU JUST WON, YOU DIDN'T HAVE
24 TO MAKE ANOTHER ARGUMENT.

25 MR. GOLDMAN: THANK YOU, YOUR HONOR. I

1 UNDERSTAND.

2 THE COURT: IT'S OVER.

3 BY MR. GOLDMAN:

4 Q. WHAT IS THE INSTITUTE OF MEDICINE?

5 THE COURT: MS. KADE, WHAT'S UP?

6 MS. KADE: YOUR HONOR, TO THE EXTENT THAT
7 THIS EXPERT TESTIMONY IS GOING TO BE OFFERED IN ORDER TO
8 DETERMINE THE CORRECTNESS OR WISDOM OF THE AGENCY'S
9 DECISION, IT SHOULD NOT BE PERMITTED, AND THAT IS A
10 QUOTE FROM ASARCO V EPA AT 1160. IT'S A 9TH CIRCUIT
11 1980 DECISION THAT THE COURT REFERRED TO IN HER MOTION
12 IN LIMINE THAT WAS ISSUED YESTERDAY.

13 THE COURT: OKAY, YOUR OBJECTION IS
14 TAKEN.

15 GO AHEAD.

16 BY MR. GOLDMAN:

17 Q. WHAT IS THE INSTITUTE OF MEDICINE AND WHAT DO
18 THEY DO?

19 A. THE INSTITUTE OF MEDICINE IS NOW CALLED THE
20 NATIONAL ACADEMY OF MEDICINE AND IT IS A NONGOVERNMENTAL
21 PRIVATE GROUP OF MEDICAL AND SCIENTIFIC EXPERTS WHO
22 CONDUCT STUDIES AND PROVIDE RECOMMENDATIONS TO
23 GOVERNMENT AND POLICYMAKERS AND OTHERS, WHEN ASKED.

24 Q. AND THIS SPECIFIC COMMITTEE THAT YOU WERE ONE OF
25 16 MEMBERS OF, WHAT WAS THE PURPOSE OF THAT COMMITTEE?

1 A. THAT COMMITTEE WAS CHARGED WITH MAKING
2 RECOMMENDATIONS TO THE DEPARTMENT OF HEALTH AND HUMAN
3 SERVICES FOR SPECIFIC PREVENTIVE SERVICES FOR WOMEN THAT
4 WERE NOT MENTIONED IN THE AFFORDABLE CARE ACT BUT MIGHT
5 HAVE SUBSTANTIAL EVIDENCE TO SUPPORT THEIR PROVISION AS
6 PART OF WOMEN'S PREVENTIVE CARE.

7 Q. AND WAS THE PURPOSE OF THAT COMMITTEE, WAS IT
8 LIMITED TO RECOMMENDATIONS INVOLVING CONTRACEPTIVE CARE
9 OR WAS IT BROADER THAN THAT?

10 A. OH, NO. OUR CHARGE WAS TO SCAN THE EXISTING
11 RECOMMENDATIONS FOR WOMEN'S PRIMARY CARE AND WHAT WE
12 KNEW OF THE SCIENTIFIC LITERATURE AROUND SPECIFIC
13 PREVENTIVE SERVICES AND MAKE RECOMMENDATIONS FOR WHAT
14 OUGHT TO BE INCLUDED IN ROUTINE PREVENTIVE CARE FOR
15 WOMEN IN GENERAL.

16 Q. AND DID THE COMMITTEE ULTIMATELY ISSUE
17 RECOMMENDATIONS?

18 A. YES, WE ISSUED EIGHT RECOMMENDATIONS.

19 Q. AND HOW MANY OF THEM, IF ANY, INVOLVED
20 CONTRACEPTIVE CARE?

21 A. ONE OF THE EIGHT.

22 Q. DID THE COMMITTEE ULTIMATELY ISSUE A REPORT WITH
23 ITS RECOMMENDATIONS?

24 A. YES.

25 Q. I WOULD LIKE TO TURN YOUR ATTENTION TO

1 EXHIBIT 5, IT SHOULD BE TAB 5 IN YOUR BINDER, AND ASK IF
2 YOU HAVE EVER SEEN THIS DOCUMENT BEFORE?

3 A. YES, THIS IS THE REPORT OF THE COMMITTEE.

4 Q. AND THAT IS ALREADY IN EVIDENCE. THROUGHOUT
5 YOUR TESTIMONY, I MAY BE REFERRING TO IT BRIEFLY.

6 IF YOU COULD FIRST, WOULD YOU TURN TO
7 PAGE 223 OF THE REPORT. IT IS APPENDIX C. AND IT
8 GOES -- THAT SECTION GOES THROUGH PAGE 230.

9 A. YES, I'M THERE.

10 Q. ARE THOSE THE BIOGRAPHIES OF THE PEOPLE ON THE
11 COMMITTEE?

12 A. YES, THEY ARE.

13 Q. IF YOU'D TURN TO THE LAST PAGE, ON PAGE 230, THE
14 LAST BIOGRAPHY, IS THAT YOUR BIOGRAPHY?

15 A. YES.

16 Q. DO YOU KNOW WHY YOU WERE LAST?

17 A. IT IS ALPHABETICAL. I THINK EXCEPT FOR THE
18 CHAIR, SHE IS FIRST.

19 Q. UNDERSTOOD.

20 IN FORMING ITS RECOMMENDATIONS, WHAT WAS
21 THE COMMITTEE ASKED TO CONSIDER?

22 A. WE WERE ASKED FIRST TO SCAN THE SOURCES OF
23 PREVENTIVE CARE GUIDELINES THAT ARE NAMED IN THE
24 AFFORDABLE CARE ACT. THOSE INCLUDE THE U.S. PREVENTIVE
25 SERVICES TASK FORCE RECOMMENDATIONS, THE ADVISORY

1 COMMITTEE ON IMMUNIZATION PRACTICE RECOMMENDATIONS AND
2 THE BRIGHT FUTURES RECOMMENDATIONS.

3 AND WE WERE ASKED TO LOOK FOR GAPS: IS
4 THERE ANY ASPECT OF WOMEN'S PREVENTIVE CARE THAT IS NOT
5 COVERED ALREADY BY THOSE EXISTING GUIDELINES. AND THEN
6 WE WERE ASKED TO REVIEW THE SCIENTIFIC LITERATURE AND
7 LISTEN TO SOME EXPERT TESTIMONY AND COME TO SOME
8 CONCLUSIONS ABOUT WHAT SERVICES IN ADDITION TO THOSE
9 ALREADY COVERED IN THOSE THREE SOURCES OUGHT TO BE PART
10 OF WOMEN'S ROUTINE PREVENTIVE CARE.

11 Q. WAS THE COMMITTEE ASKED TO CONSIDER COSTS?

12 A. NO. WE WERE IN FACT SPECIFICALLY TOLD NOT TO
13 CONSIDER COSTS.

14 Q. DID THE COMMITTEE, AS PART OF ITS STUDY AND
15 RECOMMENDATION, DID IT FOCUS AT ALL ON THE ISSUE OF
16 UNINTENDED PREGNANCY?

17 A. YES, THAT WAS ONE OF THE TOPIC AREAS IDENTIFIED
18 AS A GAP BECAUSE IT WAS NOT ADDRESSED IN EXISTING
19 GUIDELINES.

20 Q. DO YOU KNOW ROUGHLY HOW COMMON UNINTENDED
21 PREGNANCY IS IN WOMEN?

22 A. UNINTENDED PREGNANCY IN THE UNITED STATES IS
23 QUITE PREVALENT. AT THE TIME THE COMMITTEE WAS MEETING,
24 49 PERCENT OF ALL U.S. PREGNANCIES WERE UNINTENDED, AND
25 THAT MEANS THEY WERE EITHER MISTIMED OR NOT WANTED BY

1 THE WOMAN AT THE TIME THAT SHE BECAME PREGNANT.

2 Q. YOU SAID THAT IT WAS 49 PERCENT AT THE TIME THE
3 COMMITTEE MET. DO YOU KNOW IF IT HAS CHANGED TODAY?

4 A. IT CHANGED. IT WENT UP TO 51 PERCENT IN 2008,
5 AND THEN SINCE 2008, IT HAS DECLINED. IT IS NOW AT
6 45 PERCENT.

7 Q. AND IS THAT -- THE 45 PERCENT NUMBER, IS THAT AS
8 OF TODAY? DO YOU KNOW WHEN THAT NUMBER --

9 A. THAT IS AS OF 2011. THERE IS ALWAYS A GAP
10 BETWEEN DATA COLLECTION AND WHEN WE KNOW THE EXACT
11 RATES. SO THAT IS THE MOST RECENT DATA THAT WE HAVE.

12 Q. AM I CORRECT THAT IN 2011 THAT 45 PERCENT NUMBER
13 HAD GONE DOWN BEFORE THE CONTRACEPTIVE CARE MANDATE WENT
14 INTO EFFECT?

15 A. CORRECT.

16 Q. DO YOU KNOW WHY THE 45 -- THE NUMBER DECREASED
17 BEFORE THE CONTRACEPTIVE CARE MANDATE?

18 A. THERE WAS AN ARTICLE PUBLISHED IN THE NEW
19 ENGLAND JOURNAL OF MEDICINE IN 2016 BY FINER AND ZOLNA
20 THAT ANALYZED THAT DECLINE IN THE UNINTENDED PREGNANCY
21 RATE FROM THE HIGH OF 51 PERCENT TO 45 PERCENT, AND IT
22 ATTRIBUTED THE DECLINE TO IMPROVED ACCESS TO
23 CONTRACEPTION AND WOMEN USING MORE EFFECTIVE
24 CONTRACEPTION.

25 Q. BUT HOW WAS THAT SO GIVEN THAT THAT WAS BEFORE

1 THE CONTRACEPTIVE CARE MANDATE WENT INTO EFFECT?

2 A. BECAUSE IN THAT PERIOD OF TIME, INCREASING
3 NUMBERS OF EMPLOYER-BASED PLANS AND OTHER PLANS WERE
4 BEGINNING TO COVER CONTRACEPTION AS A RESULT, IT'S MY
5 UNDERSTANDING, OF STATE LEGISLATION AND CASES INVOLVING
6 DISCRIMINATION IN PRESCRIPTION DRUG COVERAGE.

7 Q. SO THEN INCREASED ACCESS TO CONTRACEPTION
8 LOWERED THE RATE OF UNINTENDED PREGNANCY?

9 A. THAT WAS THE INTERPRETATION OF THESE AUTHORS,
10 YES.

11 Q. IS AN UNINTENDED PREGNANCY A BAD THING? DOES IT
12 MATTER?

13 A. UNINTENDED PREGNANCY HAS A NUMBER OF NEGATIVE
14 CONSEQUENCES. TO BEGIN WITH, 42 PERCENT OF UNINTENDED
15 PREGNANCIES RESULT IN ABORTION. OF THOSE PREGNANCIES
16 THAT CONTINUE, THERE IS A LOT OF EVIDENCE OF NEGATIVE
17 HEALTH CONSEQUENCES FOR THE WOMEN AND FOR THE BABIES.

18 WOMEN, FOR EXAMPLE, CAN BECOME DEPRESSED
19 DURING AN UNINTENDED PREGNANCY. THEY MIGHT NOT HAVE
20 GONE INTO THE PREGNANCY WITH OPTIMAL HEALTH STATUS. FOR
21 EXAMPLE, A DIABETIC WOMAN WHO HAS AN UNINTENDED
22 PREGNANCY MIGHT NOT HAVE HAD HER GLUCOSE LEVELS UNDER
23 CONTROL AT THE TIME THAT SHE BECAME PREGNANT, LEADING TO
24 POTENTIAL CONSEQUENCES DURING THE PREGNANCY.

25 UNINTENDED PREGNANCIES OFTEN RESULT IN

1 DELAYED ENTRY INTO PRENATAL CARE BECAUSE THE WOMAN WAS
2 NOT EXPECTING TO BECOME PREGNANT, MAY NOT HAVE REALIZED
3 SHE WAS PREGNANT IN TIME TO GET OPTIMAL PRENATAL CARE.

4 THERE ARE ALSO A NUMBER OF STUDIES THAT
5 SHOW THAT BABIES BORN OF UNINTENDED PREGNANCIES ARE MORE
6 LIKELY TO BE BORN PRETERM OR WITH LOW BIRTH WEIGHT.

7 AND IN ADDITION TO THE HEALTH
8 CONSEQUENCES, UNINTENDED PREGNANCIES ARE KNOWN TO BE
9 DISRUPTIVE OF WOMEN'S PLANS FOR EDUCATION, FOR WORK, AND
10 FOR SPACING THEIR CHILDREN, AND THEREFORE, CAN HAVE
11 NEGATIVE ECONOMIC CONSEQUENCES FOR THE WOMAN AND HER
12 FAMILY.

13 Q. SO WHO IS AT RISK FOR HAVING AN UNINTENDED
14 PREGNANCY?

15 A. SO REALLY, ANY WOMAN OF REPRODUCTIVE CAPACITY
16 WHO IS HAVING SEXUAL RELATIONS WITH MEN IS AT RISK OF AN
17 UNINTENDED PREGNANCY.

18 Q. ARE THERE SOME WHO ARE MORE IMPACTED THAN
19 OTHERS? ARE THERE CERTAIN RISK GROUPS?

20 A. UNINTENDED PREGNANCIES TEND TO BE MORE COMMON IN
21 YOUNGER WOMEN AND LOW INCOME WOMEN AND WOMEN WITH LOWER
22 EDUCATIONAL LEVELS.

23 Q. AM I AT RISK FOR UNINTENDED PREGNANCY?

24 A. NO, YOU ARE NOT.

25 Q. SORRY, I'M A LAWYER, BUT WHY IS THAT?

1 A. BECAUSE YOU ARE NOT A WOMAN.

2 Q. SO?

3 A. YOU DO NOT HAVE THE CAPACITY TO BECOME PREGNANT.

4 Q. AND CAN UNINTENDED PREGNANCY BE ADDRESSED
5 THROUGH MEDICAL CARE AND PREVENTIVE MEDICAL SERVICES?

6 A. YES. 95 PERCENT OF UNINTENDED PREGNANCIES OCCUR
7 IN WOMEN WHO ARE EITHER NOT USING CONTRACEPTION OR ARE
8 USING CONTRACEPTION INCONSISTENTLY. AND WE HAVE VERY
9 EFFECTIVE CONTRACEPTIVE METHODS AVAILABLE TODAY.

10 Q. LET ME TAKE A BRIEF STEP ASIDE FOR A MOMENT AND
11 ASK YOU YOUR SPECIFIC ROLE ON THE COMMITTEE. DID YOU
12 HAVE A SPECIFIC FOCUS WITHIN THE COMMITTEE?

13 A. NO. AS A MEMBER OF THE COMMITTEE, I
14 PARTICIPATED IN ALL OF THE COMMITTEE DISCUSSIONS AND
15 DELIBERATIONS. AND WHAT WE DID WAS IDENTIFY SOME KEY
16 TOPICS FOR FURTHER INVESTIGATION AND BROKE UP INTO
17 SUBGROUPS TO INVESTIGATE THOSE TOPICS.

18 Q. WERE YOU PART OF ONE OF THOSE SUBGROUPS OR ONE
19 OR MORE?

20 A. I WAS PART OF TWO SUBGROUPS, ONE OF WHICH WAS
21 THE SUBGROUP ON CONTRACEPTION AND UNINTENDED PREGNANCY.

22 Q. WHAT WAS THE OTHER?

23 A. IT WAS A SUBGROUP ON PRECONCEPTION CARE.

24 Q. ROUGHLY HOW MANY MEMBERS OF THE COMMITTEE WERE
25 ON THE SUBGROUP INVOLVING CONTRACEPTION?

1 A. I DON'T REALLY REMEMBER. I WOULD SAY THREE TO
2 FIVE.

3 Q. AND WAS THERE A ROBUST DISCUSSION ON THE ISSUE
4 OF PREVENTATIVE CARE RECOMMENDATIONS ABOUT
5 CONTRACEPTION?

6 A. OH, YES.

7 Q. WERE ANY NEGATIVE SIDE EFFECTS OF CONTRACEPTION
8 CONSIDERED?

9 A. OH, YES. WE CONSIDERED ALL OF THE LITERATURE
10 BOTH ON EFFECTIVENESS OF CONTRACEPTION, SIDE EFFECTS OF
11 CONTRACEPTION, OTHER BENEFITS OF TAKING CONTRACEPTION
12 THAN PREVENTING PREGNANCY, BECAUSE ALL OF THOSE FACTORS
13 ARE IMPORTANT IN DECISIONS ABOUT USING CONTRACEPTION.

14 Q. AND IS CONTRACEPTION, IN FACT, EFFECTIVE AT
15 PREVENTING UNINTENDED PREGNANCY?

16 A. YES, IT IS.

17 Q. I WOULD LIKE TO DIRECT YOU BACK TO THE REPORT AT
18 EXHIBIT 5 TO PAGE 105. THAT'S TABLE 5.3. AND I'M GOING
19 TO PUT THAT UP ON THE ELMO IF YOU'LL GIVE ME ONE QUICK
20 MOMENT. BUT MY FIRST QUESTION IS, ARE YOU FAMILIAR WITH
21 THIS TABLE?

22 A. YES. IT'S PAGE 106.

23 Q. 106. I'M SORRY.

24 A. YES, I AM. THAT IS IT.

25 Q. I WAS HOPING YOU COULD BRIEFLY WALK US THROUGH

1 THAT CHART AND EXPLAIN IT TO US.

2 A. SURE. SO THESE ARE DATA FROM CONTRACEPTIVE
3 TECHNOLOGY, WHICH IS THE DEFINITIVE SOURCE ABOUT
4 CONTRACEPTIVE EFFECTIVENESS USED BY PHYSICIANS.

5 AND THESE ARE THE DATA OF AVAILABLE -- ON
6 CONTRACEPTIVE EFFECTIVENESS AT THE TIME THAT THE
7 COMMITTEE WAS MEETING. AND WHAT THIS DOES IS SHOW ALL
8 OF THE METHODS OF CONTRACEPTION AVAILABLE AT THE TIME
9 INCLUDING NONE, AT THE TOP. AND THEN IT DESCRIBES THE
10 EFFECTIVENESS OF EACH CONTRACEPTIVE METHOD BASED ON
11 DATA. AND THE WAY EFFECTIVENESS OF CONTRACEPTION IS
12 LOOKED AT IS BY LOOKING AT FAILURES, WHICH MEANS THE
13 NUMBER OF PREGNANCIES THAT OCCUR IN A YEAR WITH USE OF
14 THAT CONTRACEPTIVE METHOD.

15 SO THERE ARE TWO COLUMNS IN THE TABLE,
16 THERE IS ONE CALLED TYPICAL USE AND ONE CALLED PERFECT
17 USE. PERFECT USE IS IN A PERFECT WORLD WHERE PEOPLE
18 DON'T MAKE MISTAKES. SO WHAT WE REALLY LOOK AT IS THE
19 TYPICAL USE COLUMN, WHICH IS BASED ON DATA OF ACTUAL
20 BEHAVIOR AND OUTCOMES OF PEOPLE USING CONTRACEPTION.
21 AND WHAT THIS COLUMN SHOWS YOU IS THE NUMBER OF EXPECTED
22 PREGNANCIES IN A YEAR PER 100 WOMEN USING THAT METHOD
23 UNDER THE CONDITIONS OF TYPICAL USE.

24 Q. SORRY. GO ON.

25 A. SO IF NO CONTRACEPTION IS USED, WHICH IS THE TOP

1 ROW, WE WOULD EXPECT TO SEE 85 WOMEN BECOME PREGNANT IN
2 A YEAR.

3 Q. SO THEN IF WITHDRAWAL WAS USED, AM I CORRECT
4 THAT YOU WOULD EXPECT TO SEE 27 WOMEN GET PREGNANT
5 WITHIN ONE YEAR IF THE WITHDRAWAL METHOD WAS USED?

6 A. CORRECT. AND THEN GOING DOWN THE COLUMN, WE GET
7 TO THE MOST EFFECTIVE METHODS OF CONTRACEPTION TOWARD
8 THE BOTTOM. AT THE VERY BOTTOM ARE MALE AND FEMALE
9 STERILIZATION, BUT JUST ABOVE THAT ARE IMPLANTS AND
10 INTRAUTERINE DEVICES, WHICH RESULT IN ONE LESS THAN ONE
11 PREGNANCY PER YEAR.

12 Q. IF I UNDERSTAND THIS CHART CORRECTLY, UNDER
13 INTRAUTERINE DEVICES -- AND THAT IS AN IUD, RIGHT,
14 THAT'S THE SAME THING?

15 A. CORRECT.

16 Q. THERE IS ONE CALLED A MIRENA IUD. THAT LOOKS
17 LIKE OUT OF 100 WOMEN WHO ARE USING THAT IN A YEAR,
18 THERE WOULD BE A .2 CHANCE OF GETTING PREGNANT, CORRECT?

19 A. CORRECT.

20 Q. AND THAT IS ACTUALLY LESS THAN FEMALE
21 STERILIZATION, CORRECT --

22 A. YES.

23 Q. -- ON THE CHART?

24 A. THAT IS CORRECT.

25 Q. AND IMPLANTED, WHAT IS THAT?

1 A. THAT IS THE IMPLANT. THAT IS A HORMONAL
2 CONTRACEPTIVE THAT IS IMPLANTED UNDER THE SKIN.

3 Q. THERE THAT IS OUT OF A HUNDRED WOMEN, YOU WOULD
4 HAVE .05?

5 A. RIGHT. THE BOTTOM LINE IS WITH THESE MOST
6 EFFECTIVE METHODS AT THE BOTTOM, YOU WOULD EXPECT TO SEE
7 LESS THAN ONE PREGNANCY IN A YEAR OF USE.

8 Q. AND --

9 A. OUT OF 100 WOMEN.

10 Q. SO THE ONES AT THE BOTTOM, ARE THEY PRESCRIPTION
11 CONTRACEPTIVES?

12 A. ALL OF THE METHODS OF CONTRACEPTION ARE
13 PRESCRIPTION METHODS WITH THE EXCEPTION OF SPERMICIDES,
14 WITHDRAWAL, FERTILITY AWARENESS METHODS, AND THE SPONGE
15 AND THE CONDOM. ALL THE OTHERS ARE PRESCRIPTION
16 METHODS.

17 Q. AND NONE I ASSUME ALSO?

18 A. AND NONE, YES. THANK YOU.

19 Q. AM I CORRECT, FOR STERILIZATION YOU WOULD NEED A
20 PRESCRIPTION? IS THAT CONSIDERED A PRESCRIPTION?

21 A. WELL, YES. IT IS A SURGICAL PROCEDURE, SO IT
22 HAS TO BE PROVIDED BY A HEALTHCARE PROFESSIONAL WHO
23 AGREES TO PROVIDE THE SERVICE.

24 Q. GIVEN THE STUDIES -- SORRY. GIVEN THE COMMITTEE
25 STUDY OF CONTRACEPTION, INCLUDING NEGATIVE HEALTH

1 EFFECTS AND EFFICACY AS YOU EXPLAINED FROM THAT TABLE,
2 DID THE COMMITTEE MAKE ANY RECOMMENDATION REGARDING
3 CONTRACEPTION?

4 A. THE COMMITTEE RECOMMENDED THAT ALL FDA, THAT IS
5 FOOD AND DRUG ADMINISTRATION, APPROVED CONTRACEPTIVES
6 SHOULD BE PROVIDED AS PART OF WOMEN'S PREVENTIVE CARE,
7 ALONG WITH COUNSELING REGARDING CONTRACEPTION.

8 Q. WHAT WAS THE COSTS TO WOMEN SUPPOSED TO BE FOR
9 THIS EXPANDED CARE?

10 A. WELL, THE COMMITTEE DID NOT DISCUSS THE COST TO
11 WOMEN, BUT WE WERE MAKING RECOMMENDATIONS TO THE
12 DEPARTMENT OF HEALTH AND HUMAN SERVICES THAT WOULD THEN
13 DECIDE WHETHER TO ADOPT THESE RECOMMENDATIONS, WHICH WE
14 KNEW WOULD THEN MEAN IF THEY WERE ADOPTED THAT THEY
15 WOULD BECOME PART OF WOMEN'S PREVENTIVE CARE WITHOUT
16 COST SHARING UNDER THE AFFORDABLE CARE ACT.

17 Q. I WANT TO MAKE SURE I UNDERSTAND THAT CORRECTLY.
18 DID I UNDERSTAND YOU TO SAY THAT BY MAKING THE
19 RECOMMENDATIONS THAT THE FULL RANGE OF THIS
20 CONTRACEPTIVE CARE BE MADE AVAILABLE, INHERENT IN THE
21 RECOMMENDATIONS THAT WOULD BE RECOMMENDED WITHOUT
22 ADDITIONAL COSTS TO WOMEN?

23 A. WHAT THE COMMITTEE WAS ASKED TO DO WAS RECOMMEND
24 EFFECTIVE PREVENTIVE SERVICES FOR WOMEN THAT OUGHT TO BE
25 PART OF ROUTINE PREVENTIVE CARE. SO WE DETERMINED THAT

1 CONTRACEPTION IS HIGHLY EFFECTIVE AT PREVENTING
2 UNINTENDED PREGNANCY, WHICH IS A MAJOR WOMEN'S HEALTH
3 PROBLEM, AND THEREFORE OUGHT TO BE PART OF PREVENTIVE
4 CARE.

5 Q. ARE YOU AWARE WHETHER OR NOT THE COST OF
6 CONTRACEPTION AFFECTS WOMEN'S USE OF CONTRACEPTION?

7 A. YES.

8 Q. AND HOW DOES THAT WORK?

9 A. PRIOR TO THE AFFORDABLE CARE ACT, SOME WOMEN HAD
10 CONTRACEPTIVE COVERAGE, SOME DID NOT. THOSE WHO DID
11 HAVE CONTRACEPTIVE COVERAGE ALWAYS HAD COST SHARING, SO
12 THAT MEANS IF THEY WERE IN AN EMPLOYER-BASED OR OTHER
13 PRIVATE HEALTH PLAN, THEY EITHER PAID A CO-PAY FOR
14 CONTRACEPTIONS, CONTRACEPTIVE SERVICES SUCH AS
15 STERILIZATION WOULD BE APPLIED TO THEIR DEDUCTIBLE. SO
16 TYPICALLY WOMEN WOULD HAVE TO PAY SOMETHING OUT OF
17 POCKET FOR THEIR CONTRACEPTIVE SERVICES.

18 Q. CO-PAYS ARE GENERALLY PRETTY SMALL, RIGHT?

19 A. THAT DEPENDS ON THE HEALTH PLAN, AND IT ALSO
20 WOULD DEPEND ON THE NATURE OF THE CONTRACEPTION BEING
21 USED. IF IT IS A MONTHLY METHOD LIKE ORAL
22 CONTRACEPTIVES, THAT MEANS THERE WOULD BE A CO-PAY EVERY
23 TIME A PRESCRIPTION WAS REFILLED. THERE IS AN ABUNDANT
24 BODY OF LITERATURE SHOWING THAT EVEN VERY SMALL CO-PAYS
25 AS SMALL AS \$6 CAN DISCOURAGE PEOPLE FROM USING HEALTH

1 SERVICES.

2 Q. DO I UNDERSTAND THAT RIGHT, THAT EVEN A \$6
3 CO-PAY COULD MAKE WOMEN OR CAUSE SOME WOMEN TO NOT USE
4 CONTRACEPTION THAT WAS PRESCRIBED BY THEIR DOCTOR THAT
5 THEY WOULD USE OTHERWISE?

6 A. YES.

7 MS. KADE: OBJECTION, LEADING.

8 THE COURT: SUSTAINED.

9 GO AHEAD. REASK THE QUESTION.

10 BY MR. GOLDMAN:

11 Q. IS -- SO WHAT COULD BE THE EFFECT OF EVEN A
12 SMALL \$6 CO-PAY?

13 A. A SMALL \$6 CO-PAY TO A LOW INCOME WOMAN COULD
14 MEAN THAT SHE DIDN'T HAVE -- WOULD NOT HAVE THE MONEY TO
15 RENEW A PRESCRIPTION FOR BIRTH CONTROL PILLS, FOR
16 EXAMPLE.

17 Q. SO BASED ON THE CHART THEN ON PAGE 106 OF
18 TABLE 5.3, IS THAT IF A WOMAN HAD A \$6 CO-PAY, DID NOT
19 RENEW THE PRESCRIPTION AND DID NOT USE CONTRACEPTION, AM
20 I RIGHT THAT HER RATE OF UNINTENDED PREGNANCY WITHIN ONE
21 YEAR WOULD GO TO AN 85 PERCENT CHANCE?

22 A. WELL, IF SHE USED ORAL CONTRACEPTIVES
23 INCONSISTENTLY BECAUSE SHE DID NOT RENEW A PRESCRIPTION
24 OR IF SHE DISCONTINUED USE OF ORAL CONTRACEPTIVES
25 BECAUSE SHE COULD NOT AFFORD TO RENEW HER PRESCRIPTIONS,

1 HER RISK OF UNINTENDED PREGNANCY WOULD INCREASE, YES.

2 Q. TO 85 PERCENT IF NO CONTRACEPTION WAS USED?

3 A. THAT I DON'T KNOW.

4 Q. I WOULD LIKE TO REFER YOU TO PAGE 107 ON THE
5 CHART, SPECIFICALLY THE LAST FULL PARAGRAPH.

6 A. YES.

7 Q. I'M GOING TO PLACE THAT UP ON THE ELMO. I WOULD
8 LIKE YOU TO TAKE A MOMENT TO READ THAT PARAGRAPH. AND
9 IF I MAY, I WILL SORT OF READ IT ALONG WITH YOU:
10 ALTHOUGH IT IS BEYOND THE SCOPE OF THE COMMITTEE'S
11 CONSIDERATION, IT SHOULD BE NOTED THAT CONTRACEPTION IS
12 HIGHLY COST EFFECTIVE. THE DIRECT MEDICAL COSTS OF
13 UNINTENDED PREGNANCY IN THE UNITED STATES WAS ESTIMATED
14 TO BE NEARLY 5 BILLION IN 2002 WITH COST SAVINGS DUE TO
15 CONTRACEPTIVE USE ESTIMATED TO BE AT 19.3 BILLION. THEN
16 IT SAYS IN PARENTHESES TRUSSELL 2007.

17 WHAT DOES THAT REFER TO?

18 A. WELL, THAT REFERS TO A STUDY OF THE POTENTIAL
19 SAVINGS IN PUBLIC AND PRIVATE DOLLARS TO AVERTING
20 UNINTENDED PREGNANCIES AT THE NATIONAL LEVEL.

21 Q. SO THAT IS A CITATION TO BACK UP THE PREMISE?

22 A. CORRECT. TRUSSELL IS THE AUTHOR, YES.

23 Q. AND THEN IT SAYS: THE COST EFFECTIVENESS OF
24 FAMILY PLANNING IS ALSO DOCUMENTED IN AN EVALUATION OF
25 FAMILY PACT, CALIFORNIA'S 1115 MEDICAID FAMILY PLANNING

1 WAIVER PROGRAM. THE UNINTENDED PREGNANCIES AVERTED IN
2 THIS PROGRAM IN 2002 WOULD HAVE COST THE STATE
3 \$1.1 BILLION WITHIN TWO YEARS AND \$2.2 BILLION WITHIN
4 FIVE YEARS FOR PUBLIC SECTOR HEALTH AND SOCIAL SERVICES
5 THAT OTHERWISE WOULD HAVE BEEN NEEDED.

6 AND IS THAT ANOTHER CITATION TO PROVE
7 THAT PREMISE?

8 A. YES. THAT IS A STATE LEVEL STUDY.

9 Q. SO YOU HAD TOLD THE COURT THAT YOU WERE
10 INSTRUCTED TO NOT CONSIDER COSTS, AND YET THIS PARAGRAPH
11 SEEMS TO TALK ABOUT COSTS, AND I WAS WONDERING WHY THAT
12 IS?

13 A. THE COMMITTEE DECIDED, SINCE THERE WAS A BODY OF
14 LITERATURE ASSESSING THE COST EFFECTIVENESS OF
15 CONTRACEPTION, TO PUT THE INFORMATION INTO OUR REPORT
16 FOR THE DECISION-MAKERS WHO WERE GOING TO LOOK AT THE
17 REPORT AND DECIDE WHETHER TO APPROVE THE RECOMMENDATIONS
18 OR NOT. WE WANTED THE INFORMATION TO BE AVAILABLE TO
19 THE DECISION-MAKERS.

20 Q. IF I MAY DIRECT YOU TO PAGE 109. I WOULD LIKE
21 TO, IF I MAY, DIRECT YOU TO THAT MIDDLE PARAGRAPH?

22 A. DESPITE INCREASES?

23 Q. YES, THAT IS THE ONE.

24 THAT PARAGRAPH ALSO TALKS ABOUT COSTS,
25 DOESN'T IT?

1 A. YES, IT DOES.

2 Q. AND WITHOUT READING THE WHOLE THING BECAUSE I
3 KNOW THE COURT HAS IT, DOES THAT TALK ABOUT WHAT YOU
4 WERE JUST TELLING THE COURT BEFORE ABOUT THE EFFECT OF
5 CO-PAYMENTS IN AFFECTING WOMEN'S CONTRACEPTIVE CHOICES?

6 A. YES. AND IT SPECIFICALLY POINTS OUT TOWARD THE
7 BOTTOM OF THE PARAGRAPH THAT IT WAS KNOWN AT THE TIME
8 BECAUSE OF RECENT STUDIES THAT COST SHARING WAS A
9 BARRIER TO WOMEN CHOOSING THE MOST EFFECTIVE FORMS OF
10 CONTRACEPTION, THE IUD'S AND THE IMPLANTS.

11 Q. AND AM I CORRECT THAT THERE ARE CITATIONS TO
12 EVIDENCE IN THIS PARAGRAPH AS WELL, TO HUDMAN AND
13 O'MALLEY, A 2003, I ASSUME IT'S A PAPER; TRIVEDI,
14 ET AL., 2008; AND THEN A RECENT STUDY CONDUCTED BY
15 KAISER PERMANENTE?

16 A. CORRECT.

17 Q. WAS ALL THAT OBJECTIVE EVIDENCE THAT THE
18 COMMITTEE BASED ITS FINDINGS ON?

19 A. YES. THIS EVIDENCE DOES NOT HAVE TO DO WITH THE
20 EFFECTIVENESS OF CONTRACEPTION. THIS EVIDENCE HAS TO DO
21 WITH HOW WOMEN'S CONTRACEPTIVE CHOICES MIGHT BE AFFECTED
22 IF COST SHARING WERE ELIMINATED.

23 Q. I WANT TO TURN YOUR ATTENTION TO SORT OF THE
24 FINALIZATION OF THE REPORT. BEFORE THE COMMITTEE
25 FINALIZED ITS REPORT, DID ANYONE NOT ON THE COMMITTEE

1 REVIEW IT?

2 A. YES. WHEN THE COMMITTEE HAD FORMALIZED ITS
3 FINAL DRAFT OF THE REPORT, IT WAS REVIEWED BY A GROUP OF
4 OUTSIDE EXPERTS WHOSE NAMES ARE LISTED IN THIS DOCUMENT.
5 DO YOU KNOW THE PAGE?

6 Q. I DO. IF I MAY DIRECT YOU AND THE COURT TO THE
7 BEGINNING OF ROMAN -- SMALL ROMAN 7 THROUGH SMALL ROMAN
8 8.

9 THE COURT: WHAT PAGES ARE WE ON?

10 THE WITNESS: ROMAN NUMERAL 7 AND 8, AT
11 THE VERY BEGINNING.

12 BY MR. GOLDMAN:

13 Q. SO ARE THERE APPROXIMATELY 11 OUTSIDE REVIEWERS
14 WHO REVIEWED THIS --

15 A. YES.

16 Q. -- REPORT.

17 I WOULD ALSO LIKE TO DIRECT YOU TO
18 PAGE 231 OF THE REPORT, IF I MAY. IT'S APPENDIX D.
19 IT'S ENTITLED DISSENT AND RESPONSE. DO YOU SEE THAT?

20 A. YES.

21 Q. AM I CORRECT THAT A MEMBER OF THE COMMITTEE
22 DISSENTED FROM THE REPORT?

23 A. YES.

24 Q. DO YOU KNOW WHY -- WAS THAT PERSON A MR. SASSO
25 OR DR. SASSO MAYBE?

1 A. YES. DR. LO SASSO.

2 Q. DO YOU KNOW WHY HE DISSENTED?

3 A. DR. LO SASSO IS AN ECONOMIST, AND AS HIS DISSENT
4 DESCRIBES, HIS MAIN OBJECTION TO THE REPORT WAS THAT HE
5 WOULD HAVE PREFERRED THAT THE COMMITTEE CONSIDER COSTS
6 AND COST EFFECTIVENESS IN MAKING ITS RECOMMENDATIONS.

7 HE ALSO WOULD HAVE PREFERRED THAT THE
8 COMMITTEE HAD MORE TIME, AND HE CRITICIZES THE
9 COMMITTEE'S DECISION-MAKING AS BEING NOT EVIDENCE-BASED.

10 MS. KADE: OBJECTION, YOUR HONOR. THE
11 QUESTION DOES NOT NECESSARILY ASK FOR HEARSAY BUT THE
12 ANSWER HAS PROVIDED HEARSAY.

13 THE COURT: SUSTAINED. I WILL NOT TAKE
14 THAT INTO ACCOUNT.

15 BY MR. GOLDMAN:

16 Q. DID THAT DISSENT, WAS THAT FOCUSED ON ONE OF THE
17 EIGHT RECOMMENDATIONS INVOLVING CONTRACEPTION OR DID IT
18 APPLY TO THE ENTIRE COMMITTEE REPORT?

19 A. THE DISSENT APPLIED TO THE ENTIRE REPORT.

20 Q. AND WHAT, IF ANYTHING, DID YOU THINK OF
21 DR. LOSASSO'S DISSENT?

22 A. WELL, I AND THE OTHER COMMITTEE MEMBERS
23 DISAGREED WITH THE DISSENT.

24 Q. AND WHY IS THAT?

25 A. WELL, ON THE FIRST POINT, WE HAD SPECIFICALLY

1 BEEN TOLD IN OUR CHARGE THAT OUR JOB WAS NOT TO CONSIDER
2 COST EFFECTIVENESS OF THESE SERVICES BUT TO LOOK ONLY AT
3 EFFECTIVENESS, IN OTHER WORDS, DO THEY IMPROVE HEALTH.

4 AND OF COURSE, THE AMOUNT OF TIME THAT
5 THE COMMITTEE HAD TO WORK WAS OUT OF OUR CONTROL, AND WE
6 FELT THAT WE HAD BEEN VERY EVIDENCE BASED IN OUR
7 DELIBERATIONS.

8 MS. KADE: YOUR HONOR, WE OBJECT TO THE
9 EXTENT THAT DR. WEISMAN IS SPEAKING FOR ANYONE OTHER
10 THAN HERSELF.

11 THE COURT: SUSTAINED.

12 BY MR. GOLDMAN:

13 Q. IF I MAY DIRECT YOU TO PAGE 235, A FEW PAGES IN
14 AT THE BOTTOM, IT SAYS "RESPONSE TO DISSENTING
15 STATEMENT."

16 DO YOU SEE THAT?

17 A. YES.

18 Q. AND THERE ARE A BUNCH OF NAMES AT THE TOP.

19 WHO ARE THOSE PEOPLE?

20 A. THOSE ARE ALL THE MEMBERS OF THE COMMITTEE OTHER
21 THAN DR. LO SASSO, AND THAT IS OUR RESPONSE TO HIS
22 DISSENT.

23 Q. YOUR NAME IS LAST AGAIN, HUH?

24 A. YEP.

25 Q. SO WHAT HAPPENED TO THIS REPORT AFTER THE

1 COMMITTEE WAS FINISHED WITH IT?

2 A. THE COMMITTEE'S REPORT WENT TO THE DEPARTMENT OF
3 HEALTH AND HUMAN SERVICES, WHO ACCEPTED THE
4 RECOMMENDATIONS.

5 Q. ALL EIGHT OF THEM?

6 A. YES.

7 Q. IF YOU KNOW, WHEN YOU SAY THAT HRSA ACCEPTED THE
8 RECOMMENDATIONS, DO YOU KNOW IF THAT HAD ANY EFFECT ON
9 THE AFFORDABLE CARE ACT?

10 A. IT IS MY UNDERSTANDING THAT WHEN THE DEPARTMENT
11 OF HEALTH AND HUMAN SERVICES ACCEPTED THESE
12 RECOMMENDATIONS, THEY THEN BECAME PART OF THE AFFORDABLE
13 CARE ACT DESIGNATED PREVENTIVE SERVICES TO BE COVERED
14 WITHOUT COST SHARING.

15 Q. AND THAT IS THE LAW THEN, CORRECT?

16 A. THAT IS MY UNDERSTANDING.

17 Q. I'D LIKE TO TURN YOUR ATTENTION NOW TO THE RULES
18 WHICH ARE AT ISSUE IN THIS PARTICULAR MATTER. ARE YOU
19 GENERALLY FAMILIAR WITH THESE NEW RULES?

20 THE COURT: BEFORE YOU GO THERE,
21 MR. GOLDMAN. IF YOU ARE GOING TO GET INTO THIS EITHER
22 LATER ON WITH THIS WITNESS OR WITH ANOTHER WITNESS,
23 PLEASE STOP ME. I WANT TO FOCUS IN ON PENNSYLVANIA. IS
24 THAT SOMETHING THAT YOU INTEND TO RAISE WITH THIS
25 WITNESS LATER ON?

1 MR. GOLDMAN: IT IS IN SOME WAY, BUT IF
2 YOUR HONOR HAS QUESTIONS --

3 THE COURT: WELL, LET'S TALK ABOUT -- YOU
4 TALKED ABOUT DATA, AND YOU SAID, I THINK, THAT THE
5 LATEST DATA YOU COULD GET WAS 2011 BECAUSE THE DATA
6 TAKES SOME TIME TO ROLL IN, CORRECT?

7 THE WITNESS: THE DATA ON UNINTENDED
8 PREGNANCIES?

9 THE COURT: UNINTENDED PREGNANCIES, OKAY.
10 SO HAVE YOU, EITHER IN THIS CONTEXT OR OUTSIDE OF THIS
11 CONTEXT, LOOKED INTO DATA WITH RESPECT TO UNINTENDED
12 PREGNANCIES IN PENNSYLVANIA?

13 THE WITNESS: YES.

14 THE COURT: AND TELL ME THE PERCENTAGE.
15 WHAT IS THE PERCENTAGE OF UNINTENDED PREGNANCIES IN
16 PENNSYLVANIA?

17 THE WITNESS: IT'S CLOSE TO THE NATIONAL
18 AVERAGE. IT MIGHT BE A LITTLE BIT LOWER, AND I CANNOT
19 REMEMBER THE CURRENT NUMBER.

20 THE COURT: FAIR TO SAY SOMEWHERE BETWEEN
21 45 AND 49 PERCENT?

22 THE WITNESS: THE NATIONAL RATE CURRENTLY
23 IS 45 PERCENT. WE ARE A LITTLE BIT LOWER IN
24 PENNSYLVANIA.

25 THE COURT: SO SOMEWHERE BETWEEN 40 AND

1 45 PERCENT?

2 THE WITNESS: I THINK SO.

3 THE COURT: AND WHEN YOU SAY YOU THINK
4 SO, WHAT DEGREE OF CERTAINTY DO YOU BRING TO THAT "I
5 THINK SO"?

6 THE WITNESS: PRETTY CERTAIN. THE
7 GUTTMACHER INSTITUTE PUBLISHES THE STATE-BY-STATE DATA.
8 SO IT WOULD BE EASY TO CHECK ON.

9 THE COURT: IS THERE ANY POSSIBILITY THAT
10 IT IS BELOW 40 PERCENT?

11 THE WITNESS: IT COULD BE IN THE HIGH
12 THIRTIES, I'M NOT TOTALLY SURE.

13 THE COURT: SO IF I WERE TO SAY IT'S
14 SOMEWHERE BETWEEN 35 PERCENT AND 45 PERCENT, THAT WOULD
15 BE ABOUT RIGHT?

16 THE WITNESS: YES.

17 THE COURT: OKAY. HAVE YOU DONE ANY
18 RESEARCH INTO THE COSTS OF UNINTENDED PREGNANCIES IN
19 PENNSYLVANIA?

20 THE WITNESS: I HAVE INVESTIGATED
21 ESTIMATES OF COSTS, BUT NOT RECENTLY.

22 THE COURT: OKAY. AND WHAT ABOUT HAVE
23 YOU INVESTIGATED THE IMPACT OF PROVIDING NO COST
24 CONTRACEPTION TO WOMEN IN PENNSYLVANIA?

25 THE WITNESS: YES.

1 THE COURT: TELL ME ABOUT THAT.

2 THE WITNESS: SO WE AT PENN STATE DID A
3 RECENT STUDY OF A COHORT OF PRIVATELY-INSURED WOMEN WHO
4 HAD EMPLOYER-BASED HEALTH INSURANCE IN PENNSYLVANIA, AND
5 IN A TWO-YEAR PERIOD FOLLOWING THE PASSAGE OF THE
6 AFFORDABLE CARE ACT, WHICH MEANT THAT THEY ALL HAD
7 CO-PAY -- NO CO-PAYS FOR CONTRACEPTION, THEIR USE OF
8 IUD'S AND IMPLANTS, WHICH ARE THE MOST EFFECTIVE
9 REVERSIBLE FORMS OF CONTRACEPTION, MORE THAN DOUBLED.

10 THE COURT: SO LOOKING AT YOUR CHART THAT
11 SHOWED THE EFFECTIVENESS OF VARIOUS FORMS OF
12 CONTRACEPTION, IUD'S ARE --

13 MR. GOLDMAN: PAGE 106, AND IT IS ON THE
14 ELMO, YOUR HONOR.

15 THE COURT: WHERE DOES IT SAY -- I DON'T
16 SEE THE WORDS IUD.

17 THE WITNESS: INTRAUTERINE DEVICES, SIX
18 LINES UP.

19 THE COURT: OKAY. SO DEPENDING ON
20 WHETHER IT'S PARAGARD OR MIRENA --

21 THE WITNESS: CORRECT.

22 THE COURT: -- IT'S EITHER -- UNDER
23 "TYPICAL USE," IT'S EITHER .8 OR .20.

24 THE WITNESS: CORRECT.

25 THE COURT: AND --

1 THE WITNESS: AND THE IMPLANT IS RIGHT
2 BELOW THAT.

3 THE COURT: OKAY. WAS THERE ANY
4 INDICATION, WAS THERE ANY CONTROL DATA SHOWING WHAT
5 THESE WOMEN HAD USED PRIOR TO USING IUD'S?

6 THE WITNESS: YES, WE KNEW THAT FROM THE
7 STUDY, AND MOST OF THEM HAD BEEN USING BIRTH CONTROL
8 PILLS, BUT SOME HAD BEEN USING NOTHING OR A COMBINATION.

9 THE COURT: WHEN YOU SAY "MOST," DO YOU
10 RECALL APPROXIMATELY HOW MANY PERCENTAGE WERE USING
11 BIRTH CONTROL PILLS?

12 THE WITNESS: NO, I DON'T.

13 THE COURT: BUT THERE IS A DISTINCTION --
14 I LOOK AT THE BIRTH CONTROL PILLS, IS THAT -- WHERE DO I
15 FIND THAT?

16 THE WITNESS: SO THAT IS THE "COMBINED
17 PILL AND PROGESTIN-ONLY PILL" WHICH WOULD PRODUCE EIGHT
18 PREGNANCIES PER YEAR OUT OF 100 WOMEN.

19 THE COURT: SO THERE IS A REDUCTION IN --
20 TO THE EXTENT YOU CAN HAVE A .2 PREGNANCY, EITHER YOU
21 ARE PREGNANT OR YOU ARE NOT PREGNANT, BUT IT IS, WHAT, A
22 7.2 REDUCTION --

23 THE WITNESS: YEAH. I MEAN, ESTIMATING,
24 IT'S ALMOST AN EIGHTFOLD INCREASE, SLIGHTLY LESS THAN
25 THAT RISK.

1 THE COURT: IF ONE WERE TO USE BIRTH
2 CONTROL RATHER THAN IUD'S?

3 THE WITNESS: CORRECT.

4 THE COURT: SO LOOKING AT --

5 THE WITNESS: IN REDUCING THE RISK.

6 THE COURT: REDUCING THE RISK BY ABOUT
7 EIGHT PERCENT IF ONE WERE TO USE INTRAUTERINE DEVICES.

8 THE WITNESS: CORRECT.

9 THE COURT: SO WHY -- DID YOU REACH ANY
10 CONCLUSIONS AS TO WHY THESE WOMEN WOULD MOVE TO USING
11 IUD'S RATHER THAN OTHER FORMS OF BIRTH CONTROL?

12 THE WITNESS: YES. BECAUSE HISTORICALLY,
13 COST HAS BEEN A BARRIER TO ADOPTING THESE MOST EFFECTIVE
14 METHODS BECAUSE THE UPFRONT COST OF GETTING AN IUD OR AN
15 IMPLANT IS CONSIDERABLE. AN IUD CAN COST UP TO A
16 THOUSAND DOLLARS, WHEN YOU CONSIDER THE COST OF THE
17 DEVICE ITSELF AND THE VISIT TO HAVE THE DEVICE
18 IMPLANTED. AND AN IMPLANT I BELIEVE COSTS UP TO \$500 UP
19 FRONT, AND MANY WOMEN SIMPLY DON'T HAVE THAT KIND OF
20 MONEY TO PAY OUT OF POCKET.

21 THE COURT: YOU INDICATED THAT THIS STUDY
22 WAS PERFORMED RECENTLY. HOW RECENTLY?

23 THE WITNESS: BETWEEN 2012 AND 2014.

24 THE COURT: AND WHAT WAS THE COHORT OF
25 WOMEN IN THE STUDY?

1 THE WITNESS: IT WAS ABOUT -- OVER 900
2 PRIVATELY-INSURED WOMEN IN PENNSYLVANIA.

3 THE COURT: AND YOU AND WHO ELSE DID THE
4 STUDY?

5 THE WITNESS: COLLEAGUES AT PENN STATE
6 COLLEGE OF MEDICINE, DR. CYNTHIA CHUANG AND OTHERS.

7 THE COURT: WAS IT PUBLISHED?

8 THE WITNESS: SOME RESULTS FROM THAT
9 STUDY HAVE BEEN PUBLISHED. THE RESULT I JUST CITED TO
10 YOU HAS NOT YET BEEN PUBLISHED BECAUSE THAT PAPER IS
11 STILL IN PREPARATION.

12 THE COURT: IF YOU WANT TO FOLLOW UP ON
13 THE QUESTIONS I HAVE ASKED IN THIS PARTICULAR AREA, FEEL
14 FREE IF YOU THINK I'VE MISSED SOMETHING.

15 MR. GOLDMAN: I THOUGHT YOU DID AN
16 EXCELLENT JOB.

17 THE COURT: WELL, I APPRECIATE IT.
18 BY MR. GOLDMAN:

19 Q. IF I MAY, THE STUDY YOU JUST SPOKE ABOUT
20 CONCERNED ONLY WOMEN IN PENNSYLVANIA.

21 HAVE YOU BEEN INVOLVED IN ANOTHER STUDY
22 OF LATE INVOLVING -- BASED ON CLAIMS DATA WITH A LARGER
23 COHORT OF WOMEN, NOT JUST IN PENNSYLVANIA BUT AROUND THE
24 COUNTRY?

25 A. YES. WE HAVE JUST RECENTLY CONCLUDED A NATIONAL

1 STUDY OF PRIVATELY-INSURED WOMEN USING A HEALTH CLAIMS
2 DATABASE CALLED MARKETSCAN. AND WE WERE ABLE TO LOOK AT
3 TRENDS IN CONTRACEPTIVE USE FROM 2006 THROUGH 2014. AND
4 AS PART OF THAT ANALYSIS, WE FIRST OF ALL LOOKED AT
5 COSTS TO WOMEN, WHICH DECLINED PRECIPITOUSLY TO ZERO,
6 BASICALLY, AFTER THE AFFORDABLE CARE ACT MANDATE WENT
7 INTO EFFECT.

8 WE ALSO LOOKED AT THE METHODS OF
9 CONTRACEPTION THAT THEY USED OVER THIS TIME PERIOD, AND
10 WE WERE ABLE TO SHOW THAT AFTER THE AFFORDABLE CARE ACT
11 MANDATE WENT INTO EFFECT, THERE WAS A SIGNIFICANT
12 INCREASE IN THE USE OF IUD'S AND IMPLANTS AMONG THESE
13 INSURED WOMEN.

14 Q. AND THAT STUDY WAS BASED ON CLAIMS DATA?

15 A. CORRECT.

16 Q. IS CLAIMS DATA A RELIABLE WAY TO STUDY THIS SORT
17 OF THING?

18 A. SOME PEOPLE THINK IT'S THE MOST RELIABLE WAY TO
19 STUDY THE USE OF PRESCRIPTION MEDICATIONS IN GENERAL
20 BECAUSE EVERY TIME A PRESCRIPTION IS PROVIDED THERE IS A
21 CLAIM GENERATED, AND SO IT IS A GOOD WAY TO FOLLOW
22 PATTERNS OF PRESCRIBING AND USE OF MEDICATIONS.

23 Q. AND WHAT STATES WAS THE CLAIMS DATA FROM THE
24 STUDY FROM, IF YOU KNOW?

25 A. IT'S A NATIONAL DATABASE, SO EMPLOYER-BASED

1 INSURERS FROM ALL OVER THE COUNTRY PUT THEIR CLAIMS INTO
2 THIS DATABASE. AND I THINK IT IS MOST STATES BUT I
3 CAN'T SAY DEFINITELY.

4 Q. DO YOU KNOW IF PENNSYLVANIA WAS ONE OF THE
5 STATES INCLUDED?

6 A. YES, IT WAS.

7 Q. IF I MAY TAKE YOU TO THE RULES NOW THAT ARE AT
8 ISSUE BEFORE THE COURT. AND I WILL -- I DON'T THINK WE
9 HAVE TO LOOK AT THEM SPECIFICALLY HERE, BUT I WOULD LIKE
10 TO NOTE THAT THE RELIGIOUS EXEMPTION RULE IS MARKED AND
11 ADMITTED AS EXHIBIT 1. THE MORAL EXEMPTION RULE IS
12 EXHIBIT 2.

13 I KNOW THEY ARE LONG, BUT HAVE YOU HAD
14 OCCASION TO READ THE RELIGIOUS EXEMPTION RULE?

15 A. YES.

16 Q. AND DO YOU BELIEVE YOU UNDERSTAND IT?

17 A. I UNDERSTAND PARTS OF IT.

18 Q. DO YOU UNDER -- DO YOU BELIEVE YOU UNDERSTAND IT
19 SO FAR AS IT WOULD AFFECT WOMEN'S CONTRACEPTIVE CARE?

20 A. YES.

21 Q. DO YOU -- HAVE YOU ALSO SIMILARLY READ THE MORAL
22 EXEMPTION RULE?

23 A. YES.

24 Q. AND DO YOU SIMILARLY BELIEVE THAT YOU UNDERSTAND
25 IT AS IT WOULD IMPACT WOMEN'S CONTRACEPTIVE CHOICES?

1 A. YES.

2 Q. IN YOUR CAPACITY AS AN EXPERT IN THE FIELD OF
3 PREVENTIVE MEDICAL CARE FOR WOMEN, INCLUDING
4 CONTRACEPTIVE CARE, DO YOU HAVE AN OPINION TO A
5 REASONABLE DEGREE OF CERTAINTY AS TO THE LIKELY EFFECT
6 OF THE RULES ON THE HEALTH OF WOMEN IN PENNSYLVANIA?

7 A. YES.

8 Q. AND WHAT IS THAT OPINION?

9 A. THESE RULES OPEN UP THE OPPORTUNITY FOR MORE
10 EMPLOYERS TO OPT OUT OF CONTRACEPTIVE COVERAGE WITHOUT
11 CO-PAYS BY WOMEN. AND WE KNOW FROM A LARGE BODY OF
12 RESEARCH INVOLVING USE OF HEALTHCARE IN GENERAL AND
13 CONTRACEPTION IN PARTICULAR THAT EVEN VERY SMALL CO-PAYS
14 CAN DISCOURAGE USE.

15 SO IF WOMEN WHO HAVE HAD CO-PAYS UNDER
16 THE AFFORDABLE CARE ACT WERE -- SUDDENLY HAD THAT
17 BENEFIT REMOVED, I FEEL BASED ON WHAT I KNOW OF THIS
18 LITERATURE THAT WE WOULD SEE MORE WOMEN FAILING TO RENEW
19 THEIR PILL PRESCRIPTIONS, NOT OPTING FOR A MORE
20 EFFECTIVE METHOD THAT WOULD HAVE HIGHER UPFRONT COSTS,
21 AND AS A RESULT OF THAT, WE WOULD EXPECT TO SEE AN
22 INCREASE IN THE UNINTENDED PREGNANCY RATE AND MORE
23 ABORTIONS.

24 Q. DID THAT OPINION YOU SO CLEARLY EXPRESSED, DOES
25 THAT ALSO HOLD TRUE FOR WOMEN OUTSIDE OF PENNSYLVANIA

1 AND AROUND THE COUNTRY?

2 A. YES.

3 Q. DO YOU HOLD ALL OF YOUR OPINIONS THAT YOU HAVE
4 SHARED WITH THE COURT TODAY WITHIN A REASONABLE DEGREE
5 OF CERTAINTY FOR AN EXPERT IN PREVENTIVE MEDICAL CARE
6 FOR WOMEN, INCLUDING CONTRACEPTIVE CARE?

7 A. YES.

8 MR. GOLDMAN: YOUR HONOR, IF I MAY HAVE
9 ONE MOMENT TO CONSULT WITH MY CO-COUNSEL.

10 THE COURT: YES.

11 MR. GOLDMAN: YOUR HONOR, NOTHING FURTHER
12 WITH THIS WITNESS.

13 THE COURT: MS. KADE.

14 MS. KADE: THANK YOU, YOUR HONOR.

15 PERMISSION TO APPROACH, YOUR HONOR.

16 THE COURT: YOU MAY.

17 MS. KADE: THANK YOU, YOUR HONOR.

18 CROSS EXAMINATION

19 BY MS. KADE:

20 Q. DR. WEISMAN, GOOD MORNING.

21 A. GOOD MORNING.

22 Q. MY NAME IS ELIZABETH KADE. HOW ARE YOU DOING
23 THIS MORNING?

24 A. GOOD, THANKS.

25 Q. FIRST, WHAT DOCUMENTS DID YOU REVIEW IN ORDER TO

1 PROVIDE YOUR DECLARATION -- TO PREPARE YOUR DECLARATION?

2 A. MY CV, AND I REREAD THE IOM COMMITTEE REPORT,
3 AND RE-FAMILIARIZED MYSELF WITH SOME OF THE REFERENCES
4 IN THAT REPORT.

5 Q. IS THAT EVERYTHING?

6 A. I BELIEVE SO.

7 Q. AND WHO DID YOU MEET WITH IN ORDER TO PREPARE
8 YOUR DECLARATION?

9 A. I SPOKE ON THE PHONE WITH JONATHAN AND NICOLE.
10 THAT'S IT.

11 THE COURT: AND BY JONATHAN AND NICOLE,
12 YOU MEAN JONATHAN GOLDMAN AND NICOLE BOLAND?

13 THE WITNESS: YES.

14 THE COURT: THANK YOU. MAKING SURE THE
15 RECORD IS CLEAN.

16 BY MS. KADE:

17 Q. TURNING TO YOUR DECLARATION, LOOKING AT
18 PARAGRAPH 44, YOU HAVE TESTIFIED THAT IT IS YOUR OPINION
19 THAT THE NEW RULES WILL CAUSE IMMEDIATE AND IRREVERSIBLE
20 HARM BECAUSE THEY WILL CAUSE WOMEN TO LOSE PREVENTIVE
21 CONTRACEPTIVE CARE UNDER THEIR EMPLOYER GROUP --

22 I APOLOGIZE. YOU TESTIFIED THAT IT IS
23 YOUR OPINION THAT THE NEW RULES WILL CAUSE IMMEDIATE AND
24 IRREVERSIBLE HARM BECAUSE THEY WILL CAUSE WOMEN TO LOSE
25 PREVENTIVE CONTRACEPTION CARE UNDER THEIR EMPLOYER GROUP

1 HEALTH PLANS, CORRECT?

2 A. YES.

3 Q. DO YOU KNOW HOW MANY RELIGIOUS EMPLOYERS ARE
4 CURRENTLY PROTECTED BY INJUNCTION?

5 A. I DO NOT. I HAVE SEEN AN ESTIMATE THAT 10
6 PERCENT OF NONPROFITS HAVE CLAIMED THE EXEMPTION UNDER
7 THE EXISTING RULES.

8 Q. SO THIS IS BEFORE THE NEW RULES THAT JUST WENT
9 INTO EFFECT. CORRECT?

10 A. YES, CORRECT.

11 Q. DO YOU -- AND SO YOU KNOW THAT THE EMPLOYERS
12 THAT ARE PROTECTED BY INJUNCTIONS ARE NOT CURRENTLY
13 PROVIDING CONTRACEPTIVE COVERAGE, CORRECT?

14 A. YES.

15 Q. DO YOU KNOW ABOUT THE 2016 ZUBIK INJUNCTION?

16 A. ONLY IN VERY GENERAL TERMS. I AM NOT A LAWYER.

17 Q. I APPRECIATE THAT, THANK YOU.

18 DO YOU HAVE ANY REASON TO DOUBT THAT
19 THERE WAS ANOTHER INJUNCTION IN 2016 THAT WE'RE
20 REFERRING TO COLLECTIVELY AS THE ZUBIK INJUNCTION?

21 A. NO.

22 Q. DO YOU KNOW THAT THE ENTITIES PROTECTED BY THE
23 ZUBIK INJUNCTION ARE ALSO NOT CURRENTLY PROVIDING
24 CONTRACEPTIVE COVERAGE?

25 A. YES.

1 Q. WHEN WAS THE "MY NEW OPTIONS" STUDY THAT YOU
2 WERE REFERRING TO EARLIER, WHEN WAS THAT CONDUCTED?

3 A. THAT WAS CONDUCTED IN 2012 -- 2012 THROUGH 2014.

4 Q. CAN YOU IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA
5 WHO HAS LOST COVERAGE AS A RESULT OF THE NEW RULES?

6 A. NO.

7 Q. CAN YOU IDENTIFY A SINGLE WOMAN IN THE UNITED
8 STATES WHO HAS LOST COVERAGE AS A RESULT OF THE NEW
9 RULES?

10 A. NO.

11 Q. YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS AN
12 EXPERT ON INSURANCE MARKETPLACES, RIGHT?

13 A. CORRECT.

14 Q. AND YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS
15 AN EXPERT ON THE GOVERNMENT'S DECISION-MAKING PROCESS
16 UNDER THE ADMINISTRATIVE PROCEDURE ACT, CORRECT?

17 A. CORRECT.

18 Q. I WANT TO TURN TO ANOTHER PARAGRAPH IN YOUR
19 DECLARATION, PARAGRAPH 22. YOU HAVE TESTIFIED THAT IT
20 IS YOUR OPINION THAT THE NEW RULES ARE NOT BASED UPON
21 SOUND SCIENTIFIC OR EMPIRICAL EVIDENCE; IS THAT RIGHT?

22 A. CORRECT.

23 Q. AND HAVE YOU READ THE RULES THAT ARE AT ISSUE IN
24 THIS CASE IN THEIR ENTIRETY?

25 A. YES, ALTHOUGH I FOCUSED ON THE SECTIONS HAVING

1 TO DO WITH CONTRACEPTION EFFECTIVENESS AND THE IOM
2 REPORT.

3 Q. HAVE YOU READ ALL OF THE EVIDENCE THAT THE RULES
4 RELY UPON AND CITE?

5 A. I WOULD NOT SAY ALL OF IT, BUT SOME OF IT.

6 Q. I'M GOING TO TURN TO A SPECIFIC PAGE, 47804 OF
7 THE FEDERAL REGISTER, SO THIS IS EXHIBIT 1, AND IT
8 SHOULD BE PAGE 46 OF THAT EXHIBIT.

9 A. WHAT TAB IS THAT?

10 Q. IT IS THE FIRST TAB. I'M ALSO GOING TO PUT IT
11 ON THE ELMO FOR EVERYONE.

12 THIS IS TAB 1, PAGE 47804 OF THE FEDERAL
13 REGISTER.

14 A. GOT IT.

15 Q. YOU HAVE SERVED ON THE EDITORIAL BOARD OF
16 WOMEN'S HEALTH ISSUES SINCE 1990, CORRECT?

17 A. CORRECT.

18 Q. SO WOULD YOU SAY THAT IS A PUBLICATION THAT IS
19 GENERALLY ACCEPTED IN THE RELEVANT SCIENTIFIC COMMUNITY?

20 A. YES.

21 Q. AND THE RULES SAY -- I'M LOOKING AT THE FIRST --
22 START OF THE FIRST FULL PARAGRAPH THAT STARTS WITH
23 "SIMILARLY" ON THE LEFT-HAND SIDE: SIMILARLY, AT A
24 STUDY INVOLVING OVER 8,000 WOMEN BETWEEN 2012 AND 2015
25 CONDUCTED TO DETERMINE WHETHER CONTRACEPTIVE COVERAGE

1 UNDER THE MANDATE CHANGED CONTRACEPTIVE USE PATTERNS,
2 THE GUTTMACHER INSTITUTE CONCLUDED THAT WE HAVE OBSERVED
3 NO CHANGES IN CONTRACEPTIVE USE PATTERNS AMONG SEXUALLY
4 ACTIVE WOMEN. AND THAT CITES FOOTNOTE 31, WHICH IS AN
5 ARTICLE ENTITLED: DID CONTRACEPTIVE USE HABITS CHANGE
6 AFTER THE AFFORDABLE CARE ACT? A DESCRIPTIVE ANALYSIS,
7 WHICH WAS PUBLISHED IN THE MAY TO JUNE 2017 ISSUE OF
8 WOMEN'S HEALTH ISSUES; IS THAT CORRECT?

9 A. YES.

10 Q. YOU WERE ON THE COMMITTEE THAT PRODUCED THE 2011
11 IOM REPORT, CORRECT?

12 A. YES.

13 Q. SO LOOKING JUST BELOW WHERE THE REFERENCE TO
14 PARAGRAPH 31, THE SENTENCE THAT STARTS WITH "WITH," THE
15 RULES SAY: WITH RESPECT TO TEENS, THE SANTELLI AND
16 MELNIKAS STUDY CITED BY IOM IN 2011 OBSERVES THAT
17 BETWEEN 1960 AND 1990 AS CONTRACEPTIVE USE INCREASED,
18 TEEN SEXUAL ACTIVITY OUTSIDE OF MARRIAGE LIKEWISE
19 INCREASED, ALTHOUGH THE STUDY DID NOT ASSERT A CAUSAL
20 RELATIONSHIP. IS THAT CORRECT?

21 A. YES.

22 Q. THE NATIONAL INSTITUTES OF HEALTH IS A
23 ORGANIZATION THAT IS GENERALLY ACCEPTED IN THE
24 SCIENTIFIC COMMUNITY; IS THAT CORRECT?

25 A. YES.

1 Q. THE RULES ALSO CITE IN THIS MIDDLE PARAGRAPH,
2 JUST AGAIN, CONTRACEPTION'S ASSOCIATION, BUT I WILL
3 START READING FROM THE SECOND SENTENCE IN THAT
4 PARAGRAPH: THE RULES SAY, IN 2013, THE NATIONAL
5 INSTITUTES OF HEALTH INDICATED IN FUNDING OPPORTUNITY
6 ANNOUNCEMENT FOR THE DEVELOPMENT OF NEW CLINICALLY
7 USEFUL FEMALE CONTRACEPTIVE PRODUCTS --

8 THE COURT: I'M SORRY. I'M NOT FOLLOWING
9 YOU. WHERE ARE YOU IN THIS PARAGRAPH?

10 MS. KADE: I'M SORRY, YOUR HONOR. I'M IN
11 THE MIDDLE COLUMN, THE PARAGRAPH THAT STARTS WITH
12 CONTRACEPTION'S ASSOCIATION.

13 THE COURT: GOT IT.

14 MS. KADE: AND IN 2013, THE NATIONAL
15 INSTITUTES OF HEALTH.

16 THE COURT: OKAY.

17 BY MS. KADE:

18 Q. SO THEY INDICATED THAT HORMONAL CONTRACEPTIVES
19 HAVE THE DISADVANTAGE OF HAVING MANY UNDESIRABLE SIDE
20 EFFECTS, ARE ASSOCIATED WITH ADVERSE EVENTS, AND OBESE
21 WOMEN ARE AT HIGHER RISK FOR SERIOUS COMPLICATIONS SUCH
22 AS DEEP VENOUS THROMBOSIS; IS THAT CORRECT?

23 A. YES.

24 Q. JAMA PSYCHIATRY IS A PUBLICATION THAT IS
25 GENERALLY ACCEPTED IN THE RELEVANT SCIENTIFIC COMMUNITY,

1 CORRECT?

2 A. YES.

3 Q. IT'S PUBLISHED BY THE AMERICAN MEDICAL
4 ASSOCIATION?

5 A. CORRECT.

6 Q. IT IS PEER REVIEWED?

7 A. YES.

8 Q. I'M GOING TO FOCUS EVERYONE'S ATTENTION TO
9 FOOTNOTE 39. I REALIZE THE FONT IS GETTING SMALLER.

10 BUT FOOTNOTE 39 CITES A 2016 JAMA PSYCHIATRY PUBLICATION
11 ON THE ASSOCIATION OF HORMONAL CONTRACEPTION WITH
12 DEPRESSION; IS THAT CORRECT?

13 A. YES.

14 Q. I WANT TO TURN TO THE 2011 IOM REPORT. THE 2011
15 IOM REPORT DID NOT STUDY THE EFFECT OF RELIGIOUS
16 EXEMPTIONS, CORRECT?

17 A. CORRECT.

18 Q. AND THE 2011 IOM REPORT DID NOT STUDY THE EFFECT
19 OF MORAL EXEMPTIONS, CORRECT?

20 A. YES.

21 Q. AND THE IOM PANEL DID NOT INVITE ANY SPEAKERS TO
22 TESTIFY CONCERNING EXEMPTIONS FROM THE MANDATE, CORRECT?

23 A. CORRECT.

24 MS. KADE: THANK YOU, DR. WEISMAN.

25 THANK YOU, YOUR HONOR. I HAVE NOTHING

1 FURTHER.

2 THE COURT: OKAY. THANK YOU VERY MUCH.

3 DO YOU HAVE ANY RECROSS?

4 MR. GOLDMAN: VERY BRIEFLY, IF I MAY
5 APPROACH, YOUR HONOR.

6 RECROSS EXAMINATION

7 BY MR. GOLDMAN:

8 Q. COUNSEL ASKED YOU IF YOU HAD READ ALL OF THE
9 SOURCES CITED IN THE COMMITTEE'S REPORT. I WANT TO ASK
10 YOU, ARE YOU FAMILIAR WITH ALL OF THE SOURCES CITED IN
11 THE COMMITTEE'S REPORT, SPECIFICALLY IN THE AREA OF
12 CONTRACEPTION?

13 A. I AM FAMILIAR WITH REFERENCES 30 AND 31.

14 Q. I'M SORRY, DR. WEISMAN. I BELIEVE COUNSEL WAS
15 REFERRING TO THE COMMITTEE'S REPORT AND NOT THE FEDERAL
16 REGISTER.

17 A. WELL, I'M CONFUSED BECAUSE SHE ASKED ABOUT BOTH.

18 THE COURT: AS I UNDERSTAND IT, THE
19 QUESTION WAS ABOUT HAVE YOU READ THE FEDERAL REGISTER.
20 YOU SAID YES, I HAVE AND I FOCUSED ON THE CONTRACEPTIVE
21 AND PREVENTIVE CARE COMPONENTS.

22 THE WITNESS: YES.

23 BY MR. GOLDMAN:

24 Q. ARE YOU FAMILIAR WITH THE SOURCES THAT COUNSEL
25 ASKED YOU ABOUT?

1 A. YES. MOST OF THEM.

2 Q. AND DO YOU AGREE WITH THEM FOR THE PREMISES THEY
3 ARE CITED FOR HERE?

4 A. NO.

5 Q. AND WHY IS THAT?

6 A. BECAUSE I THINK THEY ARE SELECTIVE COMMENTS
7 WHICH DO NOT FULLY REFLECT THE BODY OF EVIDENCE THAT IS
8 AVAILABLE. DO YOU WANT ME TO SAY MORE?

9 Q. PLEASE. GO ON.

10 A. SO THE FIRST REFERENCE THAT I WAS ASKED ABOUT
11 WAS THIS FOOTNOTE 31, BEARAK AND JONES FOOTNOTE, THE
12 PUBLICATION FROM THE GUTTMACHER INSTITUTE. AND IT IS
13 CORRECT THAT THE ABSTRACT FOR THAT ARTICLE SAYS WE
14 OBSERVE NO CHANGES IN CONTRACEPTIVE USE PATTERNS AMONG
15 SEXUALLY ACTIVE WOMEN, BUT THAT STUDY FOUND AN
16 IMPROVEMENT IN CONTRACEPTIVE USE, AN INCREASED USE OF
17 CONTRACEPTION AMONG YOUNG WOMEN WHO WERE NOT SEXUALLY
18 ACTIVE IN THE LAST MONTH, WHICH SUGGESTS THAT YOUNGER
19 WOMEN WERE RESPONSIBLY -- MORE RESPONSIBLY USING
20 CONTRACEPTION IN THAT STUDY. THAT IS NOT NOTED HERE.

21 Q. AND HOW ABOUT THE OTHER SOURCES?

22 A. SO THE SANTELLI REFERENCE WHICH COMES NEXT
23 REGARDING TEEN PREGNANCIES, SANTELLI AND CO-AUTHORS JUST
24 PUBLISHED A PAPER IN 2016 SHOWING THAT TEEN PREGNANCIES
25 HAVE DECLINED MORE RECENTLY AND THAT THERE HAS BEEN NO

1 CONCOMITANT INCREASE IN SEXUAL ACTIVITY AMONG TEENS.

2 Q. DO YOU HAVE ANY OTHER EXAMPLES OF REASONS WHY

3 YOU DISAGREE WITH THE CONCLUSIONS DRAWN FROM THE STUDIES

4 THAT WERE CITED?

5 A. WELL, THE POINT ABOUT RISKS OF HORMONAL

6 CONTRACEPTION AND THE POINT ABOUT RISK OF DEPRESSION IN

7 CONTRACEPTIVE USE, I WOULD SAY THAT THE IMPLICATION IS

8 THAT THIS IS SOMETHING NEW OR IMPORTANT, WHEN, IN FACT,

9 THE MEDICAL COMMUNITY IS AWARE OF SIDE EFFECTS OF ALL

10 KINDS OF CONTRACEPTION, AND THAT IS TAKEN INTO ACCOUNT

11 IN COUNSELING WOMEN ABOUT THE APPROPRIATENESS OF THE

12 METHODS THAT THEY CHOOSE, AND IT'S ANOTHER REASON WHY

13 THE INSTITUTE OF MEDICINE COMMITTEE RECOMMENDED THAT ALL

14 METHODS BE MADE AVAILABLE TO WOMEN SO THAT THEY CAN

15 OPTIMALLY CHOOSE A METHOD THAT IS APPROPRIATE FOR THEM.

16 Q. AND, IN FACT, YOU TESTIFIED BEFORE THAT THE

17 COMMITTEE TOOK NEGATIVE EFFECTS OF CONTRACEPTION INTO

18 ACCOUNT IN MAKING ITS RECOMMENDATIONS, CORRECT?

19 A. YES.

20 Q. IF I MAY, ARE YOU FAMILIAR WITH A NEW REPORT

21 INVOLVING MODERN HORMONAL CONTRACEPTION THAT WAS

22 PERFORMED IN DANISH WOMEN THAT WAS RECENTLY IN THE FRONT

23 PAGE -- IN THE NEW YORK TIMES?

24 A. YES.

25 Q. AND CAN YOU TELL US ABOUT THAT STUDY?

1 A. THAT STUDY WAS JUST PUBLISHED, AND IT'S BASED ON
2 A LARGE SAMPLE OF DANISH WOMEN, AND IT FOUND A 1.2
3 RELATIVE RISK FOR BREAST CANCER AMONG WOMEN WHO USED
4 HORMONAL METHODS OF CONTRACEPTION OVER TIME. WHAT THIS
5 STUDY CONTRIBUTES IS THAT IT OBSERVED WOMEN WHO WERE
6 USING THE MORE MODERN HORMONAL METHODS OF CONTRACEPTION
7 AS OPPOSED TO OLDER ONES, BUT ITS FINDING OF A SMALL
8 ELEVATED RISK FOR BREAST CANCER ASSOCIATED WITH USE OF
9 HORMONAL METHODS IS NOT NEW. THAT HAS BEEN KNOWN FOR
10 SOME TIME BASED ON STUDIES OF THE OLDER HORMONAL
11 METHODS. AND IT IS TAKEN INTO ACCOUNT IN COUNSELING
12 WOMEN ABOUT THE RISKS AND SIDE EFFECTS OF CONTRACEPTION.
13 AND IT NEEDS TO BE BALANCED AGAINST OTHER STUDIES THAT
14 SHOW HORMONAL METHODS OF CONTRACEPTION TO BE PROTECTIVE,
15 THAT IS TO REDUCE THE RISKS OF OTHER CANCERS, OVARIAN
16 CANCER, ENDOMETRIAL CANCER AND COLORECTAL CANCER. SO
17 THERE ARE -- THERE IS A BALANCING REQUIRED IN MAKING A
18 DECISION ABOUT A CONTRACEPTIVE CHOICE.

19 MS. KADE: YOUR HONOR, WITH THIS ANSWER,
20 WE APPEAR TO BE BEYOND THE SCOPE OF CROSS.

21 THE COURT: WELL, I DON'T THINK WE ARE,
22 BECAUSE YOU TALKED SPECIFICALLY ABOUT THOSE IMPACTS OF
23 CONTRACEPTION.

24 BUT I DO THINK YOU SHOULD MOVE ON BECAUSE
25 THIS IS NOT A FOCUS OF MY CONCERN.

1 MR. GOLDMAN: NOTHING FURTHER, YOUR
2 HONOR.

3 THE COURT: OKAY. LET ME TALK TO YOU
4 ABOUT A FOCUS OF MY CONCERN. I WANT YOU -- YOU SAID YOU
5 HAD READ THE GUTTMACHER INSTITUTE STUDY SET FORTH IN
6 FOOTNOTE 31.

7 THE WITNESS: BEARAK AND JONES, YES.

8 THE COURT: RIGHT. YOU ALSO TOLD ME
9 ABOUT A STUDY WHICH IS CURRENTLY UNPUBLISHED THAT YOU
10 PERFORMED. I WANT TO COMPARE AND CONTRAST THEM TO SEE
11 WHETHER WE ARE TALKING ABOUT APPLES AND ORANGES OR JUST
12 APPLES.

13 SO THE GUTTMACHER INSTITUTE STUDY WAS TO
14 DETERMINE WHETHER CONTRACEPTIVE COVERAGE UNDER THE
15 MANDATE CHANGED CONTRACEPTIVE USAGE PATTERNS. WAS THAT
16 THE SAME PROPOSITION THAT YOU WERE ANALYZING IN YOUR
17 STUDY?

18 THE WITNESS: YES, ALTHOUGH OUR STUDY
19 LOOKED AT BOTH COSTS AND CONTRACEPTIVE USE PATTERNS.

20 THE COURT: AND DO YOU KNOW WHEN -- THIS
21 IS -- THIS IS WOMEN BETWEEN 2012 AND 2015 IN THIS
22 GUTTMACHER STUDY, IS THAT CORRECT?

23 WELL, THAT IS WHAT IT SAYS HERE.

24 THE WITNESS: THAT IS -- YES.

25 THE COURT: SO WHEN WAS YOUR STUDY DONE,

1 WHAT COHORT? WHAT WAS THE TIME FRAME OF YOURS?

2 THE WITNESS: THE PENNSYLVANIA STUDY?

3 THE COURT: YES.

4 THE WITNESS: 2012 THROUGH 2014.

5 THE COURT: AND HERE IT SAYS THE

6 GUTTMACHER FOLKS DID 8,000 WOMEN. AND YOU TOLD ME YOU

7 HAD HOW MANY WOMEN?

8 THE WITNESS: IN OUR PENNSYLVANIA STUDY,

9 900-SOME.

10 THE COURT: SO DO YOU KNOW WHETHER IN

11 THOSE 8,000 WOMEN THERE WERE ANY PENNSYLVANIA WOMEN?

12 THE WITNESS: I DON'T, BECAUSE THESE WERE

13 TWO SURVEYS DONE BY THE GUTTMACHER INSTITUTE, AND I

14 DON'T KNOW HOW THEY SELECTED THOSE PARTICIPANTS.

15 THE COURT: WHAT IS THE GUTTMACHER

16 INSTITUTE?

17 THE WITNESS: THE GUTTMACHER INSTITUTE IS

18 A PRIVATE NOT-FOR-PROFIT RESEARCH INSTITUTE THAT FOCUSES

19 ON REPRODUCTIVE HEALTH ISSUES IN THE UNITED STATES AND

20 GLOBALLY.

21 THE COURT: IS IT AFFILIATED WITH ANY

22 POLITICAL VIEWPOINT?

23 THE WITNESS: NO.

24 THE COURT: DO YOU KNOW WHETHER THIS

25 PAPER, THE BEARAK AND JONES PAPER WAS PEER REVIEWED?

1 THE WITNESS: YES, IT WAS.

2 THE COURT: WHAT I HAVE BEEN TRYING TO
3 ESTABLISH WAS SIMILARITIES AND DIFFERENCES. ARE THERE
4 ANY DIFFERENCES THAT I HAVE NOT IDENTIFIED AT THIS POINT
5 BETWEEN YOUR STUDY AND THE GUTTMACHER INSTITUTE STUDY
6 APART FROM THE CONCLUSION AS SET FORTH IN THE FEDERAL
7 REGISTER AS MODIFIED BY YOUR TESTIMONY WITH RESPECT TO
8 THE CONCLUSION?

9 THE WITNESS: I DON'T THINK SO.

10 THE COURT: OKAY. THANK YOU.

11 BY MR. GOLDMAN:

12 Q. VERY BRIEFLY. IS THIS GUTTMACHER INSTITUTE
13 STUDY, DO YOU KNOW IF THIS WAS BASED ON CLAIMS DATA IN
14 THE WAY THE OTHER STUDY YOU SPOKE ABOUT?

15 A. IT WAS NOT. IT WAS BASED ON SURVEY DATA.

16 Q. AND IS THERE A DIFFERENCE IN RELIABILITY BETWEEN
17 SURVEY DATA AND CLAIMS DATA?

18 A. THERE ARE THOSE WHO THINK THAT SURVEY DATA ARE
19 LESS RELIABLE IN STUDYING CONTRACEPTIVE USE PATTERNS
20 BECAUSE PEOPLE HAVE RECALL PROBLEMS AND MAY NOT RESPOND
21 ACCURATELY. BUT HAVING SAID THAT, OUR MOST DEFINITIVE
22 SOURCE OF INFORMATION ABOUT CONTRACEPTIVE USE AND
23 UNINTENDED PREGNANCY IS THE NATIONAL SURVEY OF FAMILY
24 GROWTH WHICH IS AN ONGOING NATIONAL SURVEY OF WOMEN
25 ACROSS THE COUNTRY CONDUCTED BY THE FEDERAL GOVERNMENT.

1 Q. AND YOU HAD REFERRED BEFORE WHEN WE WERE
2 SPEAKING TO A NATIONAL STUDY INCLUDING PENNSYLVANIA
3 WOMEN THAT WAS BASED ON CLAIMS DATA?

4 A. CORRECT.

5 Q. AND HOW DO THE FINDINGS YOU HAVE FOUND FROM THAT
6 STUDY COMPARE WITH THE GUTTMACHER INSTITUTE STUDY?

7 A. SO THE GUTTMACHER STUDY WAS NOT LOOKING AT
8 COSTS. I BELIEVE IT WAS ONLY LOOKING AT CONTRACEPTIVE
9 USE PATTERNS. OUR STUDY LOOKED AT BOTH, BUT WE FOUND,
10 AS I MENTIONED BEFORE, A STATISTICALLY SIGNIFICANT
11 INCREASE IN USE OF IUD'S AND IMPLANTS IN THE YEARS
12 FOLLOWING THE AFFORDABLE CARE ACT. AND UNLIKE THE
13 GUTTMACHER STUDY, WE HAD DATA BEFORE THE AFFORDABLE CARE
14 ACT WENT INTO EFFECT AND AFTER THE AFFORDABLE CARE ACT
15 WENT INTO EFFECT. THEIR DATA ARE ALL POST, POST
16 AFFORDABLE CARE ACT.

17 MR. GOLDMAN: NOTHING FURTHER, YOUR
18 HONOR, UNLESS YOU HAVE ANYTHING ELSE.

19 THE COURT: I HAVE NOTHING.

20 ANY RECROSS?

21 MS. KADE: NO, YOUR HONOR. JUST FOR THE
22 RECORD, WE WOULD RENEW OUR OBJECTION TO THE EXPERT
23 TESTIMONY TO THE EXTENT IT IS BEING OFFERED TO DETERMINE
24 THE CORRECTNESS OF THE WISDOM OF THE AGENCY'S DECISION
25 IN THIS APA CASE, YOUR HONOR.

1 THE COURT: YES, I UNDERSTAND.

2 YOU CAN LEAVE THE BENCH. THANK YOU.

3 WE WILL TAKE A BRIEF BREAK, AND WE WILL
4 BE BACK IN TEN MINUTES.

5 THE CLERK: ALL RISE.

6 (WITNESS EXCUSED.)

7 (BREAK TAKEN.)

8 MR. GOLDMAN: THE COMMONWEALTH WOULD LIKE
9 TO CALL DR. SAMANTHA BUTTS TO THE STAND, PLEASE.

10 MAY I APPROACH, YOUR HONOR.

11 THE COURT: YOU MAY.

12 SWEAR THE WITNESS.

13 THE CLERK: PLEASE RAISE YOUR RIGHT HAND
14 AND STATE YOUR NAME FOR THE RECORD.

15 THE WITNESS: SAMANTHA BUTTS.

16 (DR. SAMANTHA BUTTS, COMMONWEALTH'S
17 WITNESS, SWORN.)

18 THE CLERK: STATE AND SPELL YOUR FULL
19 NAME FOR THE RECORD, PLEASE.

20 THE WITNESS: FIRST NAME IS
21 S-A-M-A-N-T-H-A. LAST NAME IS BUTTS, B-U-T-T-S.

22 DIRECT EXAMINATION

23 BY MR. GOLDMAN:

24 Q. WILL YOU PLEASE STATE YOUR NAME FOR THE RECORD,
25 DR. BUTTS?

1 A. SAMANTHA BUTTS.

2 Q. AND WHAT DO YOU DO FOR A LIVING?

3 A. I AM AN OBSTETRICIAN GYNECOLOGIST. I SPECIALIZE
4 IN THE AREA OF REPRODUCTIVE ENDOCRINOLOGY AND
5 INFERTILITY.

6 Q. THERE IS A WITNESS EXHIBIT BINDER IN FRONT OF
7 YOU. IF I COULD DIRECT YOU TO EXHIBITS 8 AND 9 WHICH
8 ARE ALREADY ADMITTED INTO EVIDENCE, I'D LIKE YOU JUST TO
9 LOOK AT THOSE AND TELL ME IF YOU RECOGNIZE THEM, AND ASK
10 YOU WHAT THEY ARE?

11 A. THESE ARE MY DECLARATIONS PURSUANT TO THIS CASE.

12 Q. AND THE WAY THE COPY IS ON TAB 9, IF YOU LOOK TO
13 THE BACK OF THAT FIRST PAGE, WHAT IS THAT DOCUMENT?

14 A. THIS LOOKS LIKE MY CURRICULUM VITAE.

15 Q. OKAY. THE QUESTIONS ARE NOT HARD. I JUST
16 WANTED YOU TO IDENTIFY.

17 ARE YOU ABLE TO BRIEFLY LOOK THROUGH
18 THOSE DOCUMENTS AND JUST CONFIRM IF THERE ARE ANY
19 INACCURACIES IN THEM OR IF YOU BELIEVE THEY ARE
20 ACCURATE?

21 A. THE DOCUMENTS LOOK ACCURATE AND CURRENT.

22 Q. THANK YOU.

23 I WANTED TO ASK YOU BRIEFLY ABOUT YOUR
24 EDUCATION. WHERE DID YOU GO TO COLLEGE?

25 A. I WENT TO HARVARD COLLEGE.

1 Q. AND WHEN DID YOU GRADUATE?

2 A. IN 1994.

3 Q. AND WHAT DID YOU DO AFTER THAT?

4 A. I WENT TO MEDICAL SCHOOL, ALSO AT HARVARD.

5 Q. AND WHEN DID YOU GRADUATE FROM THERE?

6 A. IN 1998.

7 Q. DID YOU DO A RESIDENCY AFTER THAT?

8 A. I DID. I DID A RESIDENCY IN OBSTETRICS AND
9 GYNECOLOGY AT THE UNIVERSITY OF PENNSYLVANIA.

10 Q. AND DURING WHAT YEARS DID YOU DO YOUR RESIDENCY?

11 A. FROM 1992 -- PARDON ME, 1998 TO 2002.

12 Q. AND DID YOU DO A FELLOWSHIP ALSO?

13 A. I DID A SUBSPECIALTY FELLOWSHIP IN REPRODUCTIVE
14 ENDOCRINOLOGY AND INFERTILITY FROM 2002 UNTIL 2005, ALSO
15 AT THE UNIVERSITY OF PENNSYLVANIA.

16 Q. SO YOU'VE USED THE PHRASE REPRODUCTIVE
17 ENDOCRINOLOGY AT LEAST TWICE.

18 A. YES.

19 Q. WHAT DOES THAT MEAN?

20 A. SO REPRODUCTIVE ENDOCRINOLOGY IS THE FIELD OF
21 MEDICINE THAT INVESTIGATES HOW HORMONES AFFECT
22 REPRODUCTIVE FUNCTIONING AND DISORDERS IN WOMEN.

23 Q. DO YOU HAVE ANY OTHER RELEVANT EDUCATION HERE
24 TODAY?

25 A. I RECEIVED A MASTERS IN CLINICAL EPIDEMIOLOGY

1 AND BIOSTATISTICS AT THE UNIVERSITY OF PENNSYLVANIA
2 DURING MY FELLOWSHIP IN REPRODUCTIVE ENDOCRINOLOGY.

3 Q. HOW MANY YEARS WAS THAT MASTERS PROGRAM?

4 A. THREE YEARS, 2003 UNTIL 2006.

5 Q. ARE YOU BOARD CERTIFIED?

6 A. I AM BOARD CERTIFIED BOTH IN GENERAL OBSTETRICS
7 AND GYNECOLOGY AND IN REPRODUCTIVE ENDOCRINOLOGY AND
8 INFERTILITY.

9 Q. WAS THE REPRODUCTIVE ENDOCRINOLOGY AND
10 FERTILITY, IS THAT PART OF YOUR BOARD CERTIFICATION OR
11 IS THAT A SUBSPECIALITY?

12 A. IT'S SUBSPECIALTY BOARD CERTIFICATION.

13 Q. I WOULD LIKE TO ASK YOU BRIEFLY ABOUT YOUR
14 CURRENT WORK. WHERE DO YOU CURRENTLY WORK?

15 A. I AM ON -- I WORK AT THE UNIVERSITY OF
16 PENNSYLVANIA HOSPITAL AS A REPRODUCTIVE ENDOCRINOLOGIST
17 THERE, AND I'M ON THE FACULTY OF THE MEDICAL SCHOOL AT
18 THE UNIVERSITY OF PENNSYLVANIA.

19 MR. GOLDMAN: YOUR HONOR, JUST IN THE
20 INTEREST OF TIME FOR THESE BACKGROUND QUESTIONS, MAY I
21 ASK FOR PERMISSION TO LEAD?

22 THE COURT: YOU CAN GO AHEAD, AND IF YOU
23 ARE GOING TO OBJECT -- AT A POINT YOU FEEL IT IS
24 OBJECTIONABLE, YOU'RE GOING TO GET UP AND TELL ME.

25 MS. KADE: THANK YOU, YOUR HONOR.

1 BY MR. GOLDMAN:

2 Q. AT THE UNIVERSITY OF PENNSYLVANIA MEDICAL SCHOOL
3 AND HOSPITAL, DO YOU WORK AS A DOCTOR?

4 A. YES.

5 Q. DO YOU ALSO WORK AS A PROFESSOR?

6 A. I DO.

7 Q. DO YOU ALSO DO CLINICAL RESEARCH?

8 A. I DO.

9 Q. DO YOU ALSO PUBLISH ARTICLES AND SPEAK?

10 A. I DO.

11 Q. GENERALLY SPEAKING, WHAT KIND OF DOCTOR ARE YOU?
12 WHAT DO YOU DO FOR YOUR PATIENTS?

13 A. I SEE PATIENTS WHO COME FOR THE EVALUATION OF
14 INFERTILITY, SO HAVING DIFFICULTY ACHIEVING A PREGNANCY.
15 IN THE REPRODUCTIVE ENDOCRINE COMPONENT OF WHAT I DO, I
16 SEE WOMEN WHO SUFFER FROM A VARIETY OF DISORDERS,
17 INCLUDING DISORDERS OF MENSTRUATION, CHRONIC PELVIC PAIN
18 AND OTHER REPRODUCTIVE DISORDERS THAT I TREAT.

19 Q. IN YOUR FERTILITY WORK, YOU ACTUALLY HELP WOMEN
20 HAVE BABIES?

21 A. THAT'S CORRECT.

22 Q. IN YOUR ROLE AS PROFESSOR, IS YOUR TITLE
23 ASSOCIATE PROFESSOR?

24 A. YES.

25 Q. AND ARE YOU TENURED?

1 A. YES, I AM.

2 Q. AND DO YOU TEACH AND RESEARCH AS PART OF THAT
3 ROLE AS PROFESSOR?

4 A. I DO.

5 Q. WHO DO YOU TEACH?

6 A. I TEACH MEDICAL STUDENTS, RESIDENTS IN
7 OBSTETRICS AND GYNECOLOGY, AND FELLOWS TRAINING IN
8 REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY.

9 Q. I WILL COME BACK TO YOUR MEDICAL PRACTICE WITH
10 PATIENTS, BUT YOUR PROFESSORIAL DUTIES, ROUGHLY HOW MANY
11 HOURS A WEEK DOES THAT TAKE?

12 A. APPROXIMATELY 5 TO 10 HOURS PER WEEK.

13 Q. MOVING ON TO YOUR WORK AS A CLINICAL RESEARCHER,
14 ROUGHLY HOW MANY HOURS A WEEK DOES THAT TAKE?

15 A. THERE IS OVERLAP WITH MY RESPONSIBILITIES AS AN
16 ASSOCIATE PROFESSOR, BUT I WOULD SAY APPROXIMATELY 5 TO
17 10 HOURS PER WEEK, WITH SOME OVERLAP BETWEEN THEM.

18 Q. SO THAT NUMBER INCLUDES THE OVERLAP, CORRECT?

19 A. CORRECT.

20 Q. HAS ANY OF YOUR RESEARCH BEEN FUNDED BY GRANTS?

21 A. YES.

22 Q. AND COULD YOU NAME A FEW OF THE GRANTS YOU HAVE
23 BEEN FUNDED BY?

24 A. I HAVE BEEN FUNDED BY THE NATIONAL INSTITUTES OF
25 HEALTH, THE NATIONAL INSTITUTES OF ENVIRONMENTAL HEALTH

1 SERVICES, AND OTHER FOUNDATIONS AND INTRAMURAL SOURCES
2 AT THE UNIVERSITY OF PENNSYLVANIA.

3 MR. GOLDMAN: YOUR HONOR, I'M GOING TO
4 SKIP OVER QUESTIONS ABOUT HER -- THE DOCTOR'S CURRENT
5 PROJECTS AND PUBLICATIONS, SINCE THEY ARE IN THE RECORD,
6 BUT I JUST WANTED TO POINT OUT THAT THEY ARE AVAILABLE.
7 BY MR. GOLDMAN:

8 Q. BUT I WOULD LIKE TO FOCUS ON YOUR WORK AS A
9 MEDICAL DOCTOR. ROUGHLY HOW MANY HOURS A WEEK DO YOU
10 WORK?

11 A. ROUGHLY 50 TO 70 HOURS PER WEEK IS THE RANGE.

12 Q. AND WHY IS THERE THAT RANGE?

13 A. THERE IS A RANGE THAT DEPENDS ON PROCEDURES THAT
14 I ALSO DO. I FAILED TO MENTION BEFORE THAT AS PART OF
15 MY WORK I ALSO DO SURGICAL PROCEDURES FOR WOMEN, AND I
16 ALSO TAKE CALL ON AN APPROXIMATELY MONTHLY BASIS. SO
17 THAT REQUIRES WORK AT NIGHTS AND ON THE WEEKENDS WHEN I
18 AM ON CALL.

19 Q. AND THAT 50 TO 70 HOURS A WEEK, THAT IS ON TOP
20 OF YOUR TEACHING AND RESEARCH?

21 A. CORRECT.

22 Q. DO YOU PRESCRIBE CONTRACEPTION WHEN YOU TREAT
23 YOUR PATIENTS?

24 A. I DO.

25 Q. AND ARE YOU FAMILIAR WITH THE AFFORDABLE CARE

1 ACT?

2 A. I AM.

3 Q. ARE YOU FAMILIAR WITH THE CONTRACEPTIVE MANDATE
4 THAT IS PART OF THE AFFORDABLE CARE ACT?

5 A. YES.

6 Q. ARE YOU FAMILIAR WITH THE NEW MORAL EXEMPTION
7 RULE AND RELIGIOUS EXEMPTION RULE --

8 A. I AM.

9 Q. -- WHICH ARE AT ISSUE BEFORE THE COURT TODAY?

10 MR. GOLDMAN: BEFORE I PROCEED FURTHER,
11 YOUR HONOR, I WOULD LIKE TO PROFFER THIS WITNESS, DR.
12 SAMANTHA BUTTS, BASED ON HER KNOWLEDGE, EDUCATION,
13 TRAINING AND EXPERIENCE, AS AN EXPERT IN THE AREA OF
14 WOMEN'S REPRODUCTIVE HEALTH.

15 THE COURT: ANY OBJECTION?

16 MS. KADE: YES, YOUR HONOR. WE OBJECT
17 FOR FAILURE TO DISCLOSE AS AN EXPERT AS WELL AS TO HER
18 EXPERT TESTIMONY TO THE EXTENT IT IS BEING OFFERED TO
19 DETERMINE THE CORRECTNESS OR WISDOM OF THE AGENCY'S
20 DECISION IN THIS ACA CASE, YOUR HONOR.

21 THE COURT: I UNDERSTAND.

22 IS THE SCOPE AS NARROW OR -- THAN
23 DESCRIBED BY MS. KADE OR IS IT --

24 MR. GOLDMAN: THE TESTIMONY WILL BE ABOUT
25 WHAT SHE HAS SEEN IN HER OWN PRACTICE AS IT APPLIES TO

1 WOMEN'S REPRODUCTIVE HEALTH.

2 THE COURT: OKAY. SO SHE IS NOT GOING TO
3 TESTIFY SPECIFICALLY ABOUT WHETHER OR NOT THE TWO
4 EXEMPTIONS ARE APPROPRIATE?

5 MR. GOLDMAN: NO.

6 THE COURT: OKAY. SO THAT IS ONE OF YOUR
7 OBJECTIONS, CORRECT?

8 MS. KADE: YES, YOUR HONOR.

9 THE COURT: AND THE OTHER ONE I OVERRULE.

10 MS. KADE: THANK YOU, YOUR HONOR.

11 THE COURT: GO AHEAD.

12 BY MR. GOLDMAN:

13 Q. RETURNING TO YOUR PATIENT WORK, DOCTOR, WHERE DO
14 YOU -- WHERE DO YOUR PATIENTS COME FROM?

15 A. MY PATIENTS -- I HAVE A DIVERSE PATIENT
16 POPULATION. THEY COME FROM MANY SOURCES. MANY ARE
17 SELF-REFERRED. SOME ARE REFERRED FROM OTHER PHYSICIANS
18 IN THE HEALTH SYSTEM AND SOME ARE EMPLOYEES IN THE
19 UNIVERSITY OF PENNSYLVANIA -- AT THE UNIVERSITY OF
20 PENNSYLVANIA, BUT THEY COME FROM MANY SOURCES.

21 Q. DO PATIENTS COME TO SEE YOU FROM AROUND THE
22 WORLD?

23 A. YES.

24 Q. DO YOU ALSO SERVE AS A WEST PHILADELPHIA
25 COMMUNITY HOSPITAL DOCTOR?

1 A. I DO.

2 Q. AND YOU ALSO HAVE PATIENTS WHO ARE STUDENTS AND
3 PROFESSORS AT PENN, CORRECT?

4 A. YES.

5 Q. ROUGHLY HOW MANY PATIENTS DO YOU SEE A YEAR?

6 A. APPROXIMATELY 1500 PATIENTS PER YEAR, AND THERE
7 CAN BE SOME VARIATION WHERE THAT IS CONCERNED.

8 Q. ARE THOSE INDIVIDUAL PATIENTS OR PATIENT VISITS?

9 A. WHEN I CALCULATE BOTH INDIVIDUAL PATIENTS THAT I
10 SEE FROM A VARIETY OF SOURCES IN MY OWN PATIENT
11 PRACTICE, WORKING IN OUR GROUP INFERTILITY PRACTICE,
12 TAKING CALL AND DOING SURGICAL PROCEDURES, THAT NUMBER
13 REPRESENTS INDIVIDUAL PATIENTS.

14 Q. AND DOES THAT NUMBER INCLUDE THE SURGERIES THAT
15 YOU PERFORM?

16 A. IT DOES.

17 Q. IT DOES. AND DOES IT INCLUDE PATIENTS YOU WOULD
18 SEE WHEN YOU WERE ON CALL?

19 A. IT DOES.

20 Q. AND DOES IT INCLUDE PATIENTS YOU WOULD SEE IN
21 CONNECTION WITH YOUR TEACHING OF RESIDENTS AND FELLOWS?

22 A. IT DOES.

23 Q. HAVE YOU KEPT UP THIS PACE OF SEEING PATIENTS
24 OVER THE MORE THAN 12 YEARS YOU HAVE BEEN SEEING
25 PATIENTS?

1 A. GENERALLY, WITH SOME VARIATION FROM
2 YEAR TO YEAR, YES.

3 Q. I WOULD LIKE TO ASK YOU A LITTLE BIT MORE ABOUT
4 YOUR SPECIFIC MEDICAL PRACTICE. YOU MENTIONED THAT YOU
5 TREAT WOMEN FOR DISORDERS OF MENSTRUATION, CHRONIC
6 PELVIC PAIN AND PREMATURE OVARIAN FAILURE; IS THAT
7 CORRECT?

8 A. THAT IS CORRECT.

9 Q. CAN YOU DESCRIBE BRIEFLY WHAT IS A DISORDER OF
10 MENSTRUATION?

11 A. THE DISORDERS OF MENSTRUATION THAT I SEE INCLUDE
12 MENSTRUATION THAT IS EXCESSIVELY HEAVY, EXCESSIVELY
13 FREQUENT OR IRREGULAR IN FREQUENCY. AND SO THIS CAN
14 SIGNIFICANTLY IMPACT QUALITY OF LIFE, AND TO THE EXTENT
15 AND THE DEGREE OF THE CHRONICITY OF THE CONDITION CAN
16 SIGNIFICANTLY IMPACT HEALTH OUTCOMES, RISKS AND SEVERE
17 CONDITIONS FOR A WOMAN, AND IMPACT HER ABILITY TO BE A
18 PRODUCTIVE MEMBER OF THE WORKFORCE IF SHE IS IMPAIRED IN
19 HER ABILITY TO DO THAT BECAUSE SHE NEEDS TO ATTEND TO
20 THE SERIOUS MEDICAL DISORDER.

21 Q. FORGIVE ME, DOCTOR, I WOULD BE LYING IF I TOLD
22 YOU I HAD FIRSTHAND KNOWLEDGE OF WHAT THIS MEANS. AND
23 YOU ARE USING WORDS LIKE CHRONICITY.

24 CAN YOU TELL ME IN PRACTICAL TERMS HOW
25 THESE DISORDERS AFFECT WOMEN? WHAT DOES IT MEAN FOR

1 THEM IF YOU HAVE A MENSTRUATION DISORDER?

2 A. SO WHAT IT MEANS IS THAT A WOMAN HAS A MENSTRUAL
3 PERIOD THAT IS SIGNIFICANTLY MORE LONG IN DURATION OR
4 HEAVIER IN VOLUME THAN WE CONSIDER TO BE NORMAL, AND
5 THIS CAN OBVIOUSLY BE INCREDIBLY JARRING AND UPSETTING
6 FOR A PATIENT AND CREATE AN IMPACT ON QUALITY OF LIFE.

7 BUT TO THE EXTENT THAT THAT PROBLEM LASTS
8 FOR A SIGNIFICANT AMOUNT OF TIME, IT CAN LEAD TO CHRONIC
9 PROBLEMS, ONE OF THE MOST SEVERE OF WHICH IS MODERATE TO
10 SEVERE ANEMIA, WHICH CAN ALSO LEAD TO SIGNIFICANT
11 PROBLEMS FOR A PATIENT. IN THE MOST SEVERE CASE, SEVERE
12 ANEMIA CAN REQUIRE A PATIENT TO NEED TO BE HOSPITALIZED
13 AND RECEIVE A BLOOD TRANSFUSION.

14 Q. HAVE YOU EVER HAD TO PERFORM A BLOOD TRANSFUSION
15 ON A PATIENT WITH MENSTRUATION DISORDER?

16 A. YES.

17 Q. AND ROUGHLY HOW MANY TIMES IN YOUR CAREER --

18 A. IN MY CAREER, I WOULD SAY AT LEAST 50 TIMES.

19 Q. AND DOES THIS SORT OF THING CAUSE WOMEN TO LOSE
20 WORK?

21 A. YES.

22 Q. SORRY, HAVE TO MISS WORK?

23 A. YES.

24 Q. CAN IT AFFECT THEIR JOBS?

25 A. YES.

1 Q. TURNING TO THE DISORDERS OF CHRONIC PELVIC PAIN,
2 ROUGHLY HOW MANY WOMEN FACE THIS TYPE OF DISORDER?

3 A. SO IT'S BEEN SUGGESTED THAT UP TO 10 PERCENT OF
4 PATIENT VISITS TO THE GYNECOLOGIST HAVE TO DO WITH
5 CHRONIC PELVIC PAIN. THERE ARE A NUMBER OF CAUSES OF
6 CHRONIC PELVIC PAIN, BUT IT IS SOMETHING THAT I SEE
7 COMMONLY IN MY PRACTICE BECAUSE IT'S SOMETHING THAT IS
8 REFERRED TO ME ON A REGULAR BASIS.

9 Q. AND IS THAT THE SAME AS ENDOMETRIOSIS?

10 A. ENDOMETRIOSIS IS A COMMON CAUSE OF CHRONIC
11 PELVIC PAIN AND SEVERE PAIN WITH PERIODS. THEY ARE VERY
12 SIMILAR THINGS.

13 Q. ARE THERE TYPES OF CHRONIC PELVIC PAIN THAT ARE
14 NOT CAUSED BY ENDOMETRIOSIS?

15 A. THERE ARE SOME, AND WE SEE THOSE NOT UNCOMMONLY
16 AS WELL, BUT ENDOMETRIOSIS IS ONE OF THE MOST COMMON.

17 Q. IN PLAIN LANGUAGE, HOW DOES CHRONIC PELVIC PAIN
18 AFFECT THE REAL LIVES OF WOMEN WHO SUFFER FROM THAT
19 DISORDER?

20 A. SO I SEE PATIENTS WHO HAVE SEVERE DEBILITATING
21 PELVIC PAIN, EITHER WITH THEIR PERIODS OR OUTSIDE OF
22 THEIR PERIODS. WHEN PATIENTS COME TO SEE ME, IT'S
23 USUALLY DEBILITATING TO THE POINT THAT OVER-THE-COUNTER
24 MEDICATIONS HAVE NOT HELPED THEM AND THEY ARE LOOKING
25 FOR ADDITIONAL LEVELS OF ASSESSMENT AND CARE. SO THESE

1 ARE WOMEN WHO SOMETIMES CANNOT GO TO WORK AND CANNOT
2 FUNCTION ALONG THEIR ACTIVITIES OF DAILY LIVING BECAUSE
3 THEY ARE DEBILITATED BY PAIN AND SOMETIMES CAN'T GET OUT
4 OF BED.

5 Q. I'M GOING TO RETURN TO YOUR TREATMENT OF THESE
6 DISORDERS, BUT I WANTED TO FIRST ASK YOU ABOUT THE
7 DISORDER OF PREMATURE OVARIAN FAILURE. WHAT IS THAT?

8 A. IT'S A DISORDER WHERE THERE IS PREMATURE
9 DEPLETION OF NORMAL OVARIAN FUNCTIONING RESULTING IN
10 SIGNIFICANTLY DECREASED PRODUCTION OF NORMAL FEMALE
11 HORMONES THAT THE OVARIES ARE SUPPOSED TO PRODUCE, AND
12 SIGNIFICANTLY DECREASED ODDS OF BECOMING PREGNANT.

13 Q. IS THAT LIKE EARLY MENOPAUSE?

14 A. IT'S A SIMILAR CONDITION, YES.

15 Q. AND IF THERE IS AN AGE, ROUGHLY HOW OLD ARE YOUR
16 PATIENTS WHO SUFFER FROM PREMATURE OVARIAN FAILURE?

17 A. THE STRICT DEFINITION MEANS THAT THE ONSET OF
18 SYMPTOMS ARE HAPPENING BEFORE THE AGE OF 40. I SEE
19 PATIENTS WHO SUFFER FROM THIS DISEASE ANYWHERE FROM
20 THEIR 20S, 30S AND UP TO THE AGE OF 40.

21 Q. AND ROUGHLY HOW COMMON IS PREMATURE OVARIAN
22 FAILURE?

23 A. IT AFFECTS APPROXIMATELY ONE PERCENT OF WOMEN.

24 Q. SO IT'S ONE OUT OF A HUNDRED WOMEN?

25 A. CORRECT.

1 Q. AND IS THAT ONE OUT OF A HUNDRED WOMEN IN
2 PENNSYLVANIA OR IN THE COUNTRY OR --

3 A. THAT IS A NATIONAL PREVALENCE.

4 Q. AND AM I CORRECT THAT WITH THAT DISORDER,
5 WOMEN'S OVARIES DON'T PRODUCE ESTROGEN?

6 A. THAT'S CORRECT.

7 Q. CAN THEY STILL GET PREGNANT?

8 A. THEY HAVE A DIMINISHED ODDS OF BECOMING PREGNANT
9 BUT THEY CAN STILL ACHIEVE A PREGNANCY IN SOME CASES.

10 Q. WHAT HAPPENS TO WOMEN WHOSE OVARIES DO NOT
11 PRODUCE ESTROGEN?

12 A. SO IF A WOMAN IS DIAGNOSED WITH THIS DISEASE IN
13 HER 20S, FOR INSTANCE, AND WE KNOW THAT THE AVERAGE AGE
14 OF NATURAL MENOPAUSE WHEN THESE CHANGES ARE SUPPOSED TO
15 HAPPEN IS 51 YEARS OLD, THAT MEANS THAT SHE CAN STAND TO
16 EXPERIENCE 30 YEARS OF HER ADULT LIFE WITHOUT ONE OF THE
17 MOST CRITICAL HORMONES THAT HER BODY PRODUCES.

18 SO THE SHORT-TERM CONSEQUENCES OF THAT
19 ARE SIGNIFICANT IMPAIRMENT OF QUALITY OF LIFE; HOT
20 FLASHES, NIGHT SWEATS AND SYMPTOMS OF LOW ESTROGEN.
21 SOME OF THE MORE SERIOUS LONG-TERM CONSEQUENCES INCLUDE
22 INCREASED RISK OF CARDIOVASCULAR DISEASE. WHEN WOMEN
23 ARE PREMATURELY DEPRIVED OF ESTROGEN, INCREASED RISK OF
24 BONE LOSS AND HIP FRACTURE. AND THOSE ARE TWO OF THE
25 MOST COMMON SERIOUS CONSEQUENCES THAT WE SEE.

1 Q. CAN WOMEN WHO SUFFER FROM LOSS OF ESTROGEN DIE
2 FROM THAT?

3 A. WELL, I WOULD ARGUE THAT SINCE HEART DISEASE AND
4 HEART ATTACK IS THE NUMBER ONE KILLER OF WOMEN AND ALL
5 AMERICANS, ANYTHING THAT PUTS YOU AT GREATER RISK OF
6 EXPERIENCING THAT INCREASES YOUR RISK OF DEATH.

7 Q. IN ADDITION TO THOSE THREE CATEGORIES OF
8 DISORDERS, YOU ALSO TREAT INFERTILITY, CORRECT?

9 A. YES.

10 Q. I THINK WE ALL KNOW GENERALLY WHAT THAT IS, NOT
11 TO YOUR DEGREE OF KNOWLEDGE, BUT I WOULD JUST LIKE TO
12 INCLUDE THAT IN THE CONVERSATION.

13 SO HOW DO YOU TREAT YOUR PATIENTS WITH
14 THOSE THREE DISORDERS AND THE PATIENTS SUFFERING FROM
15 INFERTILITY?

16 A. SO FOR THE PATIENTS WE DESCRIBED, THE THREE
17 DISORDERS OF ABNORMAL MENSTRUATION, CHRONIC PELVIC PAIN,
18 SEVERE PAIN WITH PERIODS AND PREMATURE OVARIAN FAILURE,
19 THERE ARE INDICATIONS FOR ALL THREE OF THOSE TO
20 INCORPORATE HORMONAL CONTRACEPTION TO MANAGE THOSE
21 DISORDERS AND TO MITIGATE SOME OF THE ASSOCIATED RISKS
22 THAT WE TALKED ABOUT THAT ARE ASSOCIATED WITH THEM.

23 Q. WHEN YOU SAY HORMONAL CONTRACEPTION, DOES THAT
24 MEAN THE BIRTH CONTROL PILL OR CAN THAT ALSO REFER TO
25 IUD'S?

1 A. IT REFERS TO BOTH.

2 Q. AND DO YOU ALSO USE CONTRACEPTIVES ON PATIENTS
3 WHO SUFFER FROM INFERTILITY?

4 A. WE INTEGRATE HORMONAL CONTRACEPTION TO HELP WITH
5 THE PROTOCOLS THAT ARE BUILT INTO THE TREATMENTS THAT WE
6 OFFER. IT HELPS MANAGE THE CYCLES THAT WE BUILD FOR
7 PATIENTS WHEN WE ARE DOING TREATMENTS LIKE IN VITRO
8 FERTILIZATION, FOR INSTANCE.

9 Q. I FEEL LIKE I'M A LITTLE BIT IN A SCIENCE CLASS.
10 IT'S OKAY, IT'S BEEN A WHILE, BUT I'M GETTING THERE.

11 WHEN YOU TREAT WOMEN WITH -- WHO ARE
12 SUFFERING FROM INFERTILITY WITH CONTRACEPTIVES, TO ME
13 THAT SEEMS COUNTERINTUITIVE.

14 A. WE USE THE MEDICATIONS TO ACHIEVE SEVERAL THINGS
15 WITH THE INFERTILITY TREATMENTS THAT WE HAVE TO OFFER.
16 IN A CERTAIN POPULATION OF WOMEN, IT HELPS CREATE A
17 SAFER PROCESS FOR THE PATIENT, SO BIRTH CONTROL PILLS,
18 WE TAKE ADVANTAGE OF SOME OF THEIR NONCONTRACEPTIVE
19 BENEFITS TO HELP PERFORM INFERTILITY TREATMENTS IN A WAY
20 THAT IS -- ENHANCES THE SAFETY AND EFFICACY OF THOSE
21 TREATMENTS OVERALL.

22 IT HELPS US WITH THE TIMING OF INITIATING
23 THOSE TREATMENTS AS WELL. IT CAN ALSO HELP IN CERTAIN
24 WOMEN WHO HAVE ENDOMETRIOSIS, WHICH IS ONE OF THE
25 CONDITIONS I MENTIONED. IT CAN HELP THOSE WOMEN WITH

1 CONTROLLING SOME OF THEIR SYMPTOMS PRIOR TO TREATMENT
2 AND MAY IN SOME WOMEN INCREASE THE LIKELIHOOD THAT THOSE
3 TREATMENTS WILL WORK FOR THEM.

4 Q. SO WHEN YOU PRESCRIBE CONTRACEPTIVES TO THESE
5 CATEGORIES OF YOUR PATIENTS, FOR SOME PATIENTS DO YOU
6 PRESCRIBE THEM PURELY TO PREVENT PREGNANCY?

7 A. YES.

8 Q. AND IN OTHERS, DO YOU PRESCRIBE THEM NOT AT ALL
9 TO PREVENT PREGNANCY?

10 A. THAT IS CORRECT.

11 Q. THAT MIGHT BE, FOR EXAMPLE, SOMEONE WHO IS
12 POSTMENOPAUSAL BUT HAS CHRONIC PELVIC PAIN?

13 A. SOMETHING LIKE THAT, YES.

14 Q. AND ARE THERE TIMES WHEN YOU PRESCRIBE
15 CONTRACEPTION FOR BOTH PURPOSES, TO PREVENT PREGNANCY
16 BUT ALSO FOR NONPREGNANCY-PREVENTION PURPOSES?

17 A. YES.

18 Q. GENERALLY SPEAKING, WHAT TYPES OF CONTRACEPTIVES
19 DO YOU PRESCRIBE TO YOUR PATIENTS?

20 A. THE CONTRACEPTIVES THAT I USE MOST REGULARLY
21 INCLUDE THE ORAL CONTRACEPTIVE PILL AND THE MIRENA
22 INTRAUTERINE DEVICE.

23 Q. I WOULD LIKE TO ASK YOU ABOUT YOUR EXPERIENCE IN
24 PRESCRIBING CONTRACEPTIVES TO YOUR PATIENTS.

25 DO YOU HAVE EXPERIENCE PRESCRIBING

1 CONTRACEPTIVES TO YOUR PATIENTS BEFORE THE AFFORDABLE
2 CARE ACT AND ITS CONTRACEPTIVE MANDATE WERE THE LAW?

3 A. YES.

4 Q. HAVE YOU ALSO PRESCRIBED CONTRACEPTIVES TO
5 PATIENTS SINCE THE AFFORDABLE CARE ACT AND ITS
6 CONTRACEPTIVE MANDATE BECAME THE LAW?

7 A. YES.

8 Q. SO YOU HAVE EXPERIENCE IN BOTH WORLDS, PRE-ACA
9 AND POST?

10 A. YES, I DO.

11 Q. HAVE YOU SEEN ANY DIFFERENCES IN YOUR PRACTICE
12 OF PRESCRIBING CONTRACEPTIVES TO PATIENTS DURING THESE
13 TWO TIME PERIODS?

14 A. I HAVE EXPERIENCED THAT, YES.

15 Q. AND CAN YOU DESCRIBE FIRST, WHAT IT WAS LIKE
16 PRESCRIBING CONTRACEPTIVES BEFORE THE CONTRACEPTIVE
17 MANDATE WAS IN PLACE?

18 A. SO PRIOR TO THE MANDATE, THERE WAS FAR LESS
19 CERTAINTY ABOUT PATIENT ABILITY TO ACCESS SOME OF THESE
20 TREATMENTS FOR THE STATED PURPOSES WE DISCUSSED, DUE TO
21 CONCERN ABOUT AFFORDABILITY AND COVERAGE AND WHETHER
22 PATIENTS WOULD BE ABLE TO GET ACCESS ON THAT BASIS.

23 Q. SO AM I CORRECT THAT AS A DOCTOR, YOU WOULD
24 ACCESS THE PATIENTS' NEEDS --

25 A. YES.

1 Q. -- MEDICAL NEEDS, AND THEN YOU WOULD PRESCRIBE
2 THE BEST MEDICATION FOR THEM AND THEIR CONDITION; IS
3 THAT RIGHT?

4 A. THAT'S CORRECT.

5 MS. KADE: OBJECTION, LEADING.

6 THE COURT: SUSTAINED. ASK THE QUESTION
7 AGAIN.

8 BY MR. GOLDMAN:

9 Q. HOW WOULD YOU -- HOW DO YOU CHOOSE WHICH KIND OF
10 PRESCRIPTION TO PRESCRIBE TO PATIENTS?

11 A. SO I PERFORM A THOROUGH AND COMPREHENSIVE
12 EVALUATION OF THE PATIENT'S SYMPTOMS AND THE
13 UNDERPINNINGS FOR THEIR CONDITION. I CONSIDER THE
14 INDIVIDUAL CHARACTERISTICS OF THE PATIENT IN TERMS OF
15 PRIOR ASSESSMENTS, PRIOR TREATMENTS, WHAT HAS WORKED,
16 WHAT HAS NOT WORKED, AND ANY SPECIFIC RISK THEY MAY HAVE
17 FOR ANY MEDICAL TREATMENT THAT I MAY OFFER.

18 AND I INDIVIDUALIZE THE CARE FOR THEIR
19 PARTICULAR UNIQUE SET OF DIAGNOSES AND NEEDS, MAKING THE
20 BEST DECISION THAT I CAN IN CONSULTATION WITH THE
21 PATIENT.

22 Q. PRE-ACA, ONCE YOU DO YOUR ANALYSIS AND YOU MAKE
23 YOUR PRESCRIPTION OF THE BEST MEDICATION FOR A PATIENT,
24 WERE PATIENTS ALWAYS FILLING IT?

25 A. NOT ALWAYS.

1 Q. WERE THERE TIMES WHEN THEY WOULD COME BACK TO
2 YOU AND ASK YOU FOR A DIFFERENT PRESCRIPTION OR NO
3 PRESCRIPTION?

4 MS. KADE: OBJECTION, LEADING.

5 THE COURT: SUSTAINED. REASK THE
6 QUESTION IN A NONLEADING WAY.

7 BY MR. GOLDMAN:

8 Q. WHEN PATIENTS WOULD NOT FILL THE PRESCRIPTION
9 YOU GAVE THEM, WHAT WOULD HAPPEN?

10 A. WE WOULD -- I WOULD TRY TO GET AN UNDERSTANDING
11 OF THE LACK OF COMPLIANCE FROM MY PERSPECTIVE OF NOT
12 TAKING OR FILLING THE PRESCRIPTION, AND IN GETTING TO
13 THE BOTTOM OF THIS, FOR MANY PATIENTS IT HAD TO DO WITH
14 SIGNIFICANT COSTS AND INAFFORDABILITY OF THOSE
15 TREATMENTS.

16 Q. AND DID THAT REASONING TAKE PLACE WHEN YOU
17 PRESCRIBED ORAL BIRTH CONTROL PILLS?

18 A. IN SOME CASES, YES.

19 Q. CAN YOU ESTIMATE ROUGHLY WHAT PERCENTAGE OF YOUR
20 PATIENTS WOULD REFUSE A PRESCRIPTION FOR ORAL BIRTH
21 CONTROL PILLS PRE-ACA?

22 A. IN MY EXPERIENCE DURING THAT TIME, MY ESTIMATE
23 WOULD BE ROUGHLY 10 TO 20 PERCENT OF PATIENTS WOULD HAVE
24 A FINANCIAL BARRIER TO THOSE TYPES OF PRESCRIPTIONS.

25 Q. AND HOW ABOUT WHEN YOU WOULD PRESCRIBE AFTER

1 YOUR ANALYSIS IUD'S, WHAT WAS THE PERCENTAGE OF YOUR
2 PATIENTS WHO WOULD REJECT THAT PRESCRIPTION?

3 A. IT WAS APPROXIMATELY AT LEAST 30 PERCENT.

4 Q. IS THAT BECAUSE IUDS ARE MORE EXPENSIVE THAN
5 BIRTH CONTROL PILLS?

6 A. IT HAS TO DO WITH THE COSTS, TOTAL COSTS AROUND
7 THE IUD DEVICE AND THE INSERTION, WHICH HAS A
8 SIGNIFICANT ONE-TIME UP-FRONT COST WHICH, WHEN COMPARED
9 TO THE INTERVAL COST OF THE BIRTH CONTROL PILL, IS
10 SIGNIFICANTLY GREATER. BUT BECAUSE THE IUD THAT I
11 PRESCRIBE REGULARLY, THE MIRENA, LASTS FOR FIVE YEARS,
12 WHEN YOU EXTEND THAT ONE-TIME COST OVER FIVE YEARS, IT
13 ACTUALLY ENDS UP BECOMING LESS EXPENSIVE, ESPECIALLY IF
14 YOU COMPARE IT TO SOME PREPARATIONS WHERE THERE IS A
15 MONTHLY COST THAT, OVER TIME, CAN BE SIGNIFICANTLY
16 ADDITIVE.

17 Q. SO I WOULD LIKE TO DIG INTO THAT JUST A LITTLE
18 BIT MORE.

19 YOU SAID THAT A MIRENA LASTS FIVE YEARS?

20 A. YES.

21 Q. AND WHAT IS THE UP-FRONT COST?

22 A. ALL FEES, THE DEVICE AND THE INSERTION, CAN BE
23 ANYWHERE FROM ABOUT 800 TO \$1,000.

24 Q. AND AFTER THE DEVICE IS PURCHASED AND INSERTED
25 FOR 800 TO \$1,000, ARE THERE ANY FURTHER COSTS OVER THE

1 FIVE-YEAR LIFE OF THE MIRENA IUD?

2 A. IF THE PATIENT HAS NO ISSUES AND DECIDES TO KEEP
3 THE DEVICE IN PLACE FOR FIVE YEARS, THERE ARE NO
4 ADDITIONAL COSTS.

5 Q. BY CONTRAST, THE ORAL BIRTH CONTROL PILL, YOU
6 HAD SAID THAT IS A MONTHLY PRESCRIPTION?

7 A. YES.

8 Q. ROUGHLY HOW MUCH DOES THAT COST?

9 A. IT DEPENDS, OBVIOUSLY, ON THE PREPARATION. YOU
10 KNOW, THERE ARE SOME PATIENTS WHO CAN PAY ON AVERAGE \$30
11 PER MONTH OR MORE FOR A MONTHLY PRESCRIPTION. SO YOU
12 CAN SEE HOW OVER TIME THE NUMBERS CAN CHANGE.

13 Q. SO ROUGHLY -- \$30 A MONTH IS ROUGHLY, ROUGHLY
14 \$360 A YEAR?

15 A. YES.

16 Q. AND THEN OVER FIVE YEARS, WHICH IS THE TERM OF
17 THE MIRENA IUD, IT WOULD COST ROUGHLY FIVE TIMES THAT?

18 A. YES.

19 Q. AND THAT IS ROUGHLY \$1,800, IS THAT CORRECT?

20 A. YES.

21 Q. SO WHICH OF THOSE DEVICES IS MORE EFFECTIVE, OR
22 PRESCRIPTION IS MORE EFFECTIVE?

23 A. THE INTRAUTERINE DEVICE IS A MORE EFFECTIVE
24 CONTRACEPTIVE AND CAN BE MORE EFFECTIVE IN TERMS OF
25 MANAGING HEAVY MENSTRUAL PERIODS FOR SOME WOMEN COMPARED

1 HEAD TO HEAD TO THE BIRTH CONTROL PILL.

2 Q. AM I CORRECT THEN TO UNDERSTAND YOU CORRECTLY
3 THAT BECAUSE OF THE COST, WOMEN END UP PAYING MORE MONEY
4 FOR LESS GOOD CARE?

5 A. THAT IS POTENTIALLY THE CASES FOR SOME WOMEN,
6 YES.

7 MR. GOLDMAN: COURT'S INDULGENCE, YOUR
8 HONOR.

9 (PAUSE.)

10 BY MR. GOLDMAN:

11 Q. WHEN YOU -- STRIKE THAT.

12 SO ALL THAT WAS BEFORE THE ACA. AFTER
13 THE ACA AND THE CONTRACEPTIVE MANDATE WENT INTO EFFECT,
14 DID ANYTHING CHANGE?

15 A. YES. SIGNIFICANT NOTABLE CHANGE IN MY OWN
16 PRACTICE I CAN SPEAK TO WITH THE MOST AUTHORITY IN
17 ACCESS TO THE IUD BASED ON AFFORDABILITY OF THE IUD.

18 Q. AFTER THE ACA, HOW OFTEN DID YOUR PATIENTS PUSH
19 BACK ON YOUR PRESCRIPTIONS TO THEM?

20 A. FOR BOTH FORMS OR FOR EITHER?

21 Q. EITHER.

22 A. OKAY. FAR LESS. I CAN, YOU KNOW, TRY TO GIVE
23 YOU A NUMBER IN TERMS OF THE ESTIMATE, BUT I'M VERY
24 HARD-PRESSED TO THINK OF A PATIENT THAT I HAVE MANAGED
25 IN RECENT MEMORY FOR WHOM I HAVE RECOMMENDED A MIRENA

1 IUD WHO HAS HAD DIFFICULTY ACQUIRING IT.

2 Q. LET ME MAKE SURE I UNDERSTAND THAT. SINCE THE
3 ACA WENT INTO EFFECT, YOU CANNOT THINK OF A SINGLE
4 PATIENT WHO HAS REJECTED YOUR PRESCRIPTION OF A MIRENA
5 IUD?

6 A. I CAN'T THINK OF ONE THAT EASILY COMES TO
7 MEMORY.

8 Q. AND BEFORE THE ACA, ROUGHLY 30 PERCENT WERE
9 REJECTING THE MIRENA?

10 A. YES.

11 Q. DO YOU TREAT PATIENTS FOR WHOM IT IS DANGEROUS
12 TO GET PREGNANT?

13 A. I DO.

14 Q. WHAT HAPPENS TO THEM IF THEY GET PREGNANT
15 ANYWAY?

16 A. WELL, THERE ARE A VARIETY OF DISORDERS FOR WHICH
17 PREGNANCY CAN BE INCREDIBLY COMPLICATED IF YOU GO INTO
18 PREGNANCY WITH THOSE DISORDERS. THEY CAN BECOME MORE
19 SEVERE AND POTENTIALLY LIFE-THREATENING TO A WOMAN WHO
20 BECOMES PREGNANT IF SHE CARRIES THAT DISORDER INTO
21 PREGNANCY.

22 Q. I WOULD LIKE TO TURN YOUR ATTENTION TO THE
23 RULES, AND THEY ARE -- I DON'T THINK WE HAVE TO GO
24 THROUGH THEM SPECIFICALLY, BUT IF YOU'D LIKE TO LOOK AT
25 THEM, THEY ARE IN YOUR EXHIBIT BINDER. THE RELIGIOUS

1 EXEMPTION RULE IS MARKED AS EXHIBIT 1 AND THE MORAL
2 EXEMPTION RULE I BELIEVE IS EXHIBIT 2.

3 ARE YOU GENERALLY FAMILIAR WITH THESE NEW
4 RULES THAT ARE AT ISSUE IN THIS PROCEEDING?

5 A. YES.

6 Q. AND I KNOW IT'S A LONG DOCUMENT, BUT HAVE YOU
7 READ THE RELIGIOUS EXEMPTION RULE?

8 A. I HAVE.

9 Q. AND DO YOU BELIEVE YOU UNDERSTAND THAT RULE
10 INSOFAR AS IT WOULD AFFECT PATIENTS LIKE THE ONES YOU
11 TREAT IN PENNSYLVANIA?

12 A. I BELIEVE I DO.

13 Q. AND THE MORAL EXEMPTION RULE IS SIMILARLY LONG,
14 BUT HAVE YOU READ IT?

15 A. YES.

16 Q. DO YOU BELIEVE YOU UNDERSTAND IT AND CAN
17 UNDERSTAND THE IMPACT IT MIGHT HAVE ON THE PATIENTS YOU
18 TREAT?

19 A. I DO.

20 Q. IN YOUR CAPACITY AS AN EXPERT IN WOMEN'S
21 REPRODUCTIVE HEALTH, DO YOU HAVE AN OPINION TO A
22 REASONABLE DEGREE OF CERTAINTY AS TO WHETHER THESE SAME
23 RULES WOULD AFFECT THE REPRODUCTIVE HEALTH OF WOMEN IN
24 PENNSYLVANIA.

25 MS. KADE: OBJECTION, YOUR HONOR. THIS

1 GOES BEYOND THE SCOPE OF HER EXPERTISE. WE ARE NOW
2 GETTING INTO STATISTICS.

3 THE COURT: THAT WAS THE BASIS OF YOUR
4 OBJECTION, ESSENTIALLY. THE OBJECTION THAT YOU LODGED
5 AT BEGINNING INCORPORATES, I THINK, THE OBJECTION YOU
6 ARE MAKING NOW.

7 MS. KADE: WELL, MY CURRENT OBJECTION IS
8 TO HIS CURRENT QUESTION AND WHAT HE IS ASKING FOR, WHICH
9 IS A STATISTICAL QUESTION ASKING FOR A STATISTICAL
10 ANSWER, AND SHE HAS NOT BEEN QUALIFIED AS THAT TYPE OF
11 AN EXPERT, YOUR HONOR.

12 THE COURT: SUSTAINED.

13 MR. GOLDMAN: IF I MAY RESPOND TO THAT,
14 YOUR HONOR, I DON'T ACTUALLY THINK THAT IS WHAT I'M
15 ASKING FOR.

16 THE COURT: THAT IS -- OKAY. SO WHY
17 DON'T YOU ASK THE QUESTION AGAIN SO THAT WE CAN MAKE
18 SURE IT IS NOT WHAT YOU --

19 MR. GOLDMAN: SURE.

20 BY MR. GOLDMAN:

21 Q. YOU'VE TESTIFIED BASED ON YOUR EXPERIENCE THAT
22 BEFORE THE AFFORDABLE CARE ACT WOMEN WERE NOT UNIFORMLY
23 ACCEPTING YOUR PRESCRIPTION CARE, CORRECT?

24 A. CORRECT.

25 Q. AND THEN YOU ALSO TESTIFIED THAT AFTER THE

1 AFFORDABLE CARE ACT, THAT YOU CAN'T RECALL A SINGLE
2 PATIENT WHO HAS REFUSED A PRESCRIPTION FOR AN IUD,
3 CORRECT?

4 A. BASED ON -- BASED ON AFFORDABILITY ISSUES, YES.

5 Q. AND I BELIEVE YOU TESTIFIED THAT THE BASIS FOR
6 THE CHANGES THAT -- POST-ACA CONTRACEPTIVE MANDATE, YOUR
7 PATIENTS HAVE COVERAGE SO THEY DON'T HAVE TO PAY OUT OF
8 POCKET FOR THESE PRESCRIPTIONS, CORRECT?

9 A. YES.

10 Q. UNDER THE RULES AS YOU UNDERSTAND THEM, DO YOU
11 BELIEVE THE RULES WILL CHANGE THE NUMBER OF WOMEN IN
12 PENNSYLVANIA WHO HAVE CONTRACEPTIVE CARE COVERAGE?

13 MS. KADE: OBJECTION, YOUR HONOR. AGAIN,
14 SINCE SHE HAS NO PERSONAL KNOWLEDGE OF ANY OF HER
15 PATIENTS THAT ARE AFFECTED BY THE NEW RULES, THIS IS
16 ASKING FOR STATISTICAL PREDICTION.

17 THE COURT: IF YOU CAN ANSWER THE
18 QUESTION WITHOUT A STATISTICAL PREDICTION, YOU ARE FREE
19 TO ANSWER.

20 THE WITNESS: I CAN ANSWER THIS QUESTION
21 SPEAKING TO MY EXPERIENCE OVER 12 YEARS OF PRACTICING
22 WOMEN'S HEALTH IN MY CURRENT POSITION AND MY EXPERIENCE
23 OF MORE DIFFICULT ACCESS AND UTILIZATION PRIOR TO THE
24 MANDATE, AND MY SENSE THAT ANY THREAT TO ACCESS BASED ON
25 RULES SUCH AS THESE MAY CHALLENGE THAT ACCESS AGAIN IN

1 WAYS THAT I PERSONALLY HAVE EXPERIENCE WITH IN MY
2 PATIENT POPULATION.

3 BY MR. GOLDMAN:

4 Q. SO BASED ON THAT EXPERIENCE THAT YOU DESCRIBED,
5 DO YOU HAVE AN OPINION AS TO THE RULES WHICH ALLOW MORE
6 EXEMPTIONS TO THE MANDATORY COVERAGE, WHAT EFFECT THEY
7 WOULD HAVE ON WOMEN IN PENNSYLVANIA?

8 MS. KADE: SAME OBJECTION, YOUR HONOR.
9 TO THE EXTENT THAT SHE IS BEING ASKED TO PROVIDE HER
10 SENSE OF WHAT MIGHT HAPPEN NOT BASED ON ANY ACTUAL WOMEN
11 IN PENNSYLVANIA THAT SHE KNOWS ABOUT, IS OUTSIDE THE
12 SCOPE OF HER EXPERTISE.

13 THE COURT: OVERRULED.

14 YOU CAN ANSWER.

15 THE WITNESS: SO I JUST WANT TO MAKE SURE
16 I UNDERSTAND THE QUESTION ONE MORE TIME. SPEAK TO THE
17 CONSEQUENCES OF THE EXEMPTIONS?

18 BY MR. GOLDMAN:

19 Q. SURE. THE RULES WHICH CREATE EXEMPTIONS TO
20 CARE, WHAT EFFECT IF ANY DO YOU BELIEVE THEY WILL HAVE
21 ON WOMEN IN PENNSYLVANIA?

22 A. MY SENSE IS THAT IT WILL MAKE AN IMPACT
23 NEGATIVELY ON THE ABILITY OF WOMEN TO ACCESS THESE
24 TREATMENTS, AND IN SO DOING LIMIT OUR ABILITY TO TREAT
25 THE TYPES OF DISORDERS THAT I HAVE DISCUSSED WHICH

1 WILL -- COULD INCREASE PAIN AND SUFFERING FOR WOMEN WHO
2 HAVE THOSE DISORDERS, WORSENING OF SOME OF THE SERIOUS
3 MEDICAL CONSEQUENCES OF THOSE DISORDERS, AND RESULT IN
4 UNINTENDED PREGNANCIES IN GENERAL. AND TO THE EXTENT
5 THAT SOME OF THOSE UNINTENDED PREGNANCIES ARE IN WOMEN
6 WITH VERY SERIOUS MEDICAL DISORDERS FOR WHOM PREGNANCY
7 MAY BE CONTRA -- EXCUSE ME, PREGNANCY MAY BE RELATIVELY
8 OR ABSOLUTELY CONTRAINDICATED, THAT CAN INCREASE RISKS
9 IN A LIFE-THREATENING WAY FOR SOME WOMEN.

10 Q. PATIENTS MAY DIE?

11 A. YES.

12 Q. DOES THAT OPINION HOLD, IF YOU HAVE ONE, FOR
13 WOMEN OUTSIDE OF PENNSYLVANIA AS WELL BECAUSE OF THE
14 RULES?

15 MS. KADE: YOUR HONOR, WE ARE SO FAR
16 OUTSIDE THIS WITNESS' EXPERTISE, WE CONTINUE TO OBJECT
17 TO THIS LINE OF QUESTIONING.

18 THE COURT: SUSTAINED.

19 MR. GOLDMAN: NOTHING FURTHER.

20 THE COURT: YOUR WITNESS.

21 MS. KADE: THANK YOU, YOUR HONOR.

22 CROSS-EXAMINATION

23 BY MS. KADE:

24 Q. GOOD MORNING, DR. BUTTS.

25 A. GOOD MORNING.

1 Q. MY NAME IS ELIZABETH KADE.

2 A. HELLO.

3 Q. FIRST, WHAT DOCUMENTS DID YOU REVIEW IN ORDER TO
4 PREPARE YOUR DECLARATION?

5 A. TO PREPARE THE DECLARATION I REVIEWED MY OWN
6 CURRICULUM VITAE. THAT WAS THE PRIMARY DOCUMENT THAT I
7 REVIEWED AND -- PRIMARILY, YES.

8 Q. WAS THERE ANYTHING ELSE YOU CAN REMEMBER RIGHT
9 NOW?

10 A. OFF THE TOP OF MY HEAD, NO OTHER DOCUMENTS.

11 Q. WHO DID YOU MEET WITH IN ORDER TO PREPARE YOUR
12 DECLARATION?

13 A. I MET WITH COUNSEL SITTING BEFORE ME FROM THE
14 ATTORNEY GENERAL'S OFFICE TO DISCUSS PROCESS AND THE
15 DECLARATION.

16 Q. ANYBODY ELSE?

17 A. NO.

18 Q. TURNING TO YOUR DECLARATION, YOU HAVE TESTIFIED
19 IN PARAGRAPH 53 OF YOUR DECLARATION THAT --

20 THE COURT: CAN YOU JUST TELL ME WHAT TAB
21 THAT IS AGAIN?

22 MS. KADE: SURE, I BELIEVE IT IS TAB 8.

23 THE COURT: I SEE IT. 8, YES.

24 BY MS. KADE:

25 Q. I'M AT PARAGRAPH 53, WHICH IS PAGE 9 OF 35 AT

1 THE TOP, IF THAT IS HELPFUL, AND PAGE 8 AT THE BOTTOM?

2 A. OKAY.

3 Q. SO YOU HAVE TESTIFIED THAT AS A RESULT OF THE
4 RULES, SOME WOMEN WILL LOSE COVERAGE, INSURANCE
5 COVERAGE, FOR PREVENTIVE CONTRACEPTIVE CARE, CORRECT?

6 A. YES.

7 Q. DO YOU KNOW HOW MANY RELIGIOUS EMPLOYERS ARE
8 CURRENTLY PROTECTED BY INJUNCTION?

9 A. I DO NOT.

10 Q. DO YOU KNOW THAT THOSE EMPLOYERS THAT HAVE
11 INJUNCTIONS ARE NOT CURRENTLY PROVIDING CONTRACEPTIVE
12 COVERAGE?

13 A. I DO NOT.

14 Q. ARE YOU AWARE OF THE 2016 ZUBIK INJUNCTION?

15 A. I'M NOT AWARE OF THAT INJUNCTION.

16 Q. DO YOU KNOW THAT ENTITIES PROTECTED BY THAT
17 INJUNCTION ARE NOT CURRENTLY PROVIDING CONTRACEPTIVE
18 COVERAGE THEN?

19 A. AGAIN, NOT FAMILIAR WITH THAT CASE.

20 Q. DO YOU KNOW THAT THERE WERE EXEMPTIONS TO THE
21 MANDATE BEFORE THE NEW RULE WENT INTO EFFECT?

22 A. CAN YOU REPHRASE THAT QUESTION?

23 Q. ARE YOU AWARE THAT EVEN BEFORE THE NEW RULES
24 WENT INTO EFFECT, CERTAIN EMPLOYERS WERE NOT REQUIRED TO
25 PROVIDE CONTRACEPTIVE COVERAGE PURSUANT TO THE MANDATE

1 BECAUSE THEY FELL UNDER ANY ONE OF A NUMBER OF
2 EXEMPTIONS, LIKE THEY WERE A GRANDFATHERED PLAN, THEY
3 WERE A CHURCH PLAN, SOMETHING LIKE THAT?

4 A. I AM AWARE OF THAT PHENOMENON TO AN EXTENT.

5 Q. NONE OF YOUR PATIENTS HAS HAD TO ASK FOR A
6 CHEAPER FORM OF CONTRACEPTION SINCE THE MANDATE WENT
7 INTO EFFECT?

8 A. I'M NOT SURE THAT THAT IS WHAT I TESTIFIED.

9 MY TESTIMONY WAS THAT SINCE THE MANDATE
10 WENT INTO EFFECT, THERE HAS BEEN OVERALL MUCH BROADENED
11 ACCESS AND FAR LESS PUSHBACK AGAINST ACCESSING THESE
12 TREATMENTS BASED PURELY ON AFFORDABILITY.

13 Q. SO SOME OF YOUR PATIENTS HAVE STILL ASKED FOR A
14 CHEAPER FORM OF CONTRACEPTION SINCE THE MANDATE WENT
15 INTO EFFECT?

16 A. I CAN RECALL SOME, BASED ON SOME OF THE
17 INDIVIDUAL VARIATION IN COVERAGE IN TERMS OF GENERIC
18 FORMS OF THE BIRTH CONTROL PILL OR VERSUS BRAND NAMES,
19 BUT IN GENERAL AND ON BALANCE, THIS HAS BEEN FAR LESS OF
20 A PROBLEM POST MANDATE THAN PRE MANDATE.

21 Q. SO POST MANDATE, IN A POST MANDATE WORLD, WERE
22 ANY OF THE PATIENTS THAT YOU HAD THAT WERE PUSHING BACK
23 ON COST CONCERNS, WERE ANY OF THEM CONCERNED ABOUT THIS
24 BECAUSE OF A DIFFERENCE IN CONTRACEPTIVE COVERAGE FROM
25 THEIR INSURANCE BECAUSE OF AN EXEMPTION?

1 A. I DON'T THINK WE HAD THAT LEVEL OF CONVERSATION,
2 AND I CAN'T -- I COULD NOT SPEAK TO THAT SPECIFICALLY.

3 Q. SO YOU ALSO WOULD NOT KNOW IF ANY OF THEM WERE
4 CONCERNED BECAUSE THEIR EMPLOYER WAS SUBJECT TO AN
5 INJUNCTION?

6 A. I HAVE -- I DO NOT KNOW.

7 Q. DR. BUTTS, CAN YOU IDENTIFY A SINGLE WOMAN IN
8 PENNSYLVANIA WHO HAS LOST CONTRACEPTIVE COVERAGE AS A
9 RESULT OF THE NEW RULES?

10 A. AS A RESULT OF THE NEW RULES. I CANNOT IDENTIFY
11 A SPECIFIC INDIVIDUAL PERSON AT THIS MOMENT.

12 Q. AND CAN YOU IDENTIFY A SINGLE WOMAN IN THE
13 UNITED STATES WHO HAS LOST COVERAGE AS A RESULT OF THE
14 NEW RULES?

15 A. NOT AT THIS MOMENT, NO.

16 Q. SO JUST LOOKING BACK AT YOUR DECLARATION,
17 LOOKING AT PARAGRAPH 54 OF YOUR DECLARATION, YOU CANNOT
18 IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHOSE COST OF
19 CONTRACEPTIVE CARE WILL RISE AS A RESULT OF THE RULES,
20 RIGHT?

21 A. NOT A SPECIFIC INDIVIDUAL PERSON AT THIS
22 MOVEMENT IN TIME, NO.

23 Q. AND LOOKING AT PARAGRAPH 55, YOU CANNOT IDENTIFY
24 A SINGLE WOMAN IN PENNSYLVANIA WHO WILL HAVE THIS
25 BARRIER TO WOMEN'S ACCESS TO AND USE OF THE

1 CONTRACEPTIVE THAT IS MEDICALLY RECOMMENDED FOR THEM?

2 A. WELL, I CAN'T IDENTIFY AT THIS MOMENT, BUT I
3 THINK CERTAINLY A CONCERN AS A PROVIDER IS THE
4 POTENTIALLY EXPANDING NATURE OF THESE BARRIERS. SO THE
5 REASON THAT I CAN'T IDENTIFY SOMEBODY TODAY DOES NOT
6 MEAN THAT IT MAY NOT BE APPLICABLE TO FUTURE PATIENTS.

7 Q. BUT AGAIN, SITTING HERE TODAY, YOU CAN'T
8 IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO HAS LOST
9 COVERAGE AS A RESULT OF THE NEW RULES, RIGHT?

10 A. NOT AT THIS MOMENT.

11 Q. AND SO ALL OF THE HARMS THAT YOU DESCRIBE IN
12 PARAGRAPHS 54 THROUGH 58 OF YOUR DECLARATION, YOU CANNOT
13 IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHO WILL SUFFER
14 THOSE HARMS, CORRECT?

15 A. AS I SAID BEFORE --

16 MR. GOLDMAN: OBJECTION, YOUR HONOR. THE
17 QUESTION IS A QUESTION ABOUT WHETHER THE DOCTOR CAN
18 IDENTIFY SOMETHING THAT HAS NOT HAPPENED YET. IT'S
19 IMPOSSIBLE TO ANSWER.

20 THE COURT: SUSTAINED.

21 BY MS. KADE:

22 Q. DR. BUTTS, FOR ALL OF THE HARMS THAT YOU LIST IN
23 PARAGRAPHS 54 THROUGH 58, YOU CANNOT IDENTIFY A SINGLE
24 WOMAN IN PENNSYLVANIA WHO HAS CURRENTLY SUFFERED ANY OF
25 THOSE HARMS, CORRECT?

1 A. I'M JUST LOOKING AT THE DOCUMENT AS I CONSIDER
2 MY ANSWER TO YOUR QUESTION.

3 MR. GOLDMAN: OBJECTION, YOUR HONOR.
4 SORRY IT'S LATE, BUT IT'S VAGUE BECAUSE IT'S NOT CLEAR
5 IF COUNSEL IS ASKING AS A RESULT OF THE RULES OR IN
6 GENERAL PEOPLE HAVE SUFFERED THOSE CONSEQUENCES.

7 THE COURT: WELL, THE PROBLEM IS IT'S
8 COMPOUND. IF ALL OF THE AREAS LISTED IN PARAGRAPH 53,
9 54 THROUGH 58 -- THAT IS A LOT OF AREAS.

10 MS. KADE: I'M HAPPY TO WALK THROUGH THEM
11 INDIVIDUALLY, YOUR HONOR.

12 THE COURT: GO AHEAD.

13 MS. KADE: OKAY.

14 BY MS. KADE:

15 Q. OKAY. SO LOOKING AT PARAGRAPH 54, YOU CAN'T
16 IDENTIFY A SINGLE WOMAN IN PENNSYLVANIA WHOSE COSTS FOR
17 CONTRACEPTIVE CARE HAS RISEN, CORRECT?

18 MR. GOLDMAN: OBJECTION. AGAIN, HAS
19 RISEN AT ALL OR AS A RESULT OF ANYTHING ELSE?

20 MS. KADE: AS A RESULT OF THE NEW RULES,
21 CORRECT?

22 THE WITNESS: NO.

23 BY MS. KADE:

24 Q. AND IN PARAGRAPH 55, YOU CANNOT IDENTIFY A
25 SINGLE WOMAN IN PENNSYLVANIA WHO HAS HAD A BARRIER TO

1 WOMEN'S ACCESS TO AND USE OF CONTRACEPTIVES THAT IS
2 MEDICALLY RECOMMENDED FOR THEM AS A RESULT OF THE NEW
3 RULES, CORRECT?

4 A. NO.

5 Q. AND IN PARAGRAPH 56, YOU CANNOT IDENTIFY A
6 SINGLE WOMAN IN PENNSYLVANIA WHO HAS FACED FINANCIAL
7 HARM OR HAS FACED MEDICAL HARM AS A RESULT OF THE NEW
8 RULES, CORRECT?

9 A. NO.

10 Q. AND IN PARAGRAPH 57, YOU CAN'T IDENTIFY A SINGLE
11 WOMAN IN PENNSYLVANIA WHO HAS HAD DISRUPTIONS OF THEIR
12 MEDICAL TREATMENT AS A RESULT OF THE NEW RULES, CORRECT?

13 A. CORRECT.

14 Q. AND IN PARAGRAPH 58, YOU CANNOT IDENTIFY A
15 SINGLE WOMAN IN PENNSYLVANIA WHO HAS FACED UNINTENDED
16 PREGNANCY AND OTHER ADVERSE MEDICAL CONSEQUENCES AS A
17 RESULT OF THESE NEW RULES, CORRECT?

18 A. CORRECT.

19 Q. SO ZOOMING OUT A LITTLE BIT TO CONTRACEPTIVES IN
20 GENERAL, CONTRACEPTIVES ARE USED BY BOTH MEN AND WOMEN,
21 CORRECT?

22 A. YES.

23 Q. ARE YOU AWARE THAT SOME EMPLOYERS ONLY HAVE
24 SINCERE RELIGIOUS OR MORAL OBJECTIONS TO JUST A SUBSET
25 OF THE RANGE OF AVAILABLE BIRTH CONTROL METHODS?

1 MR. GOLDMAN: OBJECTION, YOUR HONOR. I
2 DON'T KNOW HOW THE WITNESS WOULD KNOW WHETHER SOMEONE'S
3 OBJECTION IS SINCERE OR NOT.

4 THE COURT: SUSTAINED. SUSTAINED. IT'S
5 ALSO BEYOND THE SCOPE.

6 BY MS. KADE:

7 Q. DR. BUTTS, THE COST OF PREGNANCIES THAT USE
8 PRENATAL CARE, THOSE ARE TYPICALLY COVERED BY INSURANCE;
9 IS THAT RIGHT?

10 A. YES.

11 Q. AND THAT COVERAGE DOES NOT VARY DEPENDING ON
12 WHETHER IT IS AN INTENDED OR UNINTENDED PREGNANCY,
13 RIGHT?

14 A. WHETHER -- YOU ARE ASKING ME WHETHER INSURANCE
15 COVERAGE VARIES WHETHER THE PERSON INTENDED OR DID NOT
16 INTEND TO BECOME PREGNANT?

17 Q. CORRECT.

18 MR. GOLDMAN: JUDGE, IF I MAY OBJECT, I
19 BELIEVE THIS IS BEYOND THE SCOPE OF THE DIRECT.

20 THE COURT: SUSTAINED.

21 MS. KADE: IT IS WITHIN THE SCOPE OF HER
22 DECLARATION. SHE TALKS ABOUT THE COSTS OF UNINTENDED
23 PREGNANCIES.

24 THE COURT: WHERE IS -- POINT ME TO THAT.

25 MS. KADE: PARAGRAPH 58: SOME OF THESE

1 WOMEN WILL FACE UNINTENDED PREGNANCY AND OTHER ADVERSE
2 MEDICAL CONSEQUENCES, AND THE COST OF THESE UNINTENDED
3 PREGNANCIES IS THE BASIS OF --

4 THE COURT: WAIT, WAIT, STOP.

5 MS. KADE: I APOLOGIZE.

6 THE COURT: WHICH PARAGRAPH ARE YOU
7 READING?

8 MS. KADE: IN PARAGRAPH 58, DR. BUTTS
9 SAYS: SOME OF THESE WOMEN WILL FACE UNINTENDED
10 PREGNANCIES AND OTHER ADVERSE MEDICAL CONSEQUENCES.

11 THE COURT: THAT IS ALL IT SAYS.

12 MS. KADE: AND THE HARM THAT PLAINTIFFS
13 ARE ALLEGING IN THEIR COMPLAINT IS -- THE COST OF
14 UNINTENDED PREGNANCIES IS ONE OF THEIR ALLEGATIONS.

15 THE COURT: YOUR QUESTION WAS ABOUT
16 INSURANCE COVERAGE.

17 MS. KADE: MY NEXT QUESTION IS GOING TO
18 BE ABOUT THE COST OF COVERING UNINTENDED PREGNANCIES ARE
19 COVERED BY AN EMPLOYEE'S HEALTH PLAN. SO IT WOULD NOT
20 BE BORNE BY THE STATE, YOUR HONOR.

21 MR. GOLDMAN: YOUR HONOR, THIS GOES FAR
22 BEYOND THE DIRECT OR THE DECLARATION.

23 THE COURT: SUSTAINED. MOVE ON.

24 BY MS. KADE:

25 Q. DR. BUTTS, HAVE YOU READ THE RULES THAT ARE AT

1 ISSUE IN THIS CASE IN THEIR ENTIRETY?

2 A. I HAVE REVIEWED THE RULES, YES.

3 Q. HAVE YOU READ ALL OF THE EVIDENCE THAT THE RULES
4 RELY UPON?

5 A. CAN YOU CLARIFY THAT QUESTION?

6 Q. SO THE RULES CITE DIFFERENT EVIDENCE AND STUDIES
7 THROUGHOUT THE RULES. HAVE YOU READ ALL OF THOSE
8 STUDIES?

9 A. NO.

10 Q. AND YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS
11 AN EXPERT ON INSURANCE MARKETPLACES, RIGHT?

12 A. NO, I HAVE NOT.

13 Q. AND YOU HAVE NOT BEEN PRESENTED TO THIS COURT AS
14 AN EXPERT ON THE GOVERNMENT'S DECISION-MAKING PROCESS
15 UNDER THE ADMINISTRATIVE PROCEDURE ACT, RIGHT?

16 A. NO, I HAVE NOT.

17 Q. THANK YOU, DR. BUTTS.

18 MS. KADE: THANK YOU, YOUR HONOR.

19 THE WITNESS: THANK YOU.

20 THE COURT: ANY REDIRECT?

21 MR. GOLDMAN: YES, YOUR HONOR.

22 REDIRECT EXAMINATION

23 BY MR. GOLDMAN:

24 Q. DR. BUTTS, IF -- SINCE THE RULES WENT INTO
25 EXISTENCE, IF A PATIENT CAME TO YOU AND TOLD YOU THAT

1 THEY COULD NOT AFFORD THE PRESCRIPTION YOU GAVE THEM,
2 WOULD YOU NECESSARILY KNOW THAT IT WAS BECAUSE THEY LOST
3 COVERAGE UNDER THE RULES?

4 A. I WOULD NOT NECESSARILY KNOW THAT WITHOUT A
5 SIGNIFICANT INVESTIGATION INTO THE REASON FOR THE LOSS,
6 WHICH USUALLY INVOLVES SOMEBODY WITH EXPERTISE IN
7 BILLING AND COVERAGE TO HELP WITH THAT INVESTIGATION.

8 Q. DO YOU KNOW IF A PATIENT WHO CAME TO YOU WOULD
9 EVEN KNOW THAT THE REASON THEIR PRESCRIPTION ALL OF A
10 SUDDEN HAD A CO-PAY WAS BECAUSE OF THESE NEW RULES?

11 A. I'M NOT SURE THEY WOULD.

12 Q. YOU AGREED WITH COUNSEL THAT CONTRACEPTIVES ARE
13 USED FOR BOTH MEN AND WOMEN. ARE PRESCRIPTION
14 CONTRACEPTIVES USED BY BOTH MEN AND WOMEN?

15 A. NO. JUST WOMEN.

16 Q. THE WOMEN WHO -- AGAIN, ONLY IF YOU KNOW, WHO
17 CAME BACK TO YOU POST ACA, OR MAY HAVE, WHO HAD CONCERNS
18 AND HAD TO REJECT THEIR PRESCRIPTIONS, DO YOU KNOW IF
19 THOSE WOMEN WERE PRIVATELY INSURED?

20 A. POST ACA OR --

21 Q. YES.

22 A. POST ACA WITH CONCERNS. I BELIEVE, AGAIN, TO
23 THE BEST OF MY RECOLLECTION THAT MANY WERE.

24 Q. DO YOU KNOW THE PERCENT OF WOMEN WHO SUFFER FROM
25 UNINTENDED PREGNANCY IN PENNSYLVANIA?

1 A. I BELIEVE THAT NUMBER IS 53 PERCENT.

2 Q. AND DO YOU KNOW IF THAT IS HIGHER OR LOWER THAN
3 THE NATIONAL AVERAGE?

4 A. ACCORDING TO DATA FROM THE GUTTMACHER INSTITUTE,
5 WHICH IS A CLEARINGHOUSE FOR INFORMATION ABOUT
6 REPRODUCTIVE HEALTH AND PREGNANCY, IT IS HIGHER, AS THE
7 NUMBER IN THE UNITED STATES IS 45 PERCENT.

8 Q. AND IS THAT INFORMATION AVAILABLE ON THE WEBSITE
9 OF THE GUTTMACHER INSTITUTE?

10 A. IT IS.

11 Q. ONE OTHER LAST LINE OF QUESTIONING I JUST WANT
12 TO CLARIFY.

13 COUNSEL ASKED YOU WHAT YOU REVIEWED PRIOR
14 TO YOUR TESTIMONY. IN ADDITION TO YOUR RÉSUMÉ, DID YOU
15 ALSO REVIEW YOUR PATIENT RECORDS?

16 A. I REVIEWED MY PATIENT RECORDS IN AN ATTEMPT TO
17 GET AN UNDERSTANDING OF PRACTICE PATTERNS OVER TIME AND
18 FLUCTUATIONS, BASED ON THE NATURE OF THIS CASE.

19 Q. AND DID YOU LOOK AT THOSE PATIENT RECORDS FOR A
20 TIME PERIOD BEFORE THE AFFORDABLE CARE ACT?

21 A. I DID.

22 Q. DID YOU ALSO LOOK AT THE RECORDS FOR AFTER THE
23 AFFORDABLE CARE ACT?

24 A. I DID.

25 Q. DID YOU NOTICE ANY TRENDS WITH RESPECT TO WHAT

1 PRESCRIPTIONS PATIENTS WERE FILLING?

2 A. SO THE DATA THAT I CAN SPEAK TO WITH THE MOST --
3 IN THE MOST DEPTH WOULD PERTAIN TO THE MIRENA IUD. AND
4 I CAN TELL YOU, IN MY OWN INDIVIDUAL PRACTICE, WHICH I
5 THINK REFLECTS OTHERS, BUT I CERTAINLY CANNOT SPEAK TO
6 ANYONE ELSE'S PRACTICE WITH AS MUCH ACCURACY AS MY OWN,
7 IN MY OWN PRACTICE, PRIOR TO THE ACA AND AFTER, THERE
8 HAS BEEN A FIVEFOLD INCREASE IN THE NUMBER OF MIRENA
9 IUD'S I HAVE INSERTED INTO -- INSERTED IN PATIENTS IN MY
10 PRACTICE. SO A SIGNIFICANTLY ELEVATED INCREASE OVER
11 TIME.

12 Q. SO PRE AND POST ACA, THE NUMBER OF PATIENTS WHO
13 HAVE HAD A MIRENA IUD IMPLANTED INCREASED FIVE TIMES?

14 A. YES, IN MY PRACTICE.

15 Q. AND HAVE YOUR PRESCRIBING PRACTICES CHANGED
16 SIGNIFICANTLY OVER THOSE YEARS?

17 A. MY MANAGEMENT OF THE CONDITIONS FOR WHICH I
18 UTILIZE THIS TREATMENT HAS NOT CHANGED, NOR HAS THE
19 EVIDENCE SUPPORTING THE USE OF A MIRENA IUD FOR THESE
20 TREATMENTS. THE BULK OF THE EVIDENCE SUPPORTING THIS AS
21 AN EXCELLENT AND OUTSTANDING TREATMENT FOR CHRONIC
22 PELVIC PAIN AND HAVING MENSTRUAL BLEEDING WAS WELL
23 ESTABLISHED PRIOR TO THE MANDATE. SO MY PRACTICE
24 APPROACH AND THE EVIDENCE WERE ESTABLISHED WELL BEFORE
25 THE MANDATE.

1 Q. SO TO WHAT DO YOU ATTRIBUTE THIS FIVEFOLD
2 INCREASE IN YOUR PATIENTS WHO ARE NOW USING MIRENA IUD'S
3 MORE EFFECTIVE FORM OF BIRTH CONTROL SINCE THE ACA WENT
4 INTO EFFECT?

5 A. OF COURSE, IT CAN BE MULTIFACTORIAL. I THINK
6 ONE OF THE FACTORS THAT WE HAVE TO CONSIDER AS
7 INCREDIBLY INFLUENTIAL IS THE ACCESS GRANTED TO WOMEN TO
8 UTILIZE THIS TREATMENT AS A BYPRODUCT OF THE MANDATE.

9 Q. COST?

10 A. YES. SIGNIFICANT REDUCTION, ELIMINATION OF
11 COSTS SUCH THAT WOMEN CAN NOW GET ACCESS TO SOMETHING
12 THAT I HAVE ALWAYS HAD IN MY MIND TO UTILIZE FOR THEIR
13 CARE, JUST HAVE A GREATER ABILITY TO DO SO.

14 Q. DO YOU KNOW IF THAT IS THE PRIMARY REASON FOR
15 THE FIVEFOLD INCREASE, DO YOU KNOW?

16 A. I MEAN, AGAIN, I THINK IT IS CERTAINLY
17 MULTIFACTORIAL, BUT IN MY OPINION, BASED ON THE THINGS I
18 MENTIONED ABOUT MY APPROACH TO CARE FOR THESE PATIENTS
19 AND THE EVIDENCE, NOT SIGNIFICANTLY CHANGING SINCE THE
20 MANDATE, I WOULD HAVE TO CONCEDE THAT THE MANDATE IS A
21 PRIMARY DRIVING FORCE FOR THE FIVEFOLD INCREASED
22 UTILIZATION OF MIRENA IUDS IN MY PRACTICE.

23 MR. GOLDMAN: NOTHING FURTHER, YOUR
24 HONOR.

25 THE COURT: OKAY. ONE QUESTION, I HAVE

1 ONE QUESTION. WHAT PERCENTAGE OF YOUR PATIENTS ARE FROM
2 PENNSYLVANIA?

3 THE WITNESS: THE MAJORITY. IF I COULD
4 GIVE YOU A NUMBER, I WOULD SAY PROBABLY 80 PERCENT OR
5 MORE.

6 THE COURT: OKAY. THANK YOU, YOU CAN
7 LEAVE THE STAND.

8 THE WITNESS: THANK YOU.

9 (WITNESS EXCUSED.)

10 THE COURT: IT IS NOW 12:30, WHICH IS A
11 PERFECT TIME FOR LUNCH. WHAT WE WILL DO IS WE WILL HAVE
12 LUNCH BREAK FOR AN HOUR AND WE WILL BE BACK AT 1:30, AND
13 WHEN WE COME BACK, I UNDERSTAND THAT YOU HAVE BEEN DOING
14 THE RESEARCH ON THE GRANDFATHERING. I HAVE SEEN YOU
15 RUNNING AROUND.

16 MR. HEALY: APOLOGIZE FOR THE RUNNING
17 AROUND.

18 THE COURT: NOT A PROBLEM. I'M HAPPY TO
19 SEE THAT YOU'RE DOING IT. SO I WILL TALK TO YOU AFTER
20 THE THIRD AND FINAL WITNESS FROM THE COMMONWEALTH.
21 THANK YOU.

22 THE CLERK: ALL RISE.

23 (LUNCHEON BREAK TAKEN.)

24 MS. BOLAND: OUR NEXT WITNESS IS CYNTHIA
25 CHUANG.

1 MR. GOLDMAN: YOUR HONOR, IF I MAY
2 ADDRESS A QUICK PROCEDURAL MATTER WITH THE COURT. MAY I
3 APPROACH, YOUR HONOR?

4 THE COURT: YOU MAY.

5 MR. GOLDMAN: I HAVE A DOCUMENT THAT I
6 WOULD LIKE TO BE ABLE TO PASS UP TO YOUR HONOR. THIS IS
7 A DOCUMENT THAT IS CITED IN OUR COMPLAINT WITH A
8 HYPERLINK AT PARAGRAPH 99.

9 THE COURT: OKAY.

10 MR. GOLDMAN: SO THE COMMONWEALTH WOULD
11 LIKE TO MOVE THIS DOCUMENT INTO EVIDENCE ALONG WITH THE
12 ATTACHMENT WHICH IS PART OF THE ARTICLE. WE APPROACHED
13 THE GOVERNMENT DURING BREAK, AND I BELIEVE THEY WILL
14 STIPULATE TO THE AUTHENTICITY AND ADMISSIBILITY OF THE
15 ARTICLE, BUT NOT TO THE ATTACHMENT.

16 THE COURT: WHAT DO YOU THINK THE
17 ATTACHMENT IS?

18 MR. GOLDMAN: THE ARTICLE SAYS THAT IT IS
19 A LEAKED COPY OF THE RULES, THE DRAFT RULES THAT ARE
20 BEFORE US NOW.

21 THE COURT: SO LET ME -- LET'S ASSUME --

22 LET ME HEAR FROM YOU JUST ON THE
23 PROCEDURAL MATTER OF WHAT YOU'RE OBJECTING TO HERE. YOU
24 ARE OKAY WITH THE ARTICLE BUT NOT THE ATTACHMENT?

25 MS. KADE: THANK YOU, YOUR HONOR. YES.

1 THE ATTACHMENT, WE WERE JUST HANDED THIS, YOU KNOW,
2 125-PAGE DOCUMENT, SO WE ARE NOT ABLE TO STIPULATE AS TO
3 THE AUTHENTICITY OF IT AT THIS POINT, BUT WE ALSO ARE
4 NOT ABLE TO STIPULATE TO THE ADMISSIBILITY OF IT BECAUSE
5 IT'S CLEARLY LABELED CONFIDENTIAL DRAFT AND COVERED BY
6 PRIVILEGES. SO WE ARE NOT ABLE TO STIPULATE TO EITHER
7 THE AUTHENTICITY OR THE ADMISSIBILITY AT THIS POINT.

8 THE COURT: I ACCEPT THAT YOU ARE NOT
9 ABLE TO DO IT. I'M NOT SURE WHETHER YOU ARE RIGHT WITH
10 RESPECT TO THE CONFIDENTIALITY AND DRAFT, THAT COMPONENT
11 OF WHAT YOU JUST SAID.

12 SO WHAT IS THE POINT OF THIS IN THE
13 CONTEXT OF THIS PRELIMINARY INJUNCTION HEARING? I MEAN,
14 IT'S NOT THE REGULATIONS. I DON'T KNOW WHAT IT IS. AND
15 THEN THERE IS A VOX ARTICLE. SO HOW DOES IT PERTAIN TO
16 WHAT WE ARE DOING HERE?

17 MR. GOLDMAN: RIGHT. SO -- AND THIS IS
18 PART OF THE REASON WHY WE STATED IT IN OUR COMPLAINT, WE
19 CITED IT. SO THIS -- IT'S A PUBLIC DOCUMENT NOW, NO
20 MATTER WHAT IT SAYS ON IT. WE DIDN'T CHANGE IT. IT IS
21 EXACTLY WHAT WAS ATTACHED TO THE ARTICLE, BUT IT
22 PURPORTS TO BE A DRAFT OF THE REGULATIONS WHICH WAS
23 LEAKED. IT IS -- I HAVE NOT LINED IT UP AGAINST THE
24 ACTUAL FINAL REGULATIONS, BUT THEY ARE REMARKABLY
25 SIMILAR. AND SO IF YOU ARE LOOKING AT WHAT THE AGENCIES

1 WERE DOING IN TERMS OF RULE MAKING AND CONSIDERATION,
2 YOU CAN LOOK -- WELL, AT THIS MOMENT IN TIME, THIS IS
3 WHAT PURPORTS TO BE A DRAFT. LATER IN TIME, THERE IS
4 THESE -- THERE HAS BEEN NO -- THERE WERE NO DRAFT RULES
5 PUT FORTH FOR COMMENT, FOR NOTICE OR COMMENT. SO YOU
6 CAN LOOK AT WHAT CHANGES, IF ANY, TOOK PLACE BETWEEN
7 THIS POINT IN TIME, THE ARTICLE IS MAY 31, AND WHEN THE
8 RULES WERE ACTUALLY PROMULGATED.

9 THE COURT: THAT IS AN INTERESTING
10 EXERCISE, BUT I STILL DON'T UNDERSTAND WHY IT IS
11 RELEVANT HERE, BECAUSE YOUR POINT IS THAT THE NEW RULES
12 WERE ISSUED WITHOUT NOTICE AND COMMENT AND WITHOUT GOOD
13 CAUSE. SO HOW DOES -- HOW DOES THIS -- I MEAN, ASSUMING
14 THAT THIS IS A DRAFT VERSION OF THE RULES ISSUED SOME
15 MONTHS BEFORE THE FINAL VERSION WAS ISSUED, HOW DOES IT
16 IMPACT ON WHAT WE ARE DOING HERE TODAY, WHICH IS
17 DECIDING THE PRELIMINARY INJUNCTION MOTION?

18 MR. GOLDMAN: COURT'S INDULGENCE, YOUR
19 HONOR, JUST TO CLARIFY.

20 (PAUSE.)

21 MR. GOLDMAN: YES, SO THE BEARAK ARTICLE
22 FROM THE GUTTMACHER INSTITUTE WAS A FOOTNOTE TO THE
23 RULES IN THE IFRS, AND THE GOVERNMENT IS TAKING THE
24 POSITION THAT THE RULES HAVE RELIED HEAVILY ON THIS
25 ARTICLE, WHICH IS IN THE FOOTNOTE OF THE FINAL.

1 THE ISSUE HERE IS, IN THIS DRAFT, IT'S
2 NOT IN HERE BUT THE RULES ARE THE SAME.

3 THE COURT: OKAY. WELL, I DON'T THINK I
4 CAN ADMIT THE ATTACHMENT BECAUSE WE DON'T KNOW WHERE IT
5 CAME FROM, WE DON'T -- IT SAYS "DRAFT" ON IT. IT SAYS
6 "DEPARTMENT OF THE TREASURY" BUT IT CERTAINLY DOES NOT
7 LOOK LIKE THE FORM THE RULES USUALLY TAKE. I DON'T KNOW
8 WHETHER ONCE THE DOCUMENT IS FINISHED IN THE AGENCY IT
9 THEN GOES OFF TO SOME DEPARTMENT AND GETS TRANSFORMED
10 INTO WHAT THE RULES USUALLY LOOK LIKE, SO I JUST DON'T
11 KNOW WHAT IT IS. WE DON'T HAVE ANYONE HERE TO TELL US
12 WHAT IT IS, SO I CAN'T ADMIT THAT.

13 AND I THINK THAT THE GOVERNMENT HAS NOT
14 OBJECTED TO THE ARTICLE BEING ADMITTED, CORRECT?

15 MS. KADE: CORRECT, YOUR HONOR.

16 THE COURT: I'M HAPPY TO ADMIT THE
17 ARTICLE, BUT I HAVE TO TELL YOU, I DON'T THINK I'M GOING
18 TO RELY ON IT BECAUSE IT'S A NEWSPAPER ARTICLE SAYING
19 THINGS THAT I -- THERE IS JUST NO TESTIMONY TO DETERMINE
20 WHETHER IT IS IN FACT THE CASE.

21 MR. GOLDMAN: I UNDERSTAND. MAY I JUST
22 TRY ONE OTHER LINE AND THEN --

23 THE COURT: GO AHEAD.

24 MR. GOLDMAN: AND THAT IS JUST THAT WE
25 DON'T KNOW -- WE ARE NOT SAYING THAT THIS IS IN FACT A

1 DRAFT OF THE RULES AT THAT TIME. THIS IS JUST WHATEVER
2 THE ARTICLE SAID.

3 THE COURT: I UNDERSTAND. SO WE ARE JUST
4 GOING TO -- WE WILL PUT IT IN THE RECORD IN THE LIMITED
5 WAY THAT IT IS. WE WILL PUT IT IN THE RECORD, BUT I CAN
6 TELL YOU NOW THAT I WON'T BE RELYING ON IT.

7 MR. GOLDMAN: FAIR ENOUGH, YOUR HONOR.

8 THE COURT: OKAY. YOUR NEXT WITNESS.

9 MS. BOLAND: MAY I APPROACH?

10 THE COURT: YOU MAY.

11 MS. BOLAND: GOOD AFTERNOON, YOUR HONOR.

12 IT'S NICOLE BOLAND AGAIN FROM THE COMMONWEALTH, AND WE
13 CALL DR. CYNTHIA CHUANG.

14 MS. KOPPLIN: YOUR HONOR, WE WOULD OBJECT
15 TO THIS WITNESS AS CUMULATIVE.

16 THE COURT: OKAY. HOLD ON A SEC AND LET
17 ME -- BEFORE YOU DO, LET ME JUST HAVE HER SWORN.

18 (CYNTHIA CHUANG, COMMONWEALTH'S WITNESS,
19 SWORN.)

20 THE CLERK: PLEASE STATE AND SPELL YOUR
21 NAME FOR THE RECORD.

22 THE WITNESS: CHUANG IS SPELLED
23 C-H-U-A-N-G.

24 THE COURT: OKAY. BEFORE I ADDRESS YOUR
25 OBJECTION, GIVE ME IN A NUTSHELL WHAT YOU INTEND TO

1 ELICIT FROM THIS WITNESS.

2 MS. BOLAND: SURE, YOUR HONOR.

3 DR. CHUANG WAS ACTUALLY THE LEAD AUTHOR ON THE "MY NEW
4 OPTIONS" STUDY THAT DR. WEISMAN PREVIOUSLY TESTIFIED
5 ABOUT, SO SHE CAN OFFER ADDITIONAL INFORMATION ABOUT
6 THAT STUDY. AND WE ALSO HAVE A DEMONSTRATIVE EXHIBIT
7 REFLECTING THOSE FINDINGS.

8 THE COURT: IS THE "MY NEW" STUDY THE
9 PENNSYLVANIA STUDY THAT WEISMAN TALKED ABOUT?

10 MS. BOLAND: YES.

11 THE COURT: OKAY. THE ONE THAT IS NOT
12 PUBLISHED YET.

13 MS. BOLAND: CORRECT, YOUR HONOR. AND
14 DR. CHUANG IS ACTUALLY THE LEAD, AND THERE'S A FEW
15 POINTS TO CLARIFY WITH RESPECT TO THE PRIOR TESTIMONY.
16 AND ALSO, DR. CHUANG IS A PRACTICING PHYSICIAN SO SHE
17 HAS THE CLINICAL PERSPECTIVE THAT DR. WEISMAN DID NOT
18 OFFER PREVIOUSLY.

19 THE COURT: OKAY. DO YOU INTEND TO GO
20 OVER ALL THE FACTS THAT YOU HAVE ALREADY GONE OVER WITH
21 PROFESSOR WEISMAN?

22 MS. BOLAND: REGARDING THE "MY NEW
23 OPTIONS" STUDY?

24 THE COURT: YES.

25 MS. BOLAND: TO A SMALL DEGREE, JUST FOR

1 CLARIFICATION OF SOME DATES OF THE STUDY. SHE IS MORE
2 PREPARED TO SPEAK TO MORE OF THE DETAILS OF THE STUDY.
3 I WON'T GO IN DEPTH AND REPEAT EVERYTHING THAT
4 DR. WEISMAN SAID, BUT JUST A VERY GENERAL OVERVIEW OF
5 THE STUDY AND JUST TO CLARIFY THE TIME FRAMES OF THE
6 STUDY FOR THE RECORD.

7 THE COURT: OKAY. WHAT IS YOUR
8 RATIONALE FOR --

9 MS. KOPPLIN: YOUR HONOR, AS PLAINTIFFS'
10 COUNSEL ALLUDES TO, THE TESTIMONY WOULD BE HIGHLY
11 DUPLICATIVE OF WHAT PROFESSOR WEISMAN AND DR. BUTTS HAVE
12 ALREADY TESTIFIED TO. BASED ON THE WITNESS'
13 DECLARATION, SHE REACHES MANY OF THE SAME CONCLUSIONS
14 AND RELIES ON MUCH OF THE SAME EVIDENCE.

15 SPECIFICALLY I WOULD POINT YOU TOWARDS,
16 IN THE THIRD CIRCUIT, ROBERT V STETSON SCHOOL INC.,
17 THAT'S 256 F.3D 159, WHERE THE EXCLUSION OF AN EXPERT
18 WAS UPHELD ON CUMULATIVE GROUNDS WHEN TWO OTHER EXPERTS
19 HAD ALREADY TESTIFIED AT LENGTH ON THE SAME ISSUE.

20 THE COURT: OKAY. I UNDERSTAND THAT
21 PRECEDENT, BUT, YOU KNOW, THERE IS NO REASON WHY IT
22 APPLIES HERE. AND WE ARE ALL HERE, WE ARE ALL FRIENDS
23 HERE. YOU KNOW, WE MIGHT AS WELL JUST GO FOR IT. WE
24 DON'T HAVE A JURY SO THEY CAN'T BE PREJUDICED BY WHAT WE
25 ARE ABOUT TO HEAR. IT'S ONLY ME.

1 OKAY. GO AHEAD.

2 MS. BOLAND: THANK YOU, YOUR HONOR.

3 DIRECT EXAMINATION

4 BY MS. BOLAND:

5 Q. JUST A FEW HOUSEKEEPING MATTERS TO START OFF.

6 DR. CHUANG, WILL YOU KINDLY REFER TO

7 TAB 6 IN THE BINDER?

8 A. YES.

9 Q. CAN YOU IDENTIFY THAT DOCUMENT FOR THE COURT,
10 PLEASE?

11 A. YES, THAT IS MY DECLARATION.

12 Q. WILL YOU JUST KINDLY FLIP THROUGH AND TELL US IF
13 IT APPEARS TO BE COMPLETE AND ACCURATE?

14 A. YES.

15 Q. GREAT. I WOULD LIKE TO POINT YOU NOW TO TAB 7.

16 WILL YOU KINDLY IDENTIFY THAT DOCUMENT FOR THE COURT?

17 A. YES, THAT IS MY CV.

18 Q. AND WILL YOU KINDLY JUST FLIP THROUGH AND
19 CONFIRM THAT IT IS COMPLETE AND ACCURATE.

20 A. YES.

21 Q. GREAT. THANK YOU, DOCTOR.

22 SO THE COURT HAS YOUR CV TO CONSIDER.

23 I'M NOT GOING TO REVIEW EVERYTHING ON IT BUT I DO WANT

24 TO HIGHLIGHT A FEW POINTS.

25 TO START OFF, WHO'S YOUR EMPLOYER?

1 A. I WORK AT THE PENN STATE HERSHEY MEDICAL CENTER.

2 Q. AND HOW ARE YOU EMPLOYED AT PENN STATE HERSHEY?

3 A. I'M A PHYSICIAN THERE. I'M A GENERAL INTERNIST.

4 I'M CHIEF OF THE DIVISION OF GENERAL INTERNAL MEDICINE

5 AND I'M A PROFESSOR OF MEDICINE AND PUBLIC HEALTH

6 SCIENCES.

7 Q. SO YOU ARE A PRACTICING DOCTOR AND A PROFESSOR?

8 A. CORRECT.

9 Q. DO YOU ALSO CONDUCT RESEARCH?

10 A. I DO.

11 Q. ARE YOU FAMILIAR WITH THE CONTRACEPTIVE MANDATE?

12 A. YES, I AM.

13 Q. WHAT IS YOUR UNDERSTANDING OF THE CONTRACEPTIVE
14 MANDATE?

15 A. THE MANDATE SAYS THAT FOR MOST PRIVATELY INSURED
16 WOMEN, THAT CONTRACEPTION -- FDA-APPROVED CONTRACEPTION
17 WOULD BE COVERED WITH NO OUT-OF-POCKET COSTS.

18 Q. AND HAVE YOU RESEARCHED THE CONTRACEPTIVE
19 MANDATE AS PART OF YOUR WORK?

20 A. YES, I HAVE.

21 Q. AND BEFORE WE GET INTO THAT RESEARCH, JUST A
22 COUPLE OF QUESTIONS ON YOUR BACKGROUND. WILL YOU JUST
23 VERY BRIEFLY DESCRIBE YOUR EDUCATIONAL BACKGROUND FOR
24 THE COURT?

25 A. SURE. I COMPLETED MY UNDERGRADUATE TRAINING AT

1 THE UNIVERSITY OF MICHIGAN, WHERE I GRADUATED WITH
2 HONORS. I THEN SPENT A YEAR LIVING IN NORTHERN
3 CALIFORNIA WHERE I WORKED IN A FAMILY PLANNING CLINIC
4 FOR A YEAR, PROVIDING REPRODUCTIVE HEALTHCARE SERVICES
5 AT A FAMILY PLANNING CLINIC.

6 I THEN STARTED MEDICAL SCHOOL AT NEW YORK
7 UNIVERSITY, AND FOLLOWING MY MEDICAL DEGREE, I COMPLETED
8 MY INTERNAL MEDICINE RESIDENCY TRAINING AT TEMPLE
9 HOSPITAL HERE IN PHILADELPHIA AS WELL AS MY CHIEF
10 RESIDENCY. THAT WAS IN 2001, AND THEN FOLLOWING THAT, I
11 DID A GENERAL INTERNAL MEDICINE FELLOWSHIP AT BOSTON
12 UNIVERSITY. I DID A GENERAL INTERNAL MEDICAL
13 FELLOWSHIP, WHICH INCLUDED A MASTERS OF EPIDEMIOLOGY AS
14 WELL AS A RESIDENCY IN PREVENTIVE MEDICINE.

15 Q. DID YOU CONDUCT RESEARCH AS PART OF YOUR
16 FELLOWSHIP?

17 A. I DID. THE PRIMARY PURPOSE OF THE FELLOWSHIP
18 WAS RESEARCH TRAINING, YES.

19 Q. AND WHAT WAS THE FOCUS OF YOUR RESEARCH?

20 A. I HAD ALREADY HAD A STRONG INTEREST IN WOMEN'S
21 HEALTH AND REPRODUCTIVE HEALTHCARE. THE PRIMARY FOCUS
22 OF MY RESEARCH THERE WAS EMERGENCY CONTRACEPTION.

23 Q. THANK YOU, DOCTOR.

24 I CAN SEE FROM YOUR RÉSUMÉ THAT YOU'VE
25 AUTHORED NUMEROUS SCHOLARLY ARTICLES. DO YOU MIND

1 GIVING THE JUDGE JUST A BALLPARK IDEA OF HOW MANY
2 SCHOLARLY ARTICLES YOU HAVE WRITTEN THROUGHOUT YOUR
3 CAREER?

4 A. I BELIEVE THERE'S 70 PUBLICATIONS RIGHT NOW.

5 Q. HAVE YOU AUTHORED ANY PUBLICATIONS REGARDING
6 CONTRACEPTION?

7 A. YES, THAT'S -- PROBABLY THE MAJORITY OF THE
8 PUBLICATIONS ARE ABOUT CONTRACEPTION.

9 Q. AND CAN YOU JUST KINDLY GIVE SOME EXAMPLES OF
10 SOME OF THE TOPICS THAT WOULD INCLUDE?

11 A. YEAH, SURE. SO LIKE I SAID, WHEN I STARTED IN
12 MY FELLOWSHIP TRAINING, THE BULK OF ARTICLES AROUND THAT
13 TIME WERE ABOUT EMERGENCY CONTRACEPTION. FOLLOWING
14 THAT, WHEN I CAME TO PENN STATE, MY FOCUS TURNED TOWARD
15 UNINTENDED PREGNANCY AND CONTRACEPTIVE USE IN WOMEN WITH
16 CHRONIC MEDICAL CONDITIONS.

17 THERE IS ALSO SOME PUBLICATIONS ABOUT
18 GESTATIONAL WEIGHT GAIN DURING PREGNANCY, AND THEN MORE
19 RECENTLY, MY PUBLICATIONS ARE ABOUT CONTRACEPTIVE
20 BEHAVIOR AND REPRODUCTIVE LIFE PLANNING AS A TOOL TO
21 ASSIST WITH CONTRACEPTIVE DECISION-MAKING.

22 Q. AND ARE SOME OF THOSE ARTICLES SPECIFICALLY
23 ABOUT THE CONTRACEPTIVE MANDATE?

24 A. SEVERAL OF THEM ARE IN THE CONTEXT OF THE
25 CONTRACEPTIVE MANDATE, YES.

1 Q. AND ARE ALL THOSE PUBLICATIONS THE PRODUCT OF
2 RESEARCH THAT YOU'VE PERSONALLY CONDUCTED?

3 A. YES.

4 Q. AND SEPARATE FROM THAT WORK, DO YOU ALSO SERVE
5 AS A PEER REVIEWER FOR ARTICLES IN OTHER PUBLICATIONS?

6 A. YES. I AM FREQUENTLY ASKED TO PEER REVIEW FOR
7 JOURNALS. I'M ON THE EDITORIAL BOARD OF A JOURNAL
8 CALLED WOMEN'S HEALTH ISSUES, SO I REVIEW FOR THEM
9 REGULARLY. AND I'M ALSO FREQUENTLY ASKED BY OTHER
10 JOURNALS TO REVIEW, USUALLY AROUND TOPICS RELATED TO
11 WOMEN'S HEALTH OR PREVENTIVE HEALTHCARE.

12 Q. I NOTICE FROM YOUR CV THAT YOU ARE AN
13 INVESTIGATOR. AND WHAT DOES IT MEAN TO BE AN
14 INVESTIGATOR?

15 A. IT MEANS YOU ARE A RESEARCHER.

16 Q. AND HOW ARE YOUR PROJECTS FUNDED WHEN YOU DO
17 INVESTIGATIONS?

18 A. SO RESEARCH CAN BE FUNDED IN ANY NUMBER OF WAYS.
19 THEY CAN BE FUNDED THROUGH THE FEDERAL GOVERNMENT LIKE
20 THROUGH THE NATIONAL INSTITUTES OF HEALTH OR THE CDC,
21 FOR EXAMPLE. THERE'S ALSO SOME NONFEDERAL AGENCIES LIKE
22 PCORI, WHICH IS THE PATIENT-CENTERED OUTCOMES RESEARCH
23 INSTITUTE WHERE SOME OF MY WORK WAS BEEN FUNDED, AS WELL
24 AS THE NIH. IT CAN BE FUNDED BY PRIVATE FOUNDATIONS.
25 IT CAN BE FUNDED ALSO BY INSTITUTIONS, BUT SO --

1 ACADEMIC INSTITUTIONS.

2 Q. ABOUT HOW MANY PROJECTS HAVE YOU BEEN INVOLVED
3 IN AS AN INVESTIGATOR THROUGHOUT YOUR CAREER?

4 A. I THINK ABOUT 20.

5 Q. AND HAVE THOSE PROJECTS BEEN FUNDED BY GRANTS?

6 A. YES, THOSE ARE ALL THE ONES THAT ARE FUNDED.

7 Q. DO YOU HAVE ANY OFFICIAL ROLES AT HERSHEY WITH
8 REGARD TO RESEARCH?

9 A. LIKE I MENTIONED EARLIER, I'M THE CHIEF OF THE
10 DIVISION OF GENERAL INTERNAL MEDICINE SO I OVERSEE ALL
11 ASPECTS OF THE DIVISION, INCLUDING THE RESEARCH
12 ACTIVITIES IN THE DIVISION.

13 PRIOR TO BECOMING DIVISION CHIEF TWO
14 YEARS AGO, I WAS THE ASSOCIATE DIRECTOR FOR RESEARCH FOR
15 THE DIVISION. I'M ALSO THE RESEARCH DIRECTOR FOR THE
16 PENN STATE BIRCWH PROGRAM. BIRCWH STANDS FOR BUILDING
17 INTERDISCIPLINARY RESEARCH CAREERS IN WOMEN'S HEALTH,
18 WHICH IS AN NIH-FUNDED PROGRAM TO HELP PROVIDE SUPPORT
19 FOR JUNIOR INVESTIGATORS TRYING TO BUILD THEIR CAREERS
20 IN WOMEN'S HEALTH RESEARCH.

21 Q. HAVE ANY OF YOUR PROJECTS INVOLVED THE IMPACT OF
22 THE CONTRACEPTIVE MANDATE?

23 A. YES.

24 Q. CAN YOU TELL US ABOUT A PROJECT TO THAT EFFECT?

25 A. SURE. SO THE PROJECT THAT WAS REFERRED TO

1 EARLIER, THE "MY NEW OPTIONS" STUDY, IS A STUDY THAT WAS
2 FUNDED BY PCORI, THE PATIENT-CENTERED OUTCOMES RESEARCH
3 INSTITUTE. AND THE "MY NEW OPTIONS" STUDY WAS A
4 TWO-YEAR STUDY WHERE WE LOOKED AT THE EFFECT OF
5 WEB-BASED CONTRACEPTIVE INTERVENTIONS TO SEE IF THEY
6 HELPED WOMEN WITH THEIR CONTRACEPTIVE DECISION-MAKING.

7 Q. OKAY. WE WILL DISCUSS THAT PROJECT A LITTLE BIT
8 MORE AT LENGTH IN A FEW MINUTES.

9 I WANTED TO TURN NOW TO YOUR MEDICAL
10 PRACTICE. IN ADDITION TO YOUR WORK AS A PROFESSOR, YOU
11 TESTIFIED THAT YOU ALSO MAINTAIN AN ACTIVE MEDICAL
12 PRACTICE; IS THAT RIGHT, DOCTOR?

13 A. CORRECT.

14 Q. WHERE IS YOUR PRACTICE LOCATED?

15 A. I PRACTICE AT THE HERSHEY MEDICAL CENTER, AT THE
16 INTERNAL MEDICINE EAST CLINIC, WHICH IS LOCATED AT 35
17 HOPE DRIVE IN HERSHEY.

18 Q. AND WHAT KIND OF PRACTICE DO YOU HAVE?

19 A. IT'S AN INTERNAL MEDICINE PRACTICE, SO IT'S
20 ADULT PRIMARY CARE. MY PRACTICE HAS MOSTLY WOMEN
21 PATIENTS, AND SO ADULT WOMEN.

22 Q. HOW LONG HAVE YOU BEEN PRACTICING MEDICINE?

23 A. WELL, I GRADUATED FROM MEDICAL SCHOOL 20 YEARS
24 AGO, SO 20 YEARS.

25 Q. AND ARE CONTRACEPTIVES PART OF YOUR MEDICAL

1 PRACTICE?

2 A. YES.

3 Q. HOW SO?

4 A. ANY TIME I HAVE A FEMALE PATIENT WHO'S OF
5 REPRODUCTIVE AGE WHO'S CAPABLE OF PREGNANCY, IT'S A PART
6 OF EVERY VISIT TO DISCUSS WHAT HER DESIRES ARE AROUND
7 PREGNANCY OR -- EITHER ACHIEVING PREGNANCY OR AVOIDING
8 PREGNANCY, AND SO OBVIOUSLY, CONTRACEPTION BECOMES AN
9 IMPORTANT PART OF THAT CONVERSATION.

10 Q. THANK YOU.

11 MS. BOLAND: AT THIS TIME, YOUR HONOR, I
12 WOULD LIKE TO OFFER DR. CHUANG AS AN EXPERT IN THE AREAS
13 OF PREVENTATIVE MEDICAL CARE FOR WOMEN, INCLUDING
14 CONTRACEPTIVE CARE.

15 MS. KOPPLIN: WE WOULD OBJECT TO THAT,
16 YOUR HONOR.

17 THE COURT: REASON?

18 MS. KOPPLIN: FIRST, FOR THE SAME REASONS
19 AS THE OTHER EXPERTS. THIS EXPERT WAS NOT DISCLOSED TO
20 US AS REQUIRED BY FEDERAL RULE OF CIVIL PROCEDURE 26(A)
21 OR FEDERAL RULES OF EVIDENCE 702, 703 AND 705. AND
22 SECOND, FOR THE SAME AS THE OTHER EXPERTS, IT'S IMPROPER
23 TO ADMIT EXPERT EVIDENCE TO THE EXTENT THAT IT IS BEING
24 USED TO DETERMINE THE CORRECTNESS OR WISDOM OF AN
25 AGENCY'S DECISION IN AN APA CASE.

1 THE COURT: ARE YOU GOING TO USE HER --
2 IS SHE GOING TO ISSUE AN OPINION ON THE CORRECTNESS OF
3 THE AGENCY IN COMING UP WITH THE EXEMPTIONS?

4 MS. BOLAND: NO, YOUR HONOR.

5 THE COURT: SO THAT PARTICULAR OBJECTION
6 IS MOOT, I THINK, AND THEN WITH RESPECT TO THE RULE 26
7 OBJECTION, OVERRULING YOU ON THAT ONE.

8 GO AHEAD.

9 BY MS. BOLAND:

10 Q. DR. CHUANG, SINCE CONTRACEPTIVES PLAY A ROLE IN
11 YOUR PRACTICE, DO YOU COUNSEL PATIENTS REGARDING
12 CONTRACEPTIVE OPTIONS?

13 A. YES, I DO.

14 Q. AND WHAT ARE SOME CONSIDERATIONS THAT GO INTO
15 RECOMMENDING A PARTICULAR CONTRACEPTION?

16 A. WELL, THERE IS MANY THINGS TO CONSIDER, AND SO,
17 LIKE I MENTIONED EARLIER, IF A WOMAN IS INTENDING TO
18 BECOME PREGNANT OR TRYING TO AVOID PREGNANCY AND WHAT
19 HER TIMING IS FOR THAT; WHEN DOES SHE THINK SHE MIGHT
20 WANT TO BE PREGNANT IN THE FUTURE.

21 I CERTAINLY ALSO ASK HER ABOUT HER
22 EXPERIENCE WITH PRIOR CONTRACEPTIVE METHODS IN THE PAST;
23 WHAT HAS WORKED WELL OR NOT WORKED WELL FOR HER
24 PERSONALLY. CERTAINLY CONSIDERING HER HEALTH SITUATION,
25 IF SHE HAS ANY CHRONIC MEDICAL ISSUES, OTHER MEDICATIONS

1 SHE IS TAKING THAT MAY AFFECT THE SAFETY OF ANY
2 CONTRACEPTIVE METHODS, THAT IS OBVIOUSLY VERY IMPORTANT
3 TO DISCUSS.

4 SIDE EFFECTS OF DIFFERENT CONTRACEPTIVE
5 METHODS, WHAT A PARTICULAR WOMAN IS WILLING TO TOLERATE
6 OR NOT TOLERATE IN TERMS OF SIDE EFFECTS. AND ALSO
7 JUST, YOU KNOW, HER OWN PERSONAL PREFERENCE. WOMEN
8 SOMETIMES HAVE VERY STRONG OPINIONS ABOUT WHAT KIND OF
9 METHODS THEY WANT TO USE OR NOT USE, AND THOSE ARE VERY
10 IMPORTANT PARTS OF THE DECISION FOR HER.

11 Q. AND DO -- THE EFFECTIVENESS OF A PARTICULAR
12 CONTRACEPTION, DOES THAT PLAY INTO YOUR COUNSELING HOW
13 EFFECTIVE A PARTICULAR METHOD OF CONTRACEPTION IS?

14 A. ABSOLUTELY. BUT INTERESTINGLY, IT CAN VARY FROM
15 WOMAN TO WOMAN. THERE ARE SOME WOMEN WHO ARE WILLING TO
16 TOLERATE LESS EFFECTIVE METHODS BECAUSE OF ALL THE OTHER
17 CONSIDERATIONS THAT SHE HAS. BUT YES, TALKING ABOUT
18 CONTRACEPTIVE EFFECTIVENESS IS VERY IMPORTANT.

19 Q. AND WHAT ARE THE MOST EFFECTIVE FORMS OF
20 CONTRACEPTION?

21 A. SURE. SO THE MOST EFFECTIVE REVERSIBLE METHODS
22 ARE WHAT WE COMMONLY CALL LARCS, L-A-R-C-S, WHICH STANDS
23 FOR LONG-ACTING REVERSIBLE CONTRACEPTIVE. THE LARCS
24 INCLUDE THE CONTRACEPTIVE IMPLANT, WHICH IS A ROD THAT
25 GETS IMPLANTED ON THE INNER PART OF THE ARM, AS WELL AS

1 THE INTRAUTERINE DEVICE OR THE IUD.

2 Q. THEY ARE THE MOST EFFECTIVE. AND THEN WHAT
3 WOULD YOU SAY WOULD BE THE NEXT LEVEL DOWN?

4 A. RIGHT. SO THE LARCS ARE THE HIGHEST TIER OF
5 EFFICACY. THE NEXT TIER DOWN ARE OTHER HORMONAL
6 METHODS, SO THAT INCLUDES THE BIRTH CONTROL PILL, THE
7 BIRTH CONTROL PATCH, THE CONTRACEPTIVE VAGINAL RING, THE
8 CONTRACEPTIVE INJECTABLE OR DEPO-PROVERA. THAT WOULD BE
9 IN THE NEXT TIER OF EFFECTIVENESS. AND THEN THE LOWEST
10 TIER OF EFFECTIVENESS ARE METHODS SUCH AS WITHDRAWAL,
11 NATURAL FAMILY PLANNING, BARRIER METHODS SUCH AS
12 CONDOMS. THOSE ARE IN THE LOWEST TIER OF EFFECTIVENESS.

13 Q. DO YOU USE ANY PARTICULAR TEACHING TOOLS IN
14 COUNSELING PATIENTS REGARDING THE VARIOUS METHODS?

15 A. I COMMONLY USE -- THERE IS A CHART THAT IS
16 AVAILABLE ON THE CDC WEBSITE. SO I USUALLY HAVE THAT
17 HANDY IN MY EXAMINATION ROOM SO WE CAN LOOK AT THE
18 EFFECTIVENESS TOGETHER.

19 Q. THANK YOU, DOCTOR.

20 I WOULD LIKE TO POINT YOU TO TAB 17 OF
21 THE BINDER.

22 A. OKAY.

23 Q. WILL YOU KINDLY IDENTIFY THAT DOCUMENT.

24 A. YEAH, THIS IS THE CDC CHART I WAS JUST REFERRING
25 TO.

1 Q. ALL RIGHT, DOCTOR. JUST VERY BRIEFLY, IF YOU
2 CAN WALK THROUGH WHAT THIS CHART REFLECTS.

3 A. SURE. SO THE CHART IS ORGANIZED IN THREE ROWS
4 SEPARATED BY THOSE BLACK LINES, SO AT THE VERY TOP ROW,
5 THOSE ARE THE MOST EFFECTIVE METHODS, THE HIGHEST TIER.
6 SO THAT IS WHERE THE LARCS ARE. YOU CAN SEE THE
7 CONTRACEPTIVE IMPLANT AND THE IUD UP THERE, AND YOU CAN
8 SEE THEIR EFFECTIVENESS RATES THERE. IT IS LISTED AS
9 LESS THAN ONE PREGNANCY PER 100 WOMEN PER YEAR. THEY
10 ARE LINED UP RIGHT NEXT TO THE PERMANENT STERILIZATION
11 METHODS. YOU MIGHT BE INTERESTED TO SEE THAT THE
12 IMPLANT AND THE IUD ARE ACTUALLY MORE EFFECTIVE THAN
13 THOSE PERMANENT STERILIZATION METHODS.

14 THE NEXT TIER AFTER THAT IS WHERE YOU SEE
15 THE SHOT, THE PILL, THE PATCH, THE RING, AND THOSE ARE
16 THE ONES THAT ARE THE NEXT LEVEL EFFECTIVENESS, SO YOU
17 CAN SEE ON THE LEFT SIDE OF THE CHART IT SAYS 6 TO 12
18 PREGNANCIES PER 100 WOMEN IN A YEAR. WOMEN ARE OFTEN
19 SURPRISED THAT THE PILL IS ASSOCIATED WITH THAT MANY
20 PREGNANCIES.

21 AND THEN IN THE LOWEST TIER AT THE BOTTOM
22 ARE THAT -- THE BARRIER METHODS WE TALKED ABOUT BEFORE,
23 THE CONDOMS, WITHDRAWAL, SPERMICIDE AND THE NATURAL
24 FAMILY PLANNING METHOD.

25 Q. ARE SOME CONTRACEPTIVES MORE EXPENSIVE THAN

1 OTHERS?

2 A. YES. IT SO HAPPENS THAT THE MOST EFFECTIVE
3 METHODS, SO THE LARCS AT THE TOP ROW, ARE THE MOST
4 EXPENSIVE METHODS, AND THEN THE SECOND TIER AND THEN THE
5 LOWEST TIER.

6 Q. THANK YOU, DOCTOR.

7 DO CONTRACEPTIVES ALSO PLAY A ROLE IN
8 PLANNING CHILDREN?

9 A. YEAH. SO I THINK CONTRACEPTION CAN BE VERY
10 HELPFUL, IMPORTANT IN HELPING WOMEN TIME THEIR
11 PREGNANCIES AND THE SPACING BETWEEN THEIR PREGNANCIES,
12 SO THERE ARE SEVERAL GUIDELINES THAT SUGGEST THAT WOMEN
13 SHOULD WAIT AT LEAST 18 MONTHS AFTER THE BIRTH OF A
14 CHILD BEFORE GETTING PREGNANT AGAIN, AND THAT IS BECAUSE
15 MORE CLOSELY-SPACED PREGNANCIES ARE ASSOCIATED WITH
16 PRE-TERM BIRTH AND LOW BIRTH WEIGHT. SO BEING ABLE TO
17 CONTROL THE SPACING OF THE PREGNANCIES CAN BE VERY
18 IMPORTANT.

19 BUT AS IMPORTANT IS ALLOWING WOMEN TO BE
20 EMPOWERED TO COMPLETE THEIR GOALS IN LIFE, SO BE ABLE TO
21 FINISH SCHOOL, BE ABLE TO ACHIEVE THEIR JOB AND CAREER
22 GOALS, REACH THEIR FINANCIAL GOALS SO THEY CAN HAVE
23 THEIR CHILDREN WHEN THEY FEEL FINANCIALLY STABLE. SO I
24 THINK BEING ABLE TO HAVE THE CHILDREN, THE NUMBER OF
25 CHILDREN THEY WANT AND WHEN IT'S RIGHT FOR THEM IS VERY

1 IMPORTANT, AND WITHOUT CONTRACEPTION, THEY WOULD NOT BE
2 ABLE TO DO THAT.

3 Q. DO MOST OF YOUR PATIENTS HAVE HEALTH INSURANCE?

4 A. YES. MY PRACTICE IN HERSHEY IS A MOSTLY INSURED
5 POPULATION, YES.

6 Q. PRIOR TO THE CONTRACEPTIVE CARE MANDATE, WAS
7 COST SOMETHING THAT YOU COUNSELED ABOUT IN THE
8 CONVERSATION ABOUT CONTRACEPTION?

9 A. YES. SO WHEN I WOULD PULL OUT THIS CHART, I
10 WOULD ALSO TALK ABOUT THE COSTS OF THE DIFFERENT METHODS
11 AND OBVIOUSLY FOR SOME WOMEN, THERE WERE SOME METHODS
12 THAT WE COULD NOT TALK ABOUT BEYOND COSTS BECAUSE THEY
13 WERE COST-PROHIBITIVE.

14 Q. AND SINCE THE AFFORDABLE CARE ACT, DO YOU STILL
15 COUNSEL YOUR PRIVATELY-INSURED PATIENTS REGARDING COSTS?

16 A. I'M ABLE TO TELL WOMEN WHO HAVE PRIVATE HEALTH
17 INSURANCE THAT THEIR HEALTH INSURANCE COVERS ALL THE
18 FDA-APPROVED METHODS WITH NO OUT-OF-POCKET COSTS, SO I'M
19 ABLE TO PUT THIS CHART IN FRONT OF THEM AND REASSURE
20 THEM THAT THEY WOULD HAVE NO CO-PAYS OR DEDUCTIBLES AND
21 WE CAN TALK ABOUT THE DIFFERENT METHODS WITHOUT COSTS.

22 Q. IN YOUR EXPERIENCE IN YOUR PRACTICE PRIOR TO THE
23 CONTRACEPTIVE MANDATE, DID YOU HAVE ANY EXPERIENCE WHERE
24 PATIENTS WOULD RETURN TO YOU AND DECIDE NOT TO CHOOSE
25 THE CONTRACEPTION THAT YOU RECOMMENDED OR TO FORGO

1 CONTRACEPTION ALTOGETHER BECAUSE OF COST?

2 A. YES, ABSOLUTELY. THERE WERE MANY OCCASIONS I
3 CAN THINK OF WHERE A WOMAN MIGHT REALLY DESIRE TO GET AN
4 IUD BUT IT WAS COST PROHIBITIVE SO SHE WOULD HAVE TO
5 CHOOSE A DIFFERENT METHOD.

6 Q. HAVE YOU EXPERIENCED THAT PHENOMENON WITH ANY
7 PATIENTS SINCE THE CONTRACEPTIVE MANDATE,
8 PRIVATELY-INSURED PATIENTS?

9 A. NO, I HAVE NOT.

10 Q. WHAT DO YOU DO WHEN YOU ENCOUNTER A WOMAN WHO
11 DOES NOT HAVE INSURANCE AND IS NEEDING CONTRACEPTIVE
12 CARE?

13 A. IN OUR PRACTICE WE HAVE A SOCIAL WORKER, WE HAVE
14 A FINANCIAL DEPARTMENT AT THE HERSHEY MEDICAL CENTER, SO
15 IF SOMEONE IS UNINSURED, I AM ABLE TO REFER THEM TO
16 THOSE SERVICES. IF THE PATIENT QUALIFIES FINANCIALLY,
17 THEY MAY BE ABLE TO HELP THAT PATIENT APPLY FOR MEDICAID
18 OR FIND OTHER ASSISTANCE, BUT IF THE PATIENT DOES NOT
19 QUALIFY FOR MEDICAID OR IS UNABLE TO OBTAIN INSURANCE IN
20 ANY OTHER WAY, I PERSONALLY WOULD REFER THAT PERSON TO
21 PLANNED PARENTHOOD OR A FEDERALLY-QUALIFIED HEALTH
22 CENTER FOR THEM TO RECEIVE THEIR CONTRACEPTIVE SERVICES.

23 THE COURT: DID YOU SAY
24 FEDERALLY-QUALIFIED HEALTH CENTER?

25 THE WITNESS: YEAH.

1 BY MS. BOLAND:

2 Q. OKAY, DOCTOR. I WOULD NOW LIKE TO TURN YOUR
3 ATTENTION TO THE "MY NEW OPTIONS" STUDY, WHICH WAS
4 REFERENCED BEFORE. CAN YOU TELL US GENERALLY ABOUT THIS
5 STUDY? I UNDERSTAND YOU BEGAN TO EXPLAIN, BUT IF YOU
6 CAN TELL THE COURT EXACTLY WHAT WERE THE PARAMETERS OF
7 THE STUDY AND WHAT WAS YOUR GOAL IN CONDUCTING THE
8 STUDY?

9 A. SURE. SURE. SO THE "MY NEW OPTIONS" STUDY WAS
10 FUNDED THROUGH PCORI, THE PATIENT-CENTERED OUTCOMES
11 RESEARCH INSTITUTE. WE RECEIVED FUNDING IN THE FALL OF
12 2013 AND WE STARTED RECRUITING THE RESEARCH PARTICIPANTS
13 IN THE SPRING OF 2014. IT WAS A TWO-YEAR STUDY, SO IT
14 RAN UNTIL THE MIDDLE OF 2016.

15 THE PURPOSE OF THE STUDY WAS TO RECRUIT
16 REPRODUCTIVE-AGE WOMEN WHO ARE PRIVATELY INSURED, AND WE
17 RECRUITED PRIVATELY-INSURED WOMEN BECAUSE WE WANTED THEM
18 TO HAVE COVERAGE FOR CONTRACEPTION. AND WE RECRUITED
19 THEM AND THEY WERE RANDOMIZED INTO THREE DIFFERENT
20 GROUPS IN ORDER TO SEE DIFFERENT -- AND SOME OF THE
21 GROUPS RECEIVED CERTAIN WEB-BASED COUNSELING
22 INTERVENTIONS TO SEE IF IT WOULD HELP THEM WITH THEIR
23 CONTRACEPTIVE DECISION-MAKING.

24 Q. OKAY. AND SO TO CLARIFY, THE TIME FRAME FOR
25 THIS STUDY WAS 2014 THROUGH 2016?

1 A. THAT'S CORRECT.

2 Q. SO IF DR. WEISMAN TESTIFIED EARLIER IT WAS 2012
3 THROUGH 2014, WAS THAT MISTAKEN?

4 A. THAT WAS MISTAKEN, YES.

5 Q. OKAY. AND WHAT DID YOU FIND AS A RESULT OF THIS
6 STUDY?

7 A. YES, SO WE ACTUALLY FOUND THAT OUR WEB-BASED
8 INTERVENTIONS DID NOT MAKE A DIFFERENCE; THEY DID NOT
9 PARTICULARLY HELP WOMEN OR CHANGE WOMEN IN THEIR
10 CONTRACEPTIVE DECISION-MAKING. HOWEVER, WE WERE ABLE TO
11 TAKE THE OPPORTUNITY TO SEE THAT WE WERE ABLE TO FOLLOW
12 THESE WOMEN FROM PENNSYLVANIA OVER THE COURSE OF TWO
13 YEARS, AND AS A PARTICIPANT IN THE STUDY, THEY COMPLETED
14 A LOT OF SURVEYS FOR US AND THE SURVEYS HAD A LOT OF
15 QUESTIONS ABOUT CONTRACEPTIVE USE AND BEHAVIOR. SO WE
16 WERE ABLE TO SEE WHAT WOMEN REPORTED THEY WERE DOING
17 ABOUT CONTRACEPTION AT THE BEGINNING OF THE STUDY,
18 THROUGHOUT THE STUDY, AND AT THE END OF THE STUDY.

19 Q. AND THE CONTRACEPTIVE MANDATE WAS ALREADY IN
20 PLACE --

21 MS. KOPPLIN: YOUR HONOR, I'M SORRY, WE
22 WOULD OBJECT TO THIS LINE OF QUESTIONING. WE HAVE NOT
23 HAD ANY DISCLOSURE ABOUT THE METHODOLOGY THAT WAS USED
24 IN THIS STUDY OR WHERE THIS DATA CAME FROM.

25 THE COURT: OVERRULED.

1 ARE YOU GOING TO TALK ABOUT THAT?

2 MS. BOLAND: YES.

3 BY MS. BOLAND:

4 Q. WILL YOU SPEAK TO THE METHODOLOGY BEHIND THIS
5 STUDY, PLEASE, DR. CHUANG?

6 A. SURE. THIS WAS A RANDOMIZED TRIAL. WE
7 RECRUITED -- YOU WANT TO HEAR THE DETAILS OF THE
8 RECRUITMENT METHODS? OKAY.

9 SO WE PARTNERED WITH HIGHMARK, A PRIVATE
10 INSURANCE PROVIDER. FOR THE REASON I STATED EARLIER, WE
11 WERE SPECIFICALLY INTERESTED IN RECRUITING PRIVATELY
12 INSURED WOMEN WHO LIVED IN THE STATE OF PENNSYLVANIA,
13 AND SO WE SENT OUT INVITATIONS TO WOMEN WHO HAD HEALTH
14 INSURANCE, WERE BETWEEN THE AGES OF 18 AND 40, AND
15 INVITED THEM TO PARTICIPATE IN THE STUDY.

16 AND FOR WOMEN WHO CONSENTED, ENROLLED IN
17 THE STUDY, THEY COMPLETED A SURVEY AT THE BEGINNING OF
18 THE STUDY AND THEY WERE RANDOMIZED INTO ONE OF THREE
19 GROUPS. ONE GROUP WAS A CONTROL GROUP; THEY DID NOT GET
20 ANY PARTICULAR INTERVENTION AT ALL. AND THE OTHER TWO
21 GROUPS WERE TWO DIFFERENT GROUPS WHERE THEY WOULD SEE
22 TWO DIFFERENT TYPES OF WEBSITES THAT PROVIDED
23 INFORMATION ABOUT CONTRACEPTION TO SEE IF THOSE WEBSITES
24 WOULD HELP THEM WITH THEIR DECISION-MAKING.

25 HOWEVER AT THE END OF THE STUDY, AT THE

1 END OF THE TWO YEARS, WE FOUND THAT ALL THREE GROUPS
2 BEHAVED SIMILARLY AND THERE WAS NO DIFFERENCE BETWEEN
3 THE GROUPS THAT GOT THE WEBSITE INTERVENTION AND THE
4 GROUP THAT DID NOT. SO UNFORTUNATELY FOR ME, WE DIDN'T
5 SEE ANY DIFFERENCES WITH OUR WEBSITE INTERVENTION, BUT
6 WE WERE ABLE TO SEE WHAT THE CONTRACEPTIVE BEHAVIORS
7 WERE AMONGST THE WOMEN WHO WERE PARTICIPATING IN THE
8 STUDY.

9 AND I DON'T THINK I SAID BEFORE, THERE
10 WERE 984 WOMEN WHO WERE IN THE STUDY.

11 Q. AND WHAT DID YOU LEARN THAT THE CONTRACEPTIVE
12 BEHAVIORS WERE OVER THIS PERIOD OF TIME FOR ALL THREE
13 GROUPS INCLUDING THE CONTROL GROUP, RIGHT?

14 A. SURE. YES. SO WE WERE ABLE TO SEE WHAT TYPES
15 OF CONTRACEPTIVE METHODS WERE BEING USED THROUGHOUT THE
16 STUDY. SO IN THE BEGINNING OF THE STUDY, THERE WERE
17 RELATIVELY FEW WOMEN USING LARCS, THE LONG-ACTING
18 REVERSIBLE CONTRACEPTIVES. THERE WERE ABOUT 8 PERCENT
19 OF WOMEN USING LARCS, AND BY THE END OF THE STUDY THERE
20 WERE ALMOST 18 PERCENT OF WOMEN USING LARCS IN THE
21 STUDY. AND SO WE THOUGHT THAT WAS AN INTERESTING
22 FINDING.

23 Q. DOCTOR, I WOULD LIKE TO POINT YOU TO TAB 18 IN
24 THE BINDER.

25 A. OKAY.

1 Q. WILL YOU PLEASE IDENTIFY THIS DOCUMENT FOR THE
2 COURT?

3 A. SURE. THIS IS A RESULTS TABLE THAT IS TAKEN
4 FROM SOME OF OUR -- TAKEN FROM A PRESENTATION THAT WE
5 HAD DONE PRESENTING THE "MY NEW OPTIONS" STUDY AT A
6 NATIONAL CONFERENCE.

7 Q. THANK YOU. IF YOU PUT --

8 MS. KOPPLIN: YOUR HONOR -- I'M SORRY --
9 WE WOULD OBJECT. WHAT IS THE SOURCE OF THIS DATA?

10 THE COURT: WELL, WHY DON'T YOU -- OFFER
11 OF PROOF. WHAT IS THE SOURCE OF DATA?

12 MS. BOLAND: DR. CHUANG HERSELF DRAFTED
13 THIS CHART AND SHE PUT IN THE DATA HERSELF. SHE HAS
14 ALREADY TESTIFIED AS TO THE METHODOLOGY BEHIND IT. THIS
15 IS JUST PUTTING HER TESTIMONY IN CHART FORM TO
16 DEMONSTRATE FOR THE COURT.

17 THE COURT: SO MS. -- MS. CHUANG, DID YOU
18 CREATE THIS FOR THIS PARTICULAR PROCEEDING OR YOU
19 CREATED IT FOR THE STUDY?

20 THE WITNESS: I CREATED IT FOR THE STUDY.
21 THIS TABLE IS ACTUALLY TAKEN FROM A PRESENTATION WE DID
22 AT THE SOCIETY OF GENERAL INTERNAL MEDICINE MEETING BACK
23 IN THE SPRING. I ALSO GAVE A PRESENTATION AT THE
24 SOCIETY FOR FAMILY PLANNING MEETING, AND THIS TABLE WAS
25 TAKEN FROM THOSE PRESENTATIONS.

1 THE COURT: AND THE DATA INCLUDED IN THE
2 TABLE IS TAKEN FROM WHERE?

3 THE WITNESS: THIS IS FROM THE "MY NEW
4 OPTIONS" RESULTS.

5 THE COURT: OKAY. OVERRULED.

6 GO AHEAD.

7 BY MS. BOLAND:

8 Q. IF YOU FLIP TO THE NEXT PAGE, CAN YOU JUST TELL
9 US WHAT THAT IS?

10 A. THAT IS ANOTHER TABLE FROM THE SAME
11 PRESENTATIONS.

12 Q. REFLECTING THE SAME DATA?

13 A. YES.

14 Q. IS IT JUST REPACKAGED A DIFFERENT WAY?

15 A. YES. SO THE FIRST TABLE SHOWS THE CONTRACEPTIVE
16 TYPES THAT ARE USED IN THE STUDY DIVIDED INTO THE FOUR
17 CATEGORIES THAT ARE SIMILAR TO THOSE TIERS THAT WE
18 LOOKED AT ON THE CDC WEBSITE. SO THE FIRST ROW IS
19 LARCS, THE SECOND ROW IS OTHER PRESCRIPTION METHODS,
20 THIRD ROW IS NONPRESCRIPTION METHODS, AND THE LAST ROW
21 IS NO METHOD. THE SECOND TABLE REALLY IS THE SAME DATA
22 BUT IT'S JUST LOOKING AT WOMEN WHO WERE ON ANY
23 CONTRACEPTIVE METHOD AT ALL VERSUS NO METHOD. SO IN THE
24 SECOND TABLE, IT JUST REALLY COLLAPSES THOSE FIRST THREE
25 ROWS INTO ONE ROW, SO IT IS REALLY SHOWING THE SAME DATA

1 IN TWO DIFFERENT FORMATS.

2 Q. AND I THINK YOU JUST TESTIFIED THAT YOU SAW A
3 STATISTICAL JUMP FROM THE NUMBER OF WOMEN USING LARCS AT
4 THE BEGINNING OF THE STUDY TO THE NUMBER OF WOMEN USING
5 LARCS AT THE END OF THE STUDY. IS THAT REFLECTED
6 SOMEWHERE ON THESE DOCUMENTS?

7 A. SO I'M LOOKING AT TABLE 1, AND SO IN THAT FIRST
8 ROW WHERE IT SAYS LARCS, AND THEN IF YOU LOOK AT THE
9 NEXT COLUMN WHERE IT SAYS BASELINE, THAT IS THE
10 BEGINNING OF THE STUDY WHERE THERE ARE 984 WOMEN
11 ENROLLED IN THE STUDY.

12 SO 83 WOMEN AT THE BEGINNING OF THE
13 STUDY, WHICH WAS 8.4 PERCENT OF THE SAMPLE, AT THAT TIME
14 WERE USING LARCS. AND THEN IF YOU GO OVER TO THE NEXT
15 ROW, WHERE IT SAYS 24 MONTHS, THERE WERE 130 WOMEN OUT
16 OF 727 WOMEN USING LARCS AT THE END OF THE STUDY, WHICH
17 WAS 17.9 PERCENT.

18 IF YOU LOOK AT THE NEXT TWO ROWS, THERE
19 ARE REALLY NO DIFFERENCES. IF YOU LOOK AT THE
20 PERCENTAGES OF OTHER PRESCRIPTION METHODS IT WAS
21 49.7 PERCENT BOTH AT BASELINE AND 24 MONTHS. AND THEN
22 IN THE THIRD ROW, NOT MUCH DIFFERENCE EITHER IN THE
23 NONPRESCRIPTION METHOD. BUT THEN IF YOU LOOK AT THE
24 LAST ROW, THE NO-METHOD ROW, YOU WILL SEE THAT BASELINE
25 THERE WERE 11.5 PERCENT OF WOMEN NOT USING ANY METHOD

1 AND THAT HAD DROPPED TO 5.1 PERCENT BY THE END OF THE
2 STUDY.

3 AND THEN IN THE THIRD COLUMN WHERE IT
4 SAYS P VALUE. THE P VALUE IS OUR TEST OF STATISTICAL
5 SIGNIFICANCE, AND IN BIOMEDICAL RESEARCH WE GENERALLY
6 ACCEPT A P VALUE OF LESS THAN .05 TO INDICATE
7 STATISTICAL SIGNIFICANCE. SO THE P VALUE WE HAD FOR
8 THESE RESULTS WAS LESS THAN .001, WHICH SHOWS THAT THERE
9 WAS A STATISTICALLY SIGNIFICANT CHANGE IN THESE NUMBERS
10 THAT I JUST REVIEWED.

11 Q. AND JUST A COUPLE OF POINTS OF CLARIFICATION.
12 IT LOOKS LIKE ALTHOUGH THE PERCENTAGE IS THE SAME FOR
13 OTHER PRESCRIPTION METHODS, THE NUMBER OF -- THE OTHER
14 NUMBER CHANGED. CAN YOU EXPLAIN WHAT WE ARE SEEING HERE
15 AND WHY THE PERCENTAGE IS THE SAME BUT THE NUMBER OF
16 PEOPLE DIFFERS?

17 A. SURE. SO I WILL TAKE YOU BACK UP TO THE HEADER
18 ROW WHERE IT SAYS BASELINE, N EQUALS 984, AND 24 MONTHS,
19 N EQUALS 727. SO IT MIGHT SEEM PECULIAR THAT THERE WAS
20 SUCH A DIFFERENT -- A DROP IN THE NUMBERS BETWEEN THE
21 BEGINNING AND THE END OF THE STUDY.

22 HOWEVER, WE JUST INCLUDED WOMEN IN THE
23 STUDY WHO WERE ACTIVELY TRYING TO AVOID PREGNANCY. SO I
24 SHOULD HAVE MENTIONED BEFORE WHEN I WAS DESCRIBING THE
25 STUDY THAT WE ENROLLED WOMEN WHO SAID THEY WERE TRYING

1 TO AVOID PREGNANCY FOR THE NEXT YEAR.

2 OVER THE COURSE OF THE TWO-YEAR STUDY,

3 WOMEN CHANGED THEIR MIND AND SOME WOMEN THEN DECIDED

4 THEY WERE TRYING TO GET PREGNANT. AND SO THOSE WOMEN

5 WERE NO LONGER COUNTED BECAUSE THEY DIDN'T HAVE AN

6 INDICATION TO USE BIRTH CONTROL ANYMORE. SO THAT IS WHY

7 THERE WAS ONLY 727 WOMEN AT 24 MONTHS.

8 THERE WERE SOME OTHER REASONS THAT WOMEN

9 WERE EXCLUDED TOO. THERE WERE SOME WHO GOT A

10 HYSTERECTOMY DURING THAT TIME FRAME OR THEY GOT THEIR

11 TUBAL STERILIZATION DURING THAT TIME FRAME, SO THAT

12 ACCOUNTED FOR SOME OF THE REDUCED NUMBERS AS WELL.

13 Q. DOES THE FACT THAT SOME WOMEN DROPPED OUT, DID

14 THAT AFFECT THE RELIABILITY OF YOUR FINDINGS?

15 A. NO, BECAUSE THAT IS ACCOUNTED FOR WHEN YOU DO

16 THE STATISTICAL TEST AND GENERATE THE P VALUE. IT

17 CONSIDERS THE SAMPLE SIZE NUMBER.

18 Q. SO WHAT IS YOUR OPINION WITH A REASONABLE DEGREE

19 OF CERTAINTY AS TO WHY WOMEN CHANGED THEIR BEHAVIOR OVER

20 THIS TIME FRAME?

21 A. WELL, WHAT I CAN SAY IS THAT THE STUDY, SINCE WE

22 STARTED THE STUDY IN 2014, IT OCCURRED PRETTY SHORTLY

23 AFTER THE CONTRACEPTIVE MANDATE WENT INTO EFFECT. WE

24 DIDN'T SEE AN EFFECT OF OUR STUDY INTERVENTION AND

25 REALLY THE ONLY OTHER THING THAT WAS GOING ON AT THE

1 TIME WAS THIS CHANGE IN CONTRACEPTIVE -- IN THE
2 CONTRACEPTIVE MANDATE.

3 SO MY HYPOTHESIS WOULD BE THAT WHAT WE
4 ARE SEEING IS THE CHANGE IN CONTRACEPTIVE BEHAVIOR THAT
5 COULD HAVE RESULTED FROM THE CONTRACEPTIVE MANDATE.

6 Q. AND IS THAT CONSISTENT WITH OTHER RESEARCH OUT
7 THERE, TO YOUR KNOWLEDGE?

8 A. YEAH. ACTUALLY THERE HAS BEEN SEVERAL OTHER
9 STUDIES IN THE LITERATURE THAT HAVE SHOWN THAT SINCE THE
10 CONTRACEPTIVE MANDATE, WE DO KNOW THAT OUT-OF-POCKET
11 COSTS FOR WOMEN HAVE GONE DOWN SINCE THE CONTRACEPTIVE
12 MANDATE. THERE'S BEEN SOME STUDIES TO SHOW THAT THERE
13 MAY BE SOME CHANGES IN METHODS THAT WOMEN ARE CHOOSING
14 WITH MORE LARCS BEING USED. SO I THINK THIS IS
15 CONSISTENT WITH THOSE OTHER STUDIES.

16 Q. IS THIS CONSISTENT WITH YOUR EXPERIENCE IN YOUR
17 OWN PRACTICE IN TERMS OF WOMEN'S DECISION-MAKING AFTER
18 THE MANDATE WAS PUT IN PLACE?

19 A. WELL, I CAN SAY THAT I CERTAINLY HAD SOME
20 PATIENTS WHO, AFTER LEARNING ABOUT THE MANDATE, HAVE
21 RETHOUGHT THEIR CONTRACEPTIVE DECISION-MAKING. SOME OF
22 THEM THAT HAS HELPED THEM CHANGE THEIR MIND. I HAVE HAD
23 SOME WOMEN WHO WERE PREVIOUSLY NOT USING A METHOD OR
24 USING A LESS-EFFECTIVE METHOD THAT HAVE THEN CHOSEN TO
25 USE A MORE-EFFECTIVE METHOD, WHETHER THAT BE A LARC OR

1 PILL OR SOMETHING ELSE, YES.

2 Q. IN YOUR OPINION, DOCTOR, HAS THE CONTRACEPTIVE
3 MANDATE BENEFITED WOMEN?

4 A. YES, I THINK IT HAS.

5 Q. AND FOR WHAT REASON?

6 A. I THINK BECAUSE IT HAS ALLOWED WOMEN TO HAVE
7 THAT FULL RANGE OF CHOICES THAT ARE ON THAT CDC CHART WE
8 LOOKED AT. SO INSTEAD OF ONLY HAVING A COUPLE OF THOSE
9 AVAILABLE TO WOMEN TO CONSIDER, THEY HAVE THE WHOLE
10 SPECTRUM OF CHOICES TO CONSIDER, AND IT GIVES THE
11 PATIENT A LOT MORE FREEDOM TO TALK WITH THEIR PROVIDER
12 ABOUT WHAT METHODS ARE REALLY BEST SUITED FOR THEM AS AN
13 INDIVIDUAL. WHEN THEY CONSIDER WHAT THEIR OWN HEALTH
14 CONDITIONS ARE, WHAT THEIR OWN PREFERENCES ARE, WHAT
15 SIDE EFFECTS ARE OKAY OR NOT OKAY FOR THEM, IT REALLY
16 ALLOWS THEM TO CONSIDER THE FULL SET OF OPTIONS.

17 Q. HAVE YOU HAD THE OPPORTUNITY TO READ THE
18 RELIGIOUS AND MORAL EXEMPTION RULES AT ISSUE IN THIS
19 CASE?

20 A. YES, I HAVE READ THEM.

21 Q. WHAT DO YOU BELIEVE THE IMPACT OF THOSE RULES
22 WILL BE ON PRIVATELY-INSURED WOMEN -- ON SOME
23 PRIVATELY-INSURED WOMEN IN PENNSYLVANIA?

24 MS. KOPPLIN: OBJECTION, YOUR HONOR.

25 THIS IS NOT AN OPINION THAT IS GOING TO BE -- THAT THERE

1 IS ANY EVIDENCE IT'S GOING TO BE THE PRODUCT OF RELIABLE
2 PRINCIPLES AND METHODS BY THE WITNESS.

3 THE COURT: OVERRULED.

4 THE WITNESS: I --

5 THE COURT: WHAT YOU KNOW FROM YOUR
6 EXPERIENCE.

7 THE WITNESS: SURE. SO BASED ON MY
8 EXPERIENCE, I WOULD IMAGINE THAT IT WOULD BE SIMILAR TO
9 BEFORE THE CONTRACEPTIVE MANDATE WHEN CONTRACEPTIVE
10 COUNSELING HAD TO INCLUDE COSTS. SO I WOULD IMAGINE
11 THAT WOULD BE THE CASE AGAIN.

12 BY MS. BOLAND:

13 Q. IS IT YOUR OPINION THAT COST IS A BARRIER TO
14 ACCESS TO CONTRACEPTIVE CARE, OR CAN BE A BARRIER TO
15 CONTRACEPTIVE CARE?

16 A. YES, I HAVE SEEN THAT BE THE CASE.

17 Q. AND IN YOUR OPINION, WHAT WILL HAPPEN IF WOMEN
18 FORGO CONTRACEPTIVE CARE BECAUSE OF COST?

19 A. I THINK THAT IF WOMEN CAN'T CHOOSE FROM THE FULL
20 SET OF OPTIONS, THEY MAY BE MORE LIKELY TO CHOOSE THE
21 LESS EXPENSIVE OPTIONS, WHICH ARE, UNFORTUNATELY, THE
22 LESS EFFECTIVE OPTIONS. AND SO MY FEAR WOULD BE THAT WE
23 WOULD SEE A RISE IN UNINTENDED PREGNANCIES AND
24 CONCOMITANTLY A RISE IN ABORTIONS.

25 Q. THANK YOU, DR. CHUANG.

1 MS. BOLAND: BEAR WITH ME ONE MOMENT,
2 YOUR HONOR.

3 THE COURT: OKAY.

4 BY MS. BOLAND:

5 Q. TWO POINTS FOR CLARIFICATION, DOCTOR. EARLIER I
6 ASKED YOU ABOUT THE MOST EXPENSIVE METHODS OF
7 CONTRACEPTION. SPEAKING IN TERMS OF UP-FRONT COST, WHAT
8 IS THE MOST EXPENSIVE METHOD OF CONTRACEPTION?

9 A. THE LARCS ARE THE MOST EXPENSIVE WITH UP-FRONT
10 COSTS, BECAUSE YOU HAVE TO PAY FOR THE DEVICE AND THE
11 INSERTION FEE ALL AT ONCE UP FRONT.

12 Q. IN REGARD TO THE "MY NEW OPTIONS" STUDY, WHY WAS
13 THERE A DELAY IN THE CHANGES OVER TIME IF THE MANDATE
14 WENT INTO EFFECT IN 2012? IN OTHER WORDS, WHY WASN'T IT
15 INSTANTANEOUS THAT YOU WOULD SEE CHANGES IN WOMEN'S
16 BEHAVIOR?

17 A. WELL, A COUPLE OF THINGS.

18 WOMEN MAY NOT HAVE BEEN AWARE OF THE
19 CHANGES IN THEIR CONTRACEPTIVE COVERAGE RIGHT AWAY. IN
20 FACT, I HAD PATIENTS COME TO ME AND SAY, OH, I THINK
21 THEY MADE A MISTAKE AT THE PHARMACY, THEY DID NOT CHARGE
22 ME A CO-PAY THIS MONTH. SO THEY DID NOT REALIZE THAT
23 THERE WAS A CHANGE IN POLICY. SO THAT IS NUMBER ONE.

24 SECONDLY, YOU KNOW, WOMEN DON'T RUSH TO
25 THE DOCTOR EVERY DAY, SO THEY MIGHT -- MOST WOMEN WHO

1 ARE HEALTHY REPRODUCTIVE-AGE WOMEN MIGHT ONLY SEE THEIR
2 PHYSICIAN ONCE A YEAR, SO PROBABLY JUST THE TIMING OF
3 WHEN THEY WERE SEEING THEIR PROVIDERS AND MAKING CHANGES
4 IN THEIR CONTRACEPTION IS WHAT I WOULD GUESS.

5 MS. BOLAND: THANK YOU VERY MUCH, DOCTOR.
6 I HAVE NO FURTHER QUESTIONS.

7 THE COURT: MS. KOPPLIN.

8 MS. KOPPLIN: YOUR HONOR, MAY I APPROACH?

9 THE COURT: YOU MAY.

10 CROSS-EXAMINATION

11 BY MS. KOPPLIN:

12 Q. GOOD AFTERNOON. DR. CHUANG, MY NAME IS REBECCA
13 KOPPLIN. I'M JUST GOING TO ASK YOU A COUPLE QUESTIONS.

14 HOW ARE YOU DOING?

15 A. GOOD, THANK YOU.

16 Q. DR. CHUANG, WHAT DOCUMENTS DID YOU CONSIDER IN
17 PREPARING YOUR DECLARATION? COULD YOU LIST THE
18 DOCUMENTS?

19 A. I'M NOT SURE WHAT TYPES OF DOCUMENTS YOU MIGHT
20 BE REFERRING TO.

21 Q. LET'S SAY ALL TYPES OF DOCUMENTS.

22 A. WELL, BEING A PRIMARY CARE PROVIDER AND BEING A
23 RESEARCHER IN THIS FIELD AND A LECTURER IN THIS AREA,
24 THE DECLARATION INCLUDED YEARS OF READING MANY
25 SCIENTIFIC ARTICLES AND DOING YEARS OF RESEARCH AND THE

1 BODY OF KNOWLEDGE THAT HAS ACCUMULATED FROM THAT.

2 Q. OTHER THAN THE GENERAL BODY OF KNOWLEDGE YOU HAD
3 WHEN YOU STARTED WORKING AND PREPARING THE DECLARATION,
4 WHAT SPECIFIC SOURCES DID YOU SEEK OUT AND REVIEW?

5 A. I'M NOT SURE I UNDERSTAND THE QUESTION.

6 Q. FOR EXAMPLE, DID YOU READ THE RULES WHEN YOU
7 WERE PREPARING YOUR DECLARATION?

8 A. AT THE TIME THAT I PREPARED MY DECLARATION --
9 I'M ACTUALLY -- I CANNOT PRECISELY REMEMBER IF I HAD
10 ALREADY READ THE RULES AT THE TIME OF THE DECLARATION.

11 Q. SO YOU DO NOT RECALL IF YOU HAD READ THE RULES
12 OR NOT WHEN YOU WROTE YOUR DECLARATION?

13 A. I DO NOT RECALL.

14 Q. DID YOU READ ANY OF THE ARTICLES THAT ARE CITED
15 IN THE RULES?

16 A. IN READING -- WHEN I DID READ THE RULES, A LOT
17 OF THE ARTICLES ARE COMMONLY-CITED ARTICLES IN FAMILY
18 PLANNING LITERATURE, SO MANY OF THEM I WAS ALREADY
19 FAMILIAR WITH AND SINCE SOME OF THEM I READ SUBSEQUENT
20 TO READING THE RULES, BUT I DID NOT READ EVERY SINGLE
21 ONE OF THEM, NO.

22 Q. DO YOU RECALL ANY OTHER THINGS THAT YOU WOULD
23 HAVE LOOKED AT IN PREPARING YOUR DECLARATION, FOR
24 EXAMPLE, NEWSPAPER ARTICLES, BLOG POSTS?

25 A. I WOULD NOT HAVE REFERRED TO THE LAY PRESS FOR

1 MY INFORMATION, NO.

2 Q. DO YOU RECALL IN PARTICULAR ANY STUDIES THAT YOU
3 READ OTHER THAN THOSE CITED IN THE RULES?

4 A. I CONSIDER AS PART OF MY DAILY WORK TO BE
5 READING RESEARCH ARTICLES ABOUT CONTRACEPTION, SO YES, I
6 READ ARTICLES ON A NEAR-DAILY BASIS ABOUT THIS FIELD.

7 Q. SURE. MY QUESTION WAS IF YOU RECALLED IN
8 PARTICULAR ANY ARTICLES THAT YOU READ TO PREPARE FOR THE
9 DECLARATION?

10 A. SURE. I HAVE READ MANY ARTICLES IN THE LAST
11 COUPLE OF WEEKS, PERHAPS MAYBE MORE FREQUENCY THAN USUAL
12 BECAUSE I KNEW THAT I WOULD BE HERE TODAY.

13 Q. SURE. IF YOU RECALL ANY IN PARTICULAR, WHO WAS
14 THE AUTHOR OF THAT STUDY AND WHAT WAS ITS TITLE?

15 A. SO I KNOW, FOR EXAMPLE, THAT YOU GUYS HAVE THE
16 BEARAK AND JONES ARTICLES, SO I HAVE READ -- I READ THAT
17 AGAIN IN PREPARATION FOR TODAY. THERE ARE SEVERAL OTHER
18 ARTICLES THAT -- AS I MENTIONED BEFORE, THERE'S OTHER
19 RESEARCH THAT HAS DOCUMENTED A -- CHANGES IN
20 CONTRACEPTIVE BEHAVIOR AND UPTAKE OF MORE EFFECTIVE
21 METHODS, SO I READ, REVIEWED SOME OF THOSE ARTICLES.
22 THERE WAS AN ARTICLE BY LYDIA PACE THAT WAS PUBLISHED IN
23 HEALTH AFFAIRS LAST YEAR. THERE WAS ANOTHER ARTICLE
24 PUBLISHED IN HEALTH AFFAIRS LAST YEAR REGARDING THE SAME
25 TOPIC. THERE IS AN ARTICLE BY KAVANAUGH AND COLLEAGUES

1 THAT WAS PUBLISHED IN CONTRACEPTION THIS YEAR THAT ALL
2 RELATE TO INCREASES IN MORE EFFECTIVE CONTRACEPTIVE USE
3 FOLLOWING THE CONTRACEPTIVE MANDATE. THOSE ARE ALL
4 ARTICLES THAT I REREAD RECENTLY IN PREPARATION FOR THIS.

5 Q. WHO DID YOU MEET WITH TO PREPARE FOR YOUR
6 DECLARATION?

7 A. I MET WITH THE LAWYERS HERE.

8 Q. ANYONE ELSE?

9 A. NO.

10 Q. SO YOU ARE HERE TODAY TO TESTIFY ABOUT THE NEW
11 EXEMPTION TO THE CONTRACEPTIVE COVERAGE MANDATE,
12 CORRECT?

13 A. YES.

14 Q. NOW, BEFORE THESE NEW EXEMPTIONS EXISTED, YOU
15 ARE AWARE THAT THERE WERE SOME GRANDFATHERED PLANS THAT
16 WERE ALREADY EXEMPT FROM THE COVERAGE MANDATE?

17 A. YES.

18 Q. AND YOU'RE AWARE THAT SOME OF THESE PLANS WERE
19 THEREFORE NOT PROVIDING COVERAGE FOR CONTRACEPTIVES?

20 A. COULD YOU REPEAT THAT? SORRY.

21 Q. SO YOU WOULD AGREE WITH ME THAT BECAUSE SOME OF
22 THESE PLANS WERE GRANDFATHERED, THOSE PLANS WERE NOT
23 PROVIDING COVERAGE FOR CONTRACEPTIVES?

24 A. YES.

25 Q. DO YOU HAVE AN IDEA OF HOW MANY OF THOSE PLANS

1 THERE WERE IN PENNSYLVANIA?

2 A. I DO NOT PRECISELY KNOW THE NUMBER, BUT I KNOW
3 THE NUMBER HAS BEEN DECLINING WITH EVERY YEAR.

4 Q. BUT YOU COULD NOT EVEN GIVE ME AN ESTIMATE OF A
5 NUMBER?

6 A. I KNOW AT THE TIME THE CONTRACEPTIVE MANDATE
7 WENT INTO PLACE, I RECALL THAT MAYBE THE NUMBER OF
8 GRANDFATHERED PLANS WAS AROUND 20 PERCENT, AND I
9 UNDERSTAND THAT IT HAS DECLINED IN EVERY YEAR SINCE
10 THEN, BUT I DON'T KNOW WHAT THE PRECISE NUMBER IS NOW.

11 Q. AND YOU ARE AWARE THAT PRIOR TO THE CURRENT
12 EXEMPTIONS, THERE WAS ALREADY AN EXEMPTION FOR HOUSES OF
13 WORSHIP?

14 A. YES.

15 Q. AND SO THEREFORE THERE WERE SOME HOUSES OF
16 WORSHIP THAT WERE NOT PROVIDING CONTRACEPTIVE COVERAGE?

17 A. CORRECT.

18 Q. ARE YOU AWARE ABOUT HOW MANY OF THOSE THERE WERE
19 IN PENNSYLVANIA?

20 A. NO, I DON'T KNOW HOW MANY.

21 Q. AND YOU ARE AWARE THAT PRIOR TO THIS LITIGATION,
22 THERE WAS OTHER LITIGATION CHALLENGING THE CONTRACEPTIVE
23 MANDATE, AND AS A RESULT OF THAT, SOME ENTITIES OBTAINED
24 INJUNCTIONS SO THEY DID NOT HAVE TO PROVIDE
25 CONTRACEPTION COVERAGE, CORRECT?

1 A. SO IF YOU ARE REFERRING TO ACCOMMODATIONS, YES,
2 I'M FAMILIAR WITH THAT.

3 Q. AND DO YOU KNOW HOW MANY OF THOSE ACCOMMODATED
4 ENTITIES WERE IN PENNSYLVANIA?

5 A. NO, I DO NOT KNOW. I DO KNOW THAT THE COMPANIES
6 THAT WERE INVOLVED, LIKE HOBBY LOBBY, ARE PENNSYLVANIA
7 COMPANIES, BUT I DO NOT KNOW BEYOND THAT HOW MANY ARE
8 FROM PENNSYLVANIA.

9 Q. SO I'M LOOKING AT YOUR DECLARATION NOW, WHICH IS
10 AT TAB 6 IN THE BINDER. AT PARAGRAPH 31, YOU STATED
11 THAT: SINCE THE ACA HAS PASSED, NO PATIENT HAS
12 CONTACTED ME TO ASK FOR A DIFFERENT, CHEAPER METHOD OF
13 CONTRACEPTION THAN THE ONE I HAD PRESCRIBED DUE TO THE
14 COST UNDER PRIVATE INSURANCE PLANS.

15 DID I READ THAT CORRECTLY?

16 A. YOU DID.

17 Q. SO YOU WOULD AGREE WITH ME THEN THAT SINCE THE
18 ACA PASSED, NONE OF YOUR PATIENTS ASKED FOR CHEAPER
19 METHODS OF CONTRACEPTION EVEN THOUGH ALL OF THESE
20 EXEMPTIONS THAT WE JUST TALKED ABOUT WERE IN EXISTENCE?

21 A. THAT'S RIGHT.

22 Q. NOW, LET'S TURN TO THE NEW EXEMPTIONS THAT ARE
23 AT ISSUE HERE. THE NEW EXEMPTIONS ARE FOR ENTITIES WITH
24 SINCERE RELIGIOUS AND MORAL OBJECTIONS, CORRECT?

25 A. CORRECT.

1 Q. BUT YOU ARE NOT AWARE OF ANY EMPLOYERS IN
2 PENNSYLVANIA THAT HAVE INVOKED THE NEW EXEMPTIONS SO
3 FAR, CORRECT?

4 A. I'M NOT AWARE, NO.

5 Q. SO YOU ARE NOT AWARE OF ANY INDIVIDUALS IN
6 PENNSYLVANIA WHO HAVE LOST THEIR CONTRACEPTIVE COVERAGE
7 DUE TO THE NEW EXEMPTIONS?

8 A. NO, I'M NOT. I DON'T KNOW.

9 Q. AND NOT JUST IN PENNSYLVANIA, BUT YOU ARE NOT
10 AWARE OF ANY PEOPLE NATIONALLY EITHER WHO HAVE LOST
11 COVERAGE BECAUSE OF THE EXEMPTION?

12 A. I'M NOT AWARE OF ANY, NO.

13 Q. AND YOU DON'T KNOW OF ANY PEOPLE EITHER IN
14 PENNSYLVANIA OR IN THE ENTIRE COUNTRY WHO WILL LOSE
15 COVERAGE, LIKE THEIR PLANS HAVE ALREADY ANNOUNCED THAT
16 THEY ARE GOING TO CHANGE, FOR EXAMPLE?

17 A. NO.

18 Q. LOOKING AT YOUR DECLARATION AT PARAGRAPH 23, YOU
19 STATED: SOME OF MY PATIENTS ALSO WORK FOR AND RECEIVE
20 THEIR HEALTH INSURANCE THROUGH CATHOLIC SCHOOLS AND
21 OTHER INSTITUTIONS WHICH MIGHT SEEK TO ELIMINATE
22 CONTRACEPTIVE COVERAGE THROUGH THEIR EMPLOYER-SPONSORED
23 PLANS UNDER THE NEW RELIGIOUS AND MORAL EXEMPTIONS.

24 DID I READ THAT CORRECTLY?

25 A. YES, YOU DID.

1 Q. SO NOW HERE TODAY IN DECEMBER, YOU STILL CAN'T
2 IDENTIFY ANY ACTUAL PATIENTS WHO WILL LOSE COVERAGE,
3 CORRECT?

4 A. I HAVE PATIENTS WHO ARE EMPLOYED OR -- AND HAVE
5 HAD PATIENTS WHO HAVE BEEN EMPLOYED AT THESE
6 INSTITUTIONS, SO THEY MAY ALREADY NOT HAVE COVERAGE.

7 Q. DO YOU KNOW OF ANY THAT HAVE ALREADY LOST
8 COVERAGE?

9 A. NOT AS A RESULT OF THE NEW RULES, NO.

10 Q. SO ALTHOUGH YOU DO HAVE SOME PATIENTS WHO ARE
11 EMPLOYED AT THESE, AS OF RIGHT NOW YOU DON'T KNOW ANY OF
12 THEM WHO ARE ACTUALLY GOING TO LOSE THEIR COVERAGE
13 BECAUSE OF THE NEW RULES?

14 A. THEY MAY ALREADY HAVE NOT HAD COVERAGE, BUT I DO
15 NOT KNOW OF ANY PATIENTS WHO MAY BE LOSING COVERAGE.

16 Q. RIGHT. AND YOU DO KNOW OF ANY PATIENTS WHOSE
17 SITUATION IS CHANGING FOR THE WORSE BECAUSE OF THE
18 RULES?

19 A. I DO NOT KNOW INDIVIDUALS IN THAT CASE RIGHT
20 NOW, NO.

21 Q. NOW, IN PARAGRAPH 34, YOU STATED THAT: AS A
22 RESULT OF THESE RULES, SOME WOMEN WILL LOSE
23 CONTRACEPTIVE -- SORRY -- SOME WOMEN WILL LOSE INSURANCE
24 COVERAGE FOR PREVENTATIVE CONTRACEPTIVE CARE.

25 DID I READ THAT CORRECTLY?

1 A. YES.

2 Q. BUT AS OF TODAY, YOU CAN'T IDENTIFY ANY ACTUAL
3 WOMEN WHO HAVE LOST COVERAGE BECAUSE OF THE NEW RULES,
4 CORRECT?

5 A. CORRECT.

6 Q. IN PARAGRAPH 35, REFERRING TO THESE WOMEN WHO
7 WOULD LOSE COVERAGE, YOU STATED: AS A RESULT THEIR
8 COSTS FOR CONTRACEPTIVE CARE WILL RISE.

9 DID I READ THAT CORRECTLY?

10 A. YES.

11 Q. BUT STILL WE CAN'T IDENTIFY ANY ACTUAL WOMEN WHO
12 COSTS HAVE RISEN BECAUSE OF THE EXEMPTION?

13 A. NO.

14 Q. AND IN PARAGRAPH 36, YOU STATED THAT: UNDER THE
15 NEW RULES, COSTS WILL AGAIN BECOME A BARRIER TO WOMEN'S
16 ACCESS TO AND USE OF THE CONTRACEPTIVE THAT IS MEDICALLY
17 RECOMMENDED FOR THEM.

18 BUT TODAY YOU CAN'T IDENTIFY ANY ACTUAL
19 WOMEN WHO ARE EXPERIENCING SUCH A BARRIER BECAUSE OF THE
20 NEW RULES, CORRECT?

21 A. CORRECT.

22 Q. AND IN PARAGRAPH 37, REFERRING TO THE SAME
23 WOMEN, YOU STATED THAT THEY WOULD FACE MEDICAL HARM, BUT
24 AS OF TODAY, YOU CAN'T IDENTIFY ANY ACTUAL WOMEN WHO ARE
25 FACING THAT MEDICAL HARM BECAUSE OF THE RULES, CORRECT?

1 A. CORRECT.

2 Q. AND IN PARAGRAPH 38, REFERRING TO THESE SAME
3 WOMEN, YOU STATED THAT THERE WOULD BE A DISRUPTION OF
4 THESE PATIENTS' MEDICAL TREATMENT, BUT AS OF TODAY, WE
5 DON'T KNOW -- YOU DON'T KNOW OF ANY ACTUAL WOMEN WHOSE
6 MEDICAL TREATMENT HAS BEEN DISRUPTED BY THE RULES,
7 CORRECT?

8 A. CORRECT.

9 Q. IN PARAGRAPH 39, YOU STATED THAT: SOME OF THESE
10 WOMEN WILL FACE UNINTENDED PREGNANCIES AND OTHER ADVERSE
11 MEDICAL CONSEQUENCES, BUT AS OF TODAY, YOU DON'T KNOW OF
12 ANY ACTUAL WOMEN WHO ARE FACING UNINTENDED PREGNANCIES
13 OR OTHER ADVERSE MEDICAL CONSEQUENCES BECAUSE OF THE
14 RULES, CORRECT?

15 A. CORRECT.

16 Q. AND IN PARAGRAPH 45, YOU STATED THAT YOU
17 BELIEVED AN INJUNCTION OF THE RULES IS NECESSARY TO
18 PREVENT IMMEDIATE AND IRREPARABLE HARM TO WOMEN IN
19 PENNSYLVANIA AND AROUND THE COUNTRY WHO WILL LOSE
20 ONGOING PREVENTATIVE CARE COVERAGE UNDER THEIR GROUP
21 HEALTH PLANS DUE TO THE RULES, BUT AS OF TODAY, YOU
22 DON'T KNOW OF ANY ACTUAL WOMEN WHO HAVE LOST THEIR
23 ONGOING PREVENTATIVE CARE COVERAGE DUE TO THE RULES,
24 CORRECT?

25 A. IT SAY "PREVENTIVE," NOT "PREVENTATIVE," BUT

1 OTHERWISE, CORRECT.

2 Q. APOLOGIES. THANK YOU.

3 HAVE YOU HEARD FROM -- I'M SORRY. IN
4 YOUR MEDICAL PRACTICE, DO YOU PRACTICE WITH OTHER
5 DOCTORS?

6 A. I DO.

7 Q. HAVE YOU HEARD FROM ANY OF THEM THAT LIKE THEY
8 DON'T -- HAVE YOU LEARNED THROUGH ANY OTHER MEANS ABOUT
9 ANY OTHER PATIENTS IN YOUR PRACTICE WHO MIGHT HAVE THIS
10 PROBLEM?

11 A. I HAVE NOT HAD THOSE CONVERSATIONS WITH MY
12 COLLEAGUES.

13 Q. HAVE YOU LEARNED, FOR EXAMPLE, THROUGH CALLS
14 FROM PHARMACIES OR PHARMACISTS ABOUT ANY PATIENTS WHO
15 ARE HAVING PROBLEMS GETTING THEIR PRESCRIPTIONS BECAUSE
16 OF THE NEW RULES?

17 MS. BOLAND: OBJECTION, CALLS FOR
18 HEARSAY.

19 THE COURT: SUSTAINED.

20 MS. KOPPLIN: IF I MIGHT CONFER WITH MY
21 COLLEAGUES FOR JUST A MOMENT, YOUR HONOR.

22 (PAUSE.)

23 MS. KOPPLIN: THANK YOU FOR YOUR
24 TESTIMONY.

25 YOUR HONOR, NO FURTHER QUESTIONS.

1 THE COURT: ANY REDIRECT?

2 MS. BOLAND: NO REDIRECT, YOUR HONOR.

3 THE COURT: THANK YOU VERY MUCH. YOU ARE
4 EXCUSED.

5 OKAY. WHAT I THINK WHAT WE WILL DO NOW
6 IF YOU ARE READY, YOU ARE UP. TELL US WHAT YOU FOUND.

7 MR. HEALY: PERMISSION TO APPROACH, YOUR
8 HONOR?

9 THE COURT: YES. AND YOU ARE MR. HEALY.

10 MR. HEALY: CHRISTOPHER HEALY.

11 THE COURT: OKAY.

12 MR. HEALY: THANK YOU, YOUR HONOR. I
13 APOLOGIZE AGAIN FOR THE SCRAMBLING BACK AND FORTH.

14 THE COURT: NOT A PROBLEM. I THINK I
15 ASKED YOU TO DO IT. YOU WERE PERFECTLY WITHIN YOUR
16 RIGHTS.

17 MR. HEALY: SO I LOOKED INTO THE AGENCY'S
18 RATIONALE BEHIND THE STATEMENT YOUR HONOR READ FROM THE
19 BENCH THIS MORNING, WHICH I BELIEVE, IF I HAVE IT
20 CORRECT, I PUT ON THE SCREEN HERE.

21 THE COURT: WHAT ARE WE LOOKING AT HERE?

22 MR. HEALY: THIS IS THE STATEMENT I
23 BELIEVE -- IF YOU COULD CONFIRM FOR ME, THE STATEMENT
24 THAT YOU READ FROM THE BENCH THIS MORNING THAT WAS: AS
25 REFLECTED IN LITIGATION PERTAINING TO THE MANDATE --

1 THE COURT: YES.

2 MR. HEALY: -- THEY WISH TO MAKE CHANGES
3 TO THEIR HEALTH PLANS THAT WILL REDUCE THE COST OF
4 INSURANCE COVERAGE FOR THE BENEFICIARIES, ET CETERA.

5 SO THIS STATEMENT READS: AS REFLECTED IN
6 LITIGATION PERTAINING TO THE MANDATE, SOME ENTITIES ARE
7 IN GRANDFATHERED HEALTH PLANS THAT DO NOT COVER
8 CONTRACEPTION. THEY WISH TO MAKE CHANGES TO THEIR
9 HEALTH PLANS THAT WILL REDUCE THE COST OF INSURANCE
10 COVERAGE FOR THEIR BENEFICIARIES OR POLICYHOLDERS BUT
11 WHICH WOULD CAUSE THE PLANS TO LOSE GRANDFATHERED
12 STATUS. THEY ARE REFRAINING FROM MAKING THOSE CHANGES
13 AND THEREFORE ARE CONTINUING TO INCUR AND PASS ON HIGHER
14 INSURANCE COSTS TO PREVENT THE MANDATE FROM APPLYING TO
15 THEIR PLANS IN VIOLATION OF THEIR CONSCIENCES.

16 THE COURT: SO WHEN I ASKED YOU -- I SAID
17 WE HAD GONE THROUGH 58,000 COMMENTS, AND WE HAD PUT IN
18 THE WORD "GRANDFATHER" OR "GRANDFATHERED" AND HAVE FOUND
19 NOTHING THAT WENT DIRECTLY TO THAT FINDING. SO WHAT YOU
20 WERE GOING TO DO WAS FIND ME -- PERHAPS THERE WAS A
21 DIFFERENT WORD THAT WAS USED IN THE COMMENTS.

22 MR. HEALY: SO THOSE 54,000 COMMENTS THAT
23 YOUR HONOR MENTIONED WERE COMMENTS WITH REGARD TO THE
24 2016 REQUEST FOR INFORMATION, WHICH HAD TO DO WITH WAYS
25 THAT THE DEPARTMENT MIGHT AMEND THE ACCOMODATION, NOT

1 THE GRANDFATHERED HEALTH PLANS, SO THAT MAY HAVE BEEN
2 THE REASON.

3 WE'VE ASKED THE AGENCY, AND THE AGENCY
4 POINTED OUT TWO PARTICULAR PREVIOUS COURT CASES THAT THE
5 AGENCY RELIED ON. AS THEY MENTION IN THE RULE -- THEY
6 WROTE -- THEN IT SAYS: AS REFLECTED IN LITIGATION
7 PERTAINING TO THE MANDATE.

8 SO THOSE TWO CASES THAT THE AGENCY --
9 THE COURT: WHICH CASES ARE THOSE?

10 MR. HEALY: THOSE ARE THE DIOCESE OF FORT
11 WAYNE VERSUS SEBELIUS. THAT'S 988 F.SUPP.2D 958. AND
12 ALSO ARCHDIOCESE OF ATLANTA. SO ARCHDIOCESE OF ATLANTA,
13 THIS IS THE COMPLAINT FROM THAT CASE. THAT IS CASE
14 NUMBER 1:12-CV-3489 IN THE NORTHERN DISTRICT OF GEORGIA.
15 I APOLOGIZE THAT I DON'T HAVE A FEDERAL CITATION FOR
16 THAT, BUT THAT IS THE CASE NUMBER.

17 AND THIS IS FROM THE COMPLAINT IN THAT
18 CASE. IT SAYS: BASED ON THE LEGAL OPINION OF COUNSEL,
19 PLAINTIFFS BELIEVE THAT THE ATLANTA PLAN AND SAVANNAH
20 PLAN CURRENTLY MEET THE AFFORDABLE CARE ACT'S DEFINITION
21 OF GRANDFATHERED PLAN. AND LATER ON: PLAINTIFFS WILL
22 LOSE THEIR GRANDFATHERED STATUS IN THE NEAR FUTURE FOR
23 REASONS THAT CANNOT BE AVOIDED --

24 THE COURT: WHICH CASE IS THIS?

25 MR. HEALY: THIS IS THE ARCHDIOCESE OF

1 ATLANTA CASE.

2 THE COURT: WHAT DATE WAS THIS DOCUMENT
3 YOU ARE SHOWING ME?

4 MR. HEALY: THAT WAS FROM 2012.

5 THE COURT: SINCE THE CONTRACEPTIVE
6 MANDATE -- SINCE THE NEW IFR HAS BEEN PUT INTO PLACE,
7 HAVE THESE FOLKS CHANGED THEIR PLAN?

8 MR. HEALY: I'M NOT AWARE WHETHER THESE
9 FOLKS HAVE CHANGED THEIR PLAN.

10 THE SECOND CASE THAT THE AGENCY RELIED ON
11 IS THIS, WHICH IS THE DIOCESE OF FORT WAYNE CASE, WHICH
12 HAS THIS HIGHLIGHTED PORTION HERE ON THE SCREEN. MAYBE
13 I CAN ZOOM OUT SO EVERYONE CAN SEE IT. THIS WAS ONE OF
14 THE PREVIOUS CHALLENGES TO THE CONTRACEPTIVE COVERAGE
15 MANDATE. IT SAYS THAT -- THIS IS FROM THE COURT'S
16 OPINION IN THAT CASE FROM THE NORTHERN DISTRICT OF
17 INDIANA.

18 THE COURT: WHAT IS THE CITE?

19 MR. HEALY: THAT WAS THE ONE I READ
20 BEFORE FROM 2013. AND THAT SAYS: CURRENTLY THE
21 DIOCESAN HEALTH PLAN ALSO MEETS THE ACA'S DEFINITION OF
22 A GRANDFATHERED PLAN AND INCLUDES A STATEMENT IN PLAN
23 MATERIALS PROVIDED TO PARTICIPANTS OR BENEFICIARIES THAT
24 IT BELIEVES IS A GRANDFATHERED PLAN AS IT IS REQUIRED TO
25 MAINTAIN ITS GRANDFATHERED STATUS. BUT IN ORDER TO

1 MAINTAIN ITS GRANDFATHERED STATUS, THE DIOCESE FORGOES
2 APPROXIMATELY \$180,000 A YEAR IN INCREASED PREMIUMS SO
3 THAT IT CAN PROTECT CATHOLIC CHARITIES FROM THE
4 CONTRACEPTIVE MANDATE.

5 ABSENT MAINTAINING ITS GRANDFATHERED
6 STATUS AT A GREAT EXPENSE, THE ONLY OTHER OPTIONS WOULD
7 BE EITHER, ONE, SPONSOR A PLAN THAT WOULD PROVIDE THE
8 EMPLOYEES OF CATHOLIC CHARITIES WITH ACCESS TO FREE
9 CONTRACEPTION, ABORTION, INDUSTRY PRODUCTS,
10 STERILIZATION, AND RELATED COUNSELING; OR TWO, NO LONGER
11 EXTEND ITS PLAN TO CATHOLIC CHARITIES, SUBJECTING IT TO
12 MASSIVE FINES IF IT DOES NOT CONTRACT WITH ANOTHER
13 INSURANCE PROVIDER THAT WILL PROVIDE THE OBJECTIONABLE
14 COVERAGE.

15 THE COURT: DO WE KNOW WHETHER THE
16 PLAINTIFF IN THIS CASE HAS -- SUBSEQUENT TO THE
17 ENACTMENT OF THE NEW -- RATHER THE ISSUANCE OF THE NEW
18 IFRS HAS CHANGED THEIR PLAN?

19 MR. HEALY: I DO NOT KNOW THAT THEY HAVE.

20 THE COURT: SO APART FROM THESE TWO
21 CASES, THAT IS -- THAT IS WHAT YOU GOT?

22 MR. HEALY: THERE MAY BE OTHER COMMENTS.
23 WE HAD LOOKED THROUGH AS MANY OF THEM AS WE COULD IN THE
24 TIME WE HAD. HOWEVER, WE HAVE IDENTIFIED NO PARTICULAR
25 COMMENTS. THAT SAID, ALTHOUGH THESE TWO CASES WERE NOT

1 IN THE ADMINISTRATIVE RECORD, IT'S NOT GENERALLY THE
2 PRACTICE TO INCLUDE PRIOR COURT CASES IN ADMINISTRATIVE
3 RECORDS. HOWEVER -- BASICALLY BECAUSE OF THE FACT THAT
4 THEY ARE ALREADY JUDICIALLY NOTICEABLE. HOWEVER, THEY
5 WERE CITED IN THE RULES AND IT WAS SOMETHING THAT THE
6 AGENCY RELIED ON.

7 THE COURT: SO TO THE EXTENT THAT THIS
8 ISSUE, THE GRANDFATHER HEALTH PLANS WANTING TO MAKE
9 CHANGES AND NOT LOSE THEIR GRANDFATHER STATUS, TO THE
10 EXTENT THAT THAT WAS A UNDERLYING RATIONALE FOR THE NEW
11 IFRS, WE HAVE TWO PLANS RIGHT NOW? TWO COURT CASES THAT
12 YOU HAVE BEEN UNABLE TO IDENTIFY, WHICH WARRANTED THE
13 CONCLUSION THAT THERE WAS GOOD LAW?

14 MR. HEALY: YES, THAT IS CORRECT, YOUR
15 HONOR, AND WE ARE HAPPY TO CONTINUE LOOKING THROUGH
16 OTHER COMMENTS THAT HAVE COME SINCE THEN. WE HAD AN
17 OPEN COMMENT PERIOD THAT ENDED ON DECEMBER 5TH.
18 HOWEVER, AT THIS TIME WE HAVE NOT BEEN ABLE TO IDENTIFY
19 FURTHER COMMENTS.

20 THE COURT: WELL, I THINK THAT THE ISSUE
21 IS WHAT COMMENTS HAD COME IN AT THE TIME THE NEW IFRS
22 WERE ISSUED, BECAUSE THAT WAS THE REASON THAT THE
23 AGENCIES WERE SAYING THEY HAD GOOD CAUSE WAS BECAUSE OF
24 THOSE. SO TO THE EXTENT THAT THINGS HAVE HAPPENED
25 SUBSEQUENTLY, I DON'T THINK IT'S RELEVANT TO MY

1 ANALYSIS.

2 MR. HEALY: THAT MAKES SENSE. THAT'S
3 CORRECT, YOUR HONOR.

4 THE COURT: OKAY. LET'S TAKE A BRIEF
5 BREAK AND THEN -- DID YOU WANT HALF AN HOUR TO CLOSE OR
6 15 MINUTES TO CLOSE?

7 MR. FISCHER: YOUR HONOR, HALF AN HOUR,
8 ALTHOUGH I WILL TRY NOT TO TAKE ALL OF IT.

9 MR. DAVIS: I THINK HALF AN HOUR IS FINE.
10 I WILL ALSO TRY NOT TO TAKE ALL OF IT.

11 THE COURT: OKAY. WE'RE DOING VERY WELL.
12 IT'S ONLY QUARTER TO 3. I HAD GIVEN YOU UNTIL 6 SO WE
13 CAN PROBABLY GET OUT EARLIER THAN WE ANTICIPATED.

14 THE CLERK: ALL RISE.

15 (BREAK TAKEN.)

16 THE COURT: WHO'S DOING CLOSINGS FOR THE
17 COMMONWEALTH?

18 MR. FISCHER: YOUR HONOR, I'M GOING TO DO
19 CLOSING FOR THE COMMONWEALTH.

20 THE COURT: OKAY.

21 MR. FISCHER: GOOD AFTERNOON, YOUR HONOR.

22 THE COURT: GOOD AFTERNOON.

23 MR. FISCHER: I THINK IT IS IMPORTANT TO
24 START BY REMEMBERING EXACTLY WHAT WE ARE CHALLENGING AND
25 WHAT WE ARE NOT CHALLENGING IN THESE PROCEEDINGS.

1 MR. DAVIS SAID IN THE BEGINNING THAT
2 THESE RULES WERE NOT ISSUED ON A BLANK SLATE, AND THAT
3 IS ABSOLUTELY CORRECT. A LOT HAS HAPPENED IN THIS AREA
4 BEFORE WE GET TO THIS POINT.

5 WE ARE NOT CHALLENGING THE ORIGINAL
6 EXEMPTION FOR CHURCHES AND CLOSELY-RELATED INSTITUTIONS.
7 WE ARE NOT CHALLENGING THE ACCOMMODATION PROCESS THAT
8 WAS ORIGINALLY CREATED AND THEN EXPANDED AS A RESULT OF
9 THE SUPREME COURT'S HOBBY LOBBY DECISION.

10 WHAT WE ARE CHALLENGING ARE TWO RULES
11 THAT ARE SWEEPING IN THEIR SCOPE. THERE ARE A LOT OF
12 CONCERNS WE HAD ABOUT THESE RULES, BUT THERE ARE THREE
13 ASPECTS IN PARTICULAR THAT I WANT TO FOCUS ON.

14 THE FIRST IS THAT FOR THE FIRST TIME, THE
15 RELIGIOUS EXEMPTION RULE ALLOWS PUBLICLY-TRADED
16 COMPANIES TO OPT OUT OF THE CONTRACEPTIVE MANDATE. THAT
17 WAS NEVER THE CASE BEFORE. THERE IS A LIMITED
18 JUSTIFICATION FOR THAT DECISION IN THE RULES, AND IT
19 POTENTIALLY THREATENS CONTRACEPTIVE COVERAGE FOR A
20 SIGNIFICANT NUMBER OF WOMEN.

21 THE SECOND FACTOR THAT I'D LIKE TO
22 MENTION IS THAT AS A RESULT OF THESE TWO RULES, THE
23 ACCOMMODATION PROCESS IS NOW OPTIONAL.

24 THE COURT: IS NOW WHAT?

25 MR. FISCHER: OPTIONAL. THERE IS NO

1 REQUIREMENT THAT COMPANIES THAT WISH TO OPT OUT NOTIFY
2 THEIR INSURANCE COMPANY OR THEIR THIRD-PARTY
3 ADMINISTRATOR OF THEIR DECISION SO THAT THEIR EMPLOYEES
4 CAN GET COVERAGE. SO AS A RESULT OF THAT, WOMEN
5 EMPLOYED BY THE COMPANIES THAT ARE CURRENTLY USING THAT
6 PROCESS FACE A LOSS OF COVERAGE.

7 AND THEN FINALLY, THE THIRD ISSUE I WOULD
8 LIKE TO TOUCH ON, WHICH YOUR HONOR DISCUSSED EARLIER, IS
9 THE MORAL EXEMPTION. THE MORAL EXEMPTION IS INCREDIBLY
10 VAGUE, DOES NOT DEFINE EXACTLY WHAT'S MEANT BY A
11 SINCERELY-HELD MORAL BELIEF, AND AS I THINK YOUR HONOR'S
12 QUESTIONING REFLECTED, OPENS UP ALL SORTS OF POTENTIAL
13 PROBLEMS OF HOW DO FEDERAL AGENCIES DETERMINE WHETHER A
14 BELIEF IS SINCERELY HELD, WHAT THE NATURE OF THE BELIEF
15 IS, WHAT BELIEFS DO QUALIFY TO ALLOW SOMEBODY TO OPT
16 OUT, WHAT BELIEFS MAY NOT QUALIFY. SO I THINK THAT RULE
17 BY ITSELF IS SIGNIFICANTLY PROBLEMATIC.

18 WHAT WE ARE SEEKING AS A RESULT OF THIS
19 IS AN INJUNCTION THAT WOULD ESSENTIALLY TAKE US BACK TO
20 THE STATUS QUO BEFORE THESE RULES WERE ISSUED, BACK TO
21 OCTOBER 5TH OF THIS YEAR.

22 IT IS OUR HOPE THAT AS A RESULT, AT THE
23 VERY LEAST, THE AGENCIES WILL FOLLOW THE CORRECT PROCESS
24 IF THEY TRY TO DO THIS AGAIN, BECAUSE WHAT WE HAVE HERE
25 IS A FLAWED PROCESS THAT PRODUCED A FLAWED RESULT.

1 WE THINK IT IS CLEAR THAT THE AGENCY HAS
2 VIOLATED THE PROCEDURAL REQUIREMENTS OF THE APA AND CAME
3 UP WITH A RESULT THAT VIOLATES THE SUBSTANTIVE
4 REQUIREMENTS OF THE APA, IS ARBITRARY AND CAPRICIOUS,
5 VIOLATES THE AFFORDABLE CARE ACT, AND HAS OTHER
6 SIGNIFICANT PROBLEMS.

7 THE COURT: LET ME FOLLOW UP WITH YOU ON
8 THAT ONE.

9 WHEN YOUR COLLEAGUE OPENED, I ASKED HIM
10 WHETHER -- THERE CLEARLY IS A DISTINCTION BETWEEN THE
11 CLAIMS THAT ARE BROUGHT UNDER THE APA AND THE CLAIMS
12 THAT ARE THE CONSTITUTIONAL CLAIMS.

13 THE FISCHER: YES, THAT'S CORRECT.

14 THE COURT: AND AS YOU KNOW, WHEN A COURT
15 CAN REACH A STATUTORY CLAIM RATHER THAN A CONSTITUTIONAL
16 CLAIM, THE ADMONITION AT ALL LEVELS ALL OF THE WAY UP TO
17 THE SUPREME COURT AND THE THIRD CIRCUIT IS THAT THE
18 COURT SHOULD NOT REACH THE CONSTITUTIONAL ISSUES BUT
19 SHOULD PROCEED WITH THE PROCEDURAL ISSUES.

20 SO IF I WERE TO PROCEED WITH THE
21 PROCEDURAL ISSUES ALONE, AND ASSUMING THAT I WOULD DO IT
22 UNDER BOTH THE PROCEDURAL COMPONENT, THE NOTICE OF
23 COMMENT, AND THE SUBSTANTIVE COMPONENT, THE LACK OF GOOD
24 CAUSE, WHAT KIND OF INJUNCTION WOULD THE COMMONWEALTH BE
25 LOOKING FOR?

1 IN THOSE CIRCUMSTANCES, I THINK YOUR
2 COLLEAGUE SAID IF IT WAS ONLY THE PROCEDURAL, THEY WOULD
3 JUST GO BACK AND GO THROUGH THE PROCEDURE AND STILL HAVE
4 THE SAME RULES.

5 SO WHAT INJUNCTION WOULD YOU BE ASKING
6 FOR IN THOSE LIMITED CIRCUMSTANCES?

7 MR. FISCHER: WE WOULD BE SEEKING AN
8 INJUNCTION PREVENTING THEM FROM ENFORCING THESE RULES,
9 AND OUR HOPE IS THAT, PARTICULARLY IF THERE IS A
10 SUBSTANTIVE COMPONENT TO YOUR HONOR'S RULING, IT WOULD
11 BE TAKEN BY THE AGENCIES -- AGENCIES AS AN INDICATION
12 THAT THE NEXT RULE THEY COME OUT WITH BETTER EITHER HAVE
13 MORE SUBSTANTIVE SUPPORT BEHIND IT OR ADDRESS THESE
14 ISSUES DIFFERENTLY, PARTICULARLY THE THREE THAT I
15 MENTIONED.

16 THE COURT: SO HOW DOES THAT ISSUE -- HOW
17 IS THAT ISSUE LINED UP IN AN ORDER? BECAUSE YOU ARE
18 NOT, YOU HAVE NOT ASKED FOR A MANDATORY INJUNCTION, YOU
19 HAVE NOT ASKED ME TO TELL THEM TO DO RULES IN A
20 PARTICULAR WAY, SO HOW WOULD AN ORDER LOOK THAT DEALS
21 WITH THE GOOD CAUSE COMPONENT IF I WERE TO RULE IN THAT
22 WAY.

23 MR. FISCHER: AN ORDER COULD SIMPLY
24 PRECLUDE THEM FROM ENFORCING THESE TWO SPECIFIC RULES,
25 WHICH WOULD THEN REQUIRE THEM TO, AT THE VERY LEAST, GO

1 THROUGH THE PROCESS AGAIN, AND DEPENDING ON WHAT COMES
2 OUT OF THAT PROCESS, WE MAY BE BACK HERE AGAIN. OUR
3 HOPE WOULD BE THAT THEY WOULD COME UP WITH A DIFFERENT
4 RESULT.

5 BUT I DON'T BELIEVE THERE IS ANYTHING
6 THIS COURT CAN DO TO ENJOIN THE NEXT RULE. AND, YOU
7 KNOW, MAYBE WE ARE BACK HERE. I HOPE THAT IS NOT THE
8 CASE. HOPEFULLY THEY WILL GET THE MESSAGE AND MAKE SOME
9 CHANGES TO THE RULES THAT ADDRESS THE REAL ISSUES.

10 BUT I THINK THAT THE INJUNCTION WE HAVE
11 REQUESTED IS OF THESE TWO RULES AS THEY ARE CURRENTLY
12 MADE.

13 THE COURT: OKAY.

14 MR. FISCHER: SO LET ME TALK A LITTLE
15 MORE ABOUT THE PROCEDURAL VIOLATION OF THE APA. THE
16 GOVERNMENT HAS ARGUED THAT THEY HAVE STATUTORY AUTHORITY
17 TO WAIVE NOTICE AND COMMENT. WE ADDRESS THIS IN OUR
18 BRIEFS. THE APA IS VERY CLEAR ABOUT THIS. SECTION 559
19 SAYS: SUBSEQUENT STATUTE MAY NOT HOLD -- MAY NOT BE
20 HELD TO SUPERSEDE OR MODIFY THIS SUBCHAPTER, AND SEVERAL
21 OTHERS, EXCEPT TO THE EXTENT IT DOES SO EXPRESSLY.

22 AND THE D.C. DISTRICT COURT IN COALITION
23 FOR PARITY VERSUS SEBELIUS LOOKED AT THE VERY SAME
24 AUTHORITY THAT THE AGENCIES ARE RELYING ON HERE,
25 ANALYZED IT UNDER SECTION 549 OF THE APA, AND SAID IT

1 CLEARLY DOES NOT EXPRESSLY MODIFY THE REQUIREMENTS OF
2 THE APA.

3 THE SECOND -- THE LANGUAGE THEY ARE
4 RELYING ON IS SIMPLY A GENERAL GRANT THAT SAYS: THE
5 SECRETARY MAY PROMULGATE ANY INTERIM FINAL RULES AS THE
6 SECRETARY DETERMINES ARE APPROPRIATE TO CARRY OUT THIS
7 PART.

8 NOTHING ABOUT WAIVING NOTICE AND COMMENT,
9 NOTHING ABOUT PREEMPTING THE APA. GIVEN THE CLEAR
10 REQUIREMENT IN THE APA THAT MODIFICATIONS HAVE TO BE
11 DONE EXPRESSLY, WE THINK IT'S CLEAR THAT THAT DOES NOT
12 GIVE THEM THE AUTHORITY THEY CLAIM IT DOES.

13 WE ALSO THINK IT IS FAIRLY CLEAR THEY
14 DON'T HAVE GOOD CAUSE. THE GOOD CAUSE ARGUMENT, AS I
15 UNDERSTAND, IS ESSENTIALLY, WELL, THERE IS A LOT OF
16 LITIGATION GOING ON. WE WANT TO WRAP IT UP, SO WE WANT
17 THESE RULES TO BE EFFECTIVE IMMEDIATELY.

18 NOW, IT IS INTERESTING, THEY HAVE ARGUED
19 THAT MANY OF THE PLAINTIFFS IN THOSE CASES ARE PROTECTED
20 BY INJUNCTIONS, WHICH IS TRUE. SO IF THE ARGUMENT IS --
21 THE ARGUMENT IS WE NEED TO PROTECT THESE PEOPLE
22 IMMEDIATELY, WELL, BY THEIR OWN ADMISSION, MANY OF THEM
23 ALREADY DO HAVE PROTECTION.

24 WE TALKED EXTENSIVELY IN OUR BRIEF ABOUT
25 THE THIRD CIRCUIT'S DECISION IN UNITED STATES VERSUS

1 REYNOLDS BECAUSE IT SQUARELY REJECTS THE ARGUMENT THAT
2 RESOLVING UNCERTAINTY IS AN ADEQUATE JUSTIFICATION FOR
3 ISSUING IFRS. THE THIRD CIRCUIT THERE SAID VERY CLEARLY
4 THAT THERE IS ALWAYS UNCERTAINTY IN THE RULEMAKING
5 PROCESS, AND PARTICULARLY IF AN IFR IS ISSUED AS THIS
6 ONE WAS, WITH A REQUEST FOR SUBSTANTIVE COMMENTS AND THE
7 STATEMENT FROM THE AGENCY THAT THEY MAY BE MAKING
8 FURTHER CHANGES TO THE RULE. THERE IS SIMPLY NO
9 CERTAINTY THAT IS ACHIEVED AS A RESULT OF THAT.

10 AND FINALLY, I THINK THERE IS AN ARGUMENT
11 THAT THEY MADE A FEW TIMES, WHICH IS THAT, WELL, IFR'S
12 WERE ISSUED EARLIER IN APPLYING THE AFFORDABLE CARE ACT
13 WOMEN'S HEALTH AMENDMENT, SO IT IS OKAY THIS TIME.

14 BUT I THINK IF THE COURT LOOKS BACK TO
15 PRIESTS FOR LIFE, WHICH ADDRESSED THE PRIOR IFR THAT
16 THEY ARE TALKING ABOUT, THE SPECIFIC IFR THAT THEY CITED
17 TO YOU, WHICH IS AVAILABLE AT 79 FEDERAL REGISTER 51092,
18 WAS ISSUED FOLLOWING THE WHEATON COLLEGE DECISION, WHICH
19 CAME RIGHT AFTER HOBBY LOBBY.

20 ON THE SAME DAY, THE AGENCIES ISSUED A
21 NOTICE OF PROPOSED RULEMAKING CALLED THE HOBBY LOBBY --
22 AND AN IFR THAT WAS BASED ON WHEATON COLLEGE. HERE IS
23 WHAT THE WHEATON COLLEGE IFR SAID: THESE INTERIM FINAL
24 REGULATIONS PROVIDED AN ALTERNATIVE PROCESS THAT AN
25 ELIGIBLE ORGANIZATION MAY USE TO PROVIDE NOTICE OF ITS

1 RELIGIOUS OBJECTIONS TO PROVIDING CONTRACEPTIVE COVERAGE
2 WHILE PRESERVING PARTICIPANTS' AND BENEFICIARIES' ACCESS
3 TO COVERAGE OF THE FULL RANGE OF FDA-APPROVED
4 CONTRACEPTIVES.

5 ALL THAT DID IS IT SAID, UNDER THE
6 ACCOMMODATION BEFORE, YOU HAD TO PROVIDE NOTICE TO YOUR
7 INSURANCE COMPANY OR YOUR THIRD-PARTY ADMINISTRATOR.
8 THE COURT IN WHEATON COLLEGE ESSENTIALLY SAID, YOU WILL
9 HAVE TO ALSO LET THEM PROVIDE NOTICE TO HHS, AND THEN
10 YOU DO THE LEGWORK AND CONTACT THE THIRD-PARTY
11 ADMINISTRATOR OR INSURANCE COMPANY.

12 SO ALL THIS REGULATION DID IS IT
13 ESSENTIALLY IMPLEMENTED WHAT THE COURT DIRECTED. IT
14 SAID, WE ARE GOING TO CREATE ANOTHER PROCESS WHERE YOU
15 CAN SEND THE FORM TO US. THAT IS A FAR CRY FROM THE
16 SWEEPING CHANGES THAT ARE AT ISSUE IN THIS CASE.

17 YOUR HONOR, I WOULD LIKE TO GET INTO THE
18 SUBSTANTIVE APA DISCUSSION A LITTLE BIT BECAUSE I THINK
19 THAT IS IN MANY WAYS THE MOST IMPORTANT -- YOU KNOW, ONE
20 OF THE MOST IMPORTANT ISSUES IN THIS CASE.

21 YOUR HONOR HAD ASKED ABOUT CHEVRON
22 DEFERENCE AND WHETHER THAT APPLIED HERE. CHEVRON DOES
23 NOT APPLY EITHER TO THEIR INTERPRETATION OF THE
24 AFFORDABLE CARE ACT OR TO THEIR INTERPRETATION OF RFRA.

25 WITH RESPECT TO RFRA, I THINK COUNSEL

1 CONCEDED EARLIER THAT -- THAT THEY DO NOT GET CHEVRON
2 DEFERENCE UNDER RFRA, AND CERTAINLY IN THE HOBBY LOBBY
3 DECISION, THERE WAS NOT EVEN A MENTION OF CHEVRON OR
4 WHETHER THE GOVERNMENT'S INTERPRETATION OF RFRA WAS
5 ENTITLED TO --

6 THE COURT: SO STEP ZERO ON RFRA.

7 MR. FISCHER: YES, IT'S A ZERO ON RFRA.
8 AND ACTUALLY, I BELIEVE IT'S STEP ZERO ON THE ACA TOO.

9 AND I WOULD REFER TO --

10 THE COURT: SO -- WELL, WHY IT WOULD BE
11 STEP 1 BUT YOU WOULD BE ARGUING THAT THEY HAVE TAKEN
12 ULTRA VIRES ACTIONS UNDER STEP 1?

13 MR. FISCHER: I BELIEVE IT COULD BE
14 FRANKLY ANY OF THE STEPS, I THINK. BUT I JUST WANT TO
15 START AT STEP ZERO AND SAY THE SUPREME COURT DECISION IN
16 KING VERSUS BURWELL I THINK IS A GOOD EXAMPLE. THAT WAS
17 THE CASE INVOLVING THE LANGUAGE IN THE ACA ABOUT TAX
18 CREDITS BEING AVAILABLE TO PEOPLE WHO PURCHASED HEALTH
19 COVERAGE ON AN EXCHANGE RUN BY THE STATE. AND THE
20 QUESTION WAS WHETHER THAT APPLIED TO THE HEALTHCARE.GOV
21 OR BY THE FEDERAL GOVERNMENT.

22 CHIEF JUSTICE ROBERTS REJECTED THE
23 ARGUMENT THAT CHEVRON DEFERENCE APPLIED, AND HIS
24 REASONING WAS -- WAS THIS: THE TAX CREDITS ARE AMONG
25 THE ACT'S KEY REFORMS INVOLVING BILLIONS OF DOLLARS IN

1 SPENDING EACH YEAR AND AFFECTING THE PRICE OF HEALTH
2 INSURANCE FOR MILLIONS OF PEOPLE. WHETHER THOSE CREDITS
3 ARE AVAILABLE UNDER FEDERAL EXCHANGES IS THUS A QUESTION
4 OF DEEP ECONOMIC AND POLITICAL SIGNIFICANCE THAT IS
5 CENTRAL TO THE STATUTORY SCHEME. HAD CONGRESS WISHED TO
6 ASSIGN THAT QUESTION TO AN AGENCY, IT SURELY WOULD HAVE
7 DONE SO EXPRESSLY. IT IS ESPECIALLY UNLIKELY THAT
8 CONGRESS WOULD HAVE DELEGATED THIS DECISION TO THE IRS,
9 WHICH HAS NO EXPERTISE IN CRAFTING HEALTH INSURANCE
10 POLICY OF THIS SORT.

11 NOW HERE, THE STATUTE HAS A CLEAR
12 DELEGATION OF AUTHORITY TO IDENTIFY APPROPRIATE
13 PREVENTIVE SERVICES. THAT IS TO THE HEALTH RESOURCES
14 AND SERVICE ADMINISTRATION. HRSA HAS SIGNIFICANT
15 EXPERTISE ON PREVENTIVE MEDICINE, ON INCREASING ACCESS
16 TO HEALTHCARE, ON PROMOTING HEALTHCARE FOR UNDERSERVED
17 COMMUNITIES. THERE IS NO EXPERTISE THERE IN DEFINING
18 EXEMPTIONS FOR EXISTING MANDATORY REQUIREMENTS.

19 IN FACT, THAT ACTUALLY RUNS COUNTER TO
20 THEIR MISSION. THEIR MISSION IS TO INCREASE ACCESS TO
21 HEALTHCARE. SO IT STRAINS CREDULITY TO SAY THAT
22 CONGRESS WOULD HAVE DELEGATED TO HRSA THE RESPONSIBILITY
23 TO INTERPRET THIS PROVISION IN A WAY THAT ALLOWED FOR
24 SIGNIFICANT EXEMPTIONS.

25 REGARDLESS, IF WE DO GET INTO THE CHEVRON

1 FRAMEWORK, THE GOVERNMENT NEEDS TO IDENTIFY THE LANGUAGE
2 IN THE ACA THAT THEY ARE INTERPRETING AND WHAT THEIR
3 INTERPRETATION IS SO THE COURT CAN ASSESS WHETHER THEIR
4 INTERPRETATION IS PRECLUDED BY THE LANGUAGE, AND IF NOT,
5 WHETHER IT'S REASONABLE.

6 AS I READ THE GOVERNMENT'S ARGUMENTS,
7 THEY REFER TO THE SECTION WHICH WE REFER TO. IT SAYS:
8 A GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER OFFERING
9 GROUP OR INDIVIDUAL HEALTH INSURANCE COVERAGE SHALL, AT
10 A MINIMUM, PROVIDE COVERAGE FOR AND SHALL NOT IMPOSE ANY
11 CAUTIONARY REQUIREMENTS FOR -- AND THEN SUBSECTION 4 IS:
12 WITH RESPECT TO WOMEN, SUCH ADDITIONAL PREVENTIVE CARE
13 AND SCREENINGS NOT DESCRIBED IN PARAGRAPH 1 AS PROVIDED
14 FOR IN COMPREHENSIVE GUIDELINES SUPPORTED BY THE HRSA.

15 THE ONLY ARGUMENT I HAVE HEARD FROM THE
16 GOVERNMENT AS TO HOW THEY ARE INTERPRETING THAT UNDER
17 CHEVRON IS THAT SOMEHOW THE USE OF THE WORD "AS" BEFORE
18 "PROVIDED FOR" IMPLIES THAT HRSA -- AND THEIR QUOTE IS:
19 MAY DETERMINE NOT ONLY THE SERVICES COVERED BUT THE
20 MANNER OR REACH OF THAT COVERAGE.

21 AND THEN THEY GO ON TO SAY: THE AGENCIES
22 READ THE STATUTE TO AUTHORIZE THEM TO CRAFT OR MODIFY
23 EXEMPTIONS FOR ANY CONTRACEPTIVE COVERAGE MANDATE AND
24 THAT REASONABLE CONSTRUCTION MUST PREVAIL. AND THAT
25 PUTS A LOT OF -- THE WORD "AS" IS DOING A LOT OF WORK

1 THERE. THAT IS THE INTERPRETATION THEY COME UP WITH.

2 HRSA HAS NO EXPERTISE IN THIS AREA AND

3 THERE IS SIMPLY NO WAY THAT I CAN SEE THAT THAT LANGUAGE

4 CAN REASONABLY BE READ TO SAY HRSA OR THE AGENCIES UNDER

5 WHICH HRSA IS WORKING CAN CREATE THESE SIGNIFICANT

6 CARVE-OUTS.

7 THE COURT: SORRY, GO ON.

8 MR. FISCHER: NO.

9 THE COURT: SO I ASKED THE GOVERNMENT --

10 THE DEFENSE -- YOU ARE BOTH THE GOVERNMENT -- WHETHER --

11 JUST TO TALK ME THROUGH THIS NOTION THAT THERE IS THE --

12 THE ACA SAYS TO HRSA: PROVIDES SOME GUIDELINES. THE

13 GUIDELINES THAT ARE CREATED ON THE CONTRACEPTIVE

14 MANDATE. AND THEN THE RULES, THE NEW IFR'S, ARE CREATED

15 AS AN EXCEPTION TO THE GUIDELINES, SO IT'S AN AGENCY

16 MODIFYING A GUIDELINE OR A RULE OF AN AGENCY.

17 AND I THINK THE RESPONSE OF THE

18 DEFENDANTS WAS PERFECTLY FINE, IT HAPPENS ALL THE TIME.

19 SO CAN YOU RESPOND TO THAT PARTICULAR POINT AND TELL

20 ME -- IT SEEMS A LITTLE ODD, AND TELL ME WHETHER IT'S

21 JUST ODD OR WHETHER THERE IS SOMETHING PROBLEMATIC ABOUT

22 IT.

23 MR. FISCHER: WE BELIEVE IT'S SERIOUSLY

24 PROBLEMATIC. THE AGENCY CANNOT MODIFY GUIDELINES IN A

25 WAY THAT CONFLICTS WITH THE STATUTORY DIRECTION THAT

1 CREATED THOSE GUIDELINES, AND THE DELEGATION WAS TO HRSA
2 AND IT WAS TO HRSA FOR A REASON, BECAUSE THEY HAVE
3 EXPERTISE IN IDENTIFYING PREVENTIVE MEDICINE.

4 THERE HAS BEEN A LOT OF DISCUSSION ABOUT
5 HOW CONTRACEPTIVE COVERAGE IS NOT SPECIFICALLY MENTIONED
6 IN THE ACA. WELL, I DON'T THINK WE WANT CONGRESS TO
7 IDENTIFY THE SPECIFIC PREVENTIVE CARE THAT INSURANCE
8 COMPANIES MUST PROVIDE. CONGRESS, I BELIEVE, MADE A
9 WISE DECISION THAT THAT DECISION WAS GOING TO BE
10 DELEGATED TO HRSA, WHICH HAS EXPERTISE AND THEN COULD
11 MODIFY THE SERVICES THAT IT RECOMMENDED ON AN AS-NEEDED
12 BASIS, AS MEDICINE CHANGED, AS SCIENTIFIC ADVANCES MOVED
13 US FORWARD.

14 SO THE IDEA THAT AN AGENCY CAN SIMPLY
15 TAKE A GRANT OF AUTHORITY THAT IS FAIRLY CLEARLY LIMITED
16 TOWARD IDENTIFYING THE SERVICES THAT HAVE TO BE PROVIDED
17 AND BLOW THAT UP INTO, WELL, WE CAN CREATE ENTIRE
18 EXEMPTIONS, BROAD EXEMPTIONS FROM THIS RULE THAT SAYS --
19 AND I REFER BACK TO THE PREFATORY LANGUAGE IN 42 U.S.C.
20 30GG-13, WHICH SAYS PROVIDERS OF HEALTH COVERAGE SHALL,
21 AT A MINIMUM, PROVIDE COVERAGE AND SHALL NOT IMPOSE ANY
22 COST SHARING REQUIREMENTS FOR. THAT LANGUAGE IS ABOUT
23 AS MANDATORY AS YOU CAN GET.

24 AND THEN IT LISTS THE FOUR THINGS. AT
25 THE VERY BOTTOM IS THE WOMEN'S HEALTH AMENDMENT. THE

1 GOVERNMENT SOMEHOW READS THE LANGUAGE IN THE WOMEN'S
2 HEALTH AMENDMENT TO APPLY BACK TO THE MANDATORY LANGUAGE
3 IN THE BEGINNING AND ALLOW HRSA, WHICH AGAIN, HAS NO
4 EXPERTISE HERE, TO CREATE BROAD EXEMPTIONS FROM IT.

5 WE THINK THAT SIMPLY CAN'T BE SQUARED
6 WITH LANGUAGE OF THE STATUTE, AND IN ADDITION, FLIES
7 DIRECTLY IN THE FACE OF THE PURPOSE OF THE WOMEN'S
8 HEALTH AMENDMENT, WHICH WAS INTENDED TO IMPROVE WOMEN'S
9 ACCESS TO PREVENTIVE CARE.

10 THE GOVERNMENT ALSO RELIES A LOT ON THE
11 EXISTENCE OF GRANDFATHER PLANS. I THINK YOUR HONOR
12 DISCUSSED THAT. THERE IS VERY LITTLE EVIDENCE IN THE
13 RECORD THAT GRANDFATHERED PLANS ARE CLAMORING FOR THE
14 ABILITY TO CHANGE, AND THIS -- THE CONTRACEPTIVE MANDATE
15 IS SOMEHOW BLOCKING THEM.

16 BUT ALSO, AS YOU HEARD FROM DR. CHUANG,
17 THE NUMBER OF GRANDFATHER PLANS CONTINUES TO DECLINE.
18 IT WAS LIMITED TO BEGIN WITH. AND THE FACT THAT
19 CONGRESS MADE WHAT APPARENTLY WAS A NECESSARY COMPROMISE
20 TO GET THE ACA PASSED DOES NOT UNDERMINE THE ARGUMENT
21 THAT THE CONTRACEPTIVE COVERAGE HERE SERVES A COMPELLING
22 AND IMPORTANT GOVERNMENT INTEREST.

23 I ALSO THINK IT IS IMPORTANT TO REMEMBER
24 THAT THE ACA DOES NOT HAVE A CONSCIENCE CLAUSE. ONE WAS
25 PROPOSED AND IT WAS REJECTED. THROUGHOUT THE RULES, THE

1 ARGUMENT THE GOVERNMENT MAKES IS, WELL, OTHER STATUTES
2 HAVE THEM SO WE CAN RELY ON THAT HERE. THAT IS SIMPLY
3 NOT THE CASE. YOU CAN'T TAKE LANGUAGE FROM ANOTHER
4 STATUTE AND APPLY IT WHERE IT DOES NOT EXIST.

5 AND WHAT'S MORE IS THE FACT THAT CONGRESS
6 REJECTED IT IS A PRETTY GOOD INDICATION THAT CONGRESS
7 DOES NOT BELIEVE THERE IS AN IMPLICIT CONSCIENCE CLAUSE
8 THAT IS ALREADY THERE.

9 NOW, IN THEIR BRIEFING, AND THE
10 GOVERNMENT TO SOME EXTENT THE RULES SAID ALL OF THIS IS
11 REQUIRED UNDER RFRA, THAT WE'RE ALL THIS -- EXCEPT FOR
12 THE MORAL EXCEPTION, WHICH IS NOT A LAW REQUIRED UNDER
13 RFRA.

14 AGAIN, THAT IS A MUCH BROADER READING OF
15 RFRA THAN ANY COURT HAS EVER ADOPTED. AT THE VERY
16 LEAST, I'M NOT AWARE OF ANY DECISION HOLDING THAT RFRA
17 APPLIES TO PUBLICLY-TRADED COMPANIES. I THINK IN SOME
18 WAYS THE IDEA THAT A PUBLICLY-TRADED COMPANY COULD
19 ENGAGE IN THE FREE EXERCISE OF RELIGION IS A LITTLE
20 QUESTIONABLE. CERTAINLY THE SUPREME COURT HAS NEVER
21 HELD THAT.

22 AND FOR THE AGENCIES TO UNILATERALLY SAY
23 WE THINK THIS IS WHAT RFRA MEANS I THINK GOES WELL
24 BEYOND THE SCOPE OF THEIR AUTHORITY. THEY HAVE ALSO
25 DECIDED APPARENTLY THAT THE CONTRACEPTIVE MANDATE DOES

1 NOT SERVE A COMPELLING INTEREST.

2 WELL, FIVE JUSTICES IN THE SUPREME COURT
3 IN HOBBY LOBBY SEEM TO DISAGREE. THE FOUR CENTERS
4 CLEARLY SAID THAT IT SERVES A COMPELLING INTEREST, AND
5 JUSTICE KENNEDY DISCUSSED THE COMPELLING INTEREST, NEVER
6 ACTUALLY SAID SPECIFICALLY "I BELIEVE IT SERVES A
7 COMPELLING GOVERNMENT INTEREST," BUT MADE IT PRETTY
8 CLEAR THAT THAT WAS HIS BELIEF. AND FRANKLY, THE
9 MAJORITY IN HOBBY LOBBY NEVER EVEN QUESTIONED THAT.
10 THEY JUST ASSUMED IT FOR PURPOSES OF THE OPINION.

11 SO THE IDEA THAT RFRA SOMEHOW REQUIRES
12 WHAT THE GOVERNMENT IS DOING, THAT IT REQUIRES APPLYING
13 THIS TO PUBLICLY-TRADED COMPANIES, THAT IT REQUIRES
14 MAKING THE ACCOMMODATION PROCESS OPTIONAL IS NOT
15 SUPPORTED BY ANY OF THE CASE LAW THAT IS RELEVANT HERE.
16 AND IT'S NOT SUPPORTED BY A FAIR READING OF THE STATUTE.

17 AND I THINK TO SEE THAT THAT IS THE CASE,
18 WE DON'T NEED TO LOOK ANY FURTHER THAN THE ZUBIK
19 DECISION, WHERE THE SUPREME COURT CLEARLY STRUGGLED WITH
20 APPLYING RFRA IN THE CONTEXT OF AN ENTITY WHO DID OBJECT
21 TO THE ACCOMMODATION PROCESS. IF THE GOVERNMENT WAS
22 CORRECT AND THIS WAS A SLAM DUNK UNDER RFRA, ZUBIK WOULD
23 HAVE BEEN AN EASY DECISION FOR THE SUPREME COURT.

24 IT WAS NOT. ZUBIK EMPHASIZED THE NEED TO
25 BALANCE WHAT IT SAW AS LEGITIMATE EXERCISE OF RELIGION

1 AND THE NEEDS OF WOMEN AND THE COMPELLING GOVERNMENT
2 INTEREST IN SERVING AND PROVIDING ACCESS TO CARE --
3 WELL, ZUBIK DID NOT SPECIFICALLY FIND THAT IT WAS A
4 COMPELLING INTEREST, BUT I THINK THE FACT THAT THAT
5 DECISION CAME OUT THE WAY IT DID IS A SIGN -- IS A CLEAR
6 INDICATION THAT RFRA SIMPLY DOES NOT SAY WHAT THE
7 GOVERNMENT HERE BELIEVES IT SAYS.

8 I THINK -- I'M HAPPY TO COME BACK TO THE
9 CONSTITUTIONAL CLAIMS. I WOULD ALSO LIKE TO GET INTO
10 THE HARM THAT PENNSYLVANIA WILL SUFFER, BECAUSE I THINK
11 THAT IS IMPORTANT AS WELL. IT GOES BOTH TO THE
12 IRREPARABLE INJURY PRONG OF THE INJUNCTION AS WELL AS
13 STANDING THAT THE COMMONWEALTH HAS IN THIS CASE.

14 THERE HAS BEEN A LOT OF QUESTIONING TODAY
15 SUGGESTING, WELL, THE COMMONWEALTH CAN'T POINT TO ANY
16 SPECIFIC EMPLOYER WHO IS GOING TO TAKE ADVANTAGE OR WHO
17 HAS ANNOUNCED THEY ARE TAKING ADVANTAGE OF THIS.
18 WELL --

19 THE COURT: WELL, ALSO, THEY CAN'T POINT
20 TO ANY PARTICULAR WOMAN. SO TELL ME WHY -- GIVE ME A
21 RESPONSE TO THAT.

22 MR. FISCHER: WELL, THAT IS A FUNCTION IN
23 MANY RESPECTS OF THE WAY THE RULES ARE DRAFTED. THE
24 RULES ARE DRAFTED SO THAT EMPLOYERS CAN DO THIS QUIETLY.
25 THERE IS NO REQUIREMENT TO NOTIFY HHS. THERE'S NO

1 REQUIREMENT TO MAKE A PUBLIC ANNOUNCEMENT. THERE IS NOT
2 EVEN A REQUIREMENT TO CLEARLY COMMUNICATE TO ALL PLAN
3 MEMBERS WE ARE DROPPING YOUR CONTRACEPTION COVERAGE.

4 AN EMPLOYER CAN DO THIS BY SIMPLY
5 INCLUDING IN THE SUMMARY OF BENEFITS OF COVERAGE THAT
6 THEY PROVIDE ON AN ANNUAL BASIS, THAT WE ALL GET, AND
7 PROBABLY MOST OF US DON'T NECESSARILY READ THAT
8 THOROUGHLY. AS LONG AS SOMEWHERE IN THAT DOCUMENT THERE
9 IS AN INDICATION THAT CONTRACEPTION COVERAGE IS NOT
10 PROVIDED AND THAT DOCUMENT IS PROVIDED 30 DAYS PRIOR TO
11 THE START OF THE PLAN YEAR, THAT SATISFIES THE NOTICE
12 REQUIREMENTS.

13 SO THE IDEA THAT SOMEHOW WE WOULD KNOW
14 ABOUT THIS, THAT IT WOULD BE WIDESPREAD KNOWLEDGE WHO IS
15 OPTING OUT, IS NOT CONSISTENT WITH THE WAY THE RULES ARE
16 WRITTEN. NOW, THEY COULD HAVE WRITTEN THE RULES IN SUCH
17 A WAY THAT IT WOULD BE CLEAR HOW MANY COMPANIES ARE
18 TAKING ADVANTAGE, HOW MANY WOMEN ARE AFFECTED. THEY
19 COULD HAVE REQUIRED -- THIS IS HHS -- THEY COULD HAVE
20 REQUIRED NOTICE TO STATE REGULATORS. THEY DID NOT.

21 AND HERE WE ARE IN A SITUATION WHERE IT
22 IS EXTREMELY DIFFICULT FOR ANYONE TO ESTIMATE EXACTLY
23 HOW MANY WOMEN ARE AFFECTED. IN FACT, THE GOVERNMENT
24 CONCEDES THAT. THEY SAY THEY DON'T EVEN KNOW HOW MANY
25 WOMEN ARE AFFECTED BY THE CURRENT ACCOMMODATION PROCESS.

1 THE ONLY NUMBERS THEY COME UP WITH ARE BASED ON THE
2 COMPANIES THAT HAVE NOTIFIED HHS UNDER THAT SPECIFIC
3 OPTION, AS WELL AS SOME COMPANIES THAT ARE SELF-INSURERS
4 WHERE THE THIRD-PARTY ADMINISTRATOR HAS BEEN IN CONTACT
5 WITH HHS.

6 NOW, DESPITE NOT FULLY KNOWING HOW MANY
7 PEOPLE USE THE ACCOMMODATION, THEY DO TRY TO COME UP
8 WITH ESTIMATES IN THE RULES AS TO HOW MANY WOMEN WILL BE
9 AFFECTED. THEY ESTIMATE THAT OVER 1 MILLION INDIVIDUALS
10 ARE COVERED BY PLANS THAT CURRENTLY USE THE
11 ACCOMMODATION PROCESS. AND THEY GET THAT DOWN TO AN
12 ESTIMATE OF ROUGHLY 32,000 WOMEN NATIONWIDE WHO MAY LOSE
13 COVERAGE -- WHO WILL LOSE COVERAGE AS A RESULT OF THESE
14 RULES.

15 NOW, WE BELIEVE THAT THERE ARE PROBLEMS
16 WITH THE WAY THEY ESTIMATED THOSE NUMBERS, BUT
17 REGARDLESS, THEIR OWN ESTIMATES TELL YOU THAT LARGE
18 NUMBERS OF WOMEN WILL BE AFFECTED, AND THAT WILL INCLUDE
19 LARGE NUMBERS OF WOMEN HERE IN PENNSYLVANIA. AS WE
20 DETAIL IN OUR BRIEF, MANY OF THE PLAINTIFFS IN THESE
21 CASES WERE PENNSYLVANIA ENTITIES.

22 YOU HAVE SEEN EVIDENCE OR YOU HAVE SEEN
23 ARGUMENTS IN SOME OF THE AMICUS BRIEFS ABOUT HOW THIS
24 RULE WILL AFFECT WOMEN IN DIFFERENT STATES ACROSS THE
25 COUNTRY. I BELIEVE IN THE AMICUS BRIEFS SUBMITTED BY

1 THE OTHER STATES, THERE WAS AN ESTIMATE THAT OVER HALF A
2 MILLION WOMEN IN PENNSYLVANIA WHO CURRENTLY RECEIVE
3 EMPLOYER-SPONSORED COVERAGE WOULD BE ELIGIBLE FOR
4 STATE-FUNDED PROGRAMS IF THEY LOST THEIR COVERAGE AND
5 THEREFORE COULD WIND UP POSING A DIRECT COST TO THE
6 STATES.

7 AND YOU HAVE ALSO HEARD TESTIMONY FROM
8 OUR EXPERTS ABOUT THEIR EXPERIENCE WITH THE AFFORDABLE
9 CARE ACT, WHAT THAT HAS MEANT TO PENNSYLVANIA WOMEN, AND
10 THEREFORE WHAT THEY BELIEVE WILL HAPPEN IF WOMEN ARE
11 DENIED COVERAGE.

12 SO BECAUSE OF THIS 30-DAY OPTION THAT
13 ALLOWS AN EMPLOYER TO -- AN EMPLOYER OR ANY PLAN ENTITY,
14 ANY PLAN SPONSOR TO MODIFY OR ELIMINATE ITS
15 CONTRACEPTIVE BENEFITS AT THE BEGINNING OF A PLAN YEAR
16 WITH ONLY 30 DAYS' NOTICE, THAT IS WHY WE BELIEVE AN
17 INJUNCTION BY JANUARY 1ST IS IMPORTANT. JANUARY 1ST IS
18 THE START OF THE PLAN YEAR FOR MANY EMPLOYERS, AND
19 THEREFORE WE BELIEVE ON THAT DAY MANY WOMEN WILL BE AT A
20 RISK OF LOSING THEIR COVERAGE.

21 PENNSYLVANIA IS ACTUALLY IN A UNIQUE
22 SITUATION AS WELL, BECAUSE UNLIKE A LOT OF OTHER STATES,
23 WE DO NOT HAVE A CONTRACEPTIVE PARITY STATUTE. SO WOMEN
24 WHO ARE COVERED BY FULLY-INSURED PLANS THAT ARE NOT
25 REGULATED UNDER ERISA DO NOT HAVE A FALLBACK OPTION

1 WHERE THERE IS A STATE LAW THAT WOULD REQUIRE THEIR
2 EMPLOYER TO CONTINUE COVERING CONTRACEPTION. SO THE
3 HARM IN PENNSYLVANIA WILL BE MORE SIGNIFICANT THAN IT IS
4 IN SOME OTHER STATES LIKE NEW YORK AND MASSACHUSETTS,
5 CALIFORNIA, WHERE THEY DO HAVE CONTRACEPTION PARITY
6 STATUTES.

7 SO THE RESULT OF ALL OF THIS IS THAT
8 WOMEN WILL LOSE COVERAGE, THERE WILL BE COSTS IMPOSED ON
9 THE STATE BECAUSE SIGNIFICANT NUMBERS OF THESE WOMEN
10 WILL BE ELIGIBLE FOR STATE-FUNDED PROGRAMS OR WILL GO TO
11 CLINICS THAT RECEIVE STATE FUNDING, AND ULTIMATELY THE
12 STATE AND OTHER ENTITIES WILL BE PAYING THOSE COSTS.

13 AGAIN, THAT IS NOT SOMETHING WE ARE JUST
14 SPECULATING ABOUT. THERE IS EVIDENCE IN THE RECORD
15 ABOUT HOW THOSE PROGRAMS WORK AND IT'S ALSO REFLECTED IN
16 THE GOVERNMENT'S RULES. WHEN THEY ARGUE THAT THE RULES
17 WILL NOT IMPOSE A SIGNIFICANT IMPACT ON WOMEN, ONE OF
18 THE POINTS THEY MAKE IS, WELL, THERE ARE ALL THESE OTHER
19 PROGRAMS OUT THERE, ALL THESE OTHER STATE-FUNDED
20 PROGRAMS, STATE AND FEDERAL GOVERNMENT-FUNDED PROGRAMS
21 THAT CAN PROVIDE COVERAGE, AND THEY POINT SPECIFICALLY
22 TO TITLE 10 CLINICS.

23 SO EVEN THE GOVERNMENT ACKNOWLEDGES THAT
24 THERE WILL BE A SHIFT FROM EMPLOYERS TO PUBLICLY-FUNDED
25 PROGRAMS AS A RESULT OF THESE RULES.

1 FINALLY, YOUR HONOR, IN GETTING INTO
2 PENNSYLVANIA ENTITIES THAT MAY TAKE ADVANTAGE OF THE
3 EXEMPTION, WE HAVE INCLUDED IN EXHIBIT 20, WHICH IS IN
4 THE RECORD, A SUBSET OF DOCUMENTS FROM A FOIA REQUEST
5 THAT WAS A MADE OF THE GOVERNMENT, OF THE FEDERAL
6 AGENCIES, AND WHAT THESE DOCUMENTS ARE ARE SOME OF THE
7 NOTICES TO HHS AND SUBSEQUENT RESPONSES ABOUT ENTITIES,
8 AND MOST OF THE ONES IN EXHIBIT 20 ARE PENNSYLVANIA
9 ENTITIES, ENTITIES THAT WERE USING THE ACCOMMODATION
10 PROCESS.

11 NOW, AS I SAID EARLIER, THE GOVERNMENT
12 DOES NOT KNOW EVERYBODY WHO USES THE ACCOMMODATION
13 PROCESS BECAUSE NOT EVERYBODY NOTIFIES THE GOVERNMENT,
14 BUT HERE ARE SOME OF THE EXAMPLES OF PENNSYLVANIA
15 ENTITIES THAT HAVE USED THE ACCOMMODATION PROCESS, WHICH
16 AS A RESULT OF THESE RULES IS NOW OPTIONAL, AND IT'S
17 CERTAINLY A REASONABLE INFERENCE THAT ENTITIES THAT HAVE
18 A SINCERELY-HELD RELIGIOUS OBJECTION TO PROVIDING
19 CONTRACEPTIVE COVERAGE WILL CHOOSE, IF GIVEN THE
20 OPPORTUNITY, TO OPT OUT ENTIRELY RATHER THAN TO
21 PARTICIPATE IN A PROCESS WHICH SOME ENTITIES HAVE
22 ARGUED -- AND THIS HAS BEEN THE SUBJECT OF ZUBIK
23 LITIGATION -- SOME ENTITIES HAVE ARGUED NEVERTHELESS
24 STILL IMPOSES A SUBSTANTIAL BURDEN ON THEIR RELIGIOUS
25 BELIEFS.

1 SO FOR ALL OF THOSE REASONS, WE THINK IT
2 IS FAIRLY CLEAR THAT THE RULES VIOLATE THE APA. THEY
3 ARE ARBITRARY AND CAPRICIOUS, THEY ARE INCONSISTENT WITH
4 THE AFFORDABLE CARE ACT AND THE PROCESS THAT WAS
5 FOLLOWED WAS NOT LEGITIMATE, AND BECAUSE OF THAT HARM,
6 BECAUSE OF THAT ILLEGALITY, SUBSTANTIAL INJURY WILL
7 OCCUR IN THE COMMONWEALTH.

8 I WANT TO RETURN TO JUST ONE ISSUE ON
9 STANDING BEFORE I WILL CONCLUDE, BUT THE COURT ASKED
10 EARLIER ABOUT THE EXTENT OF PENNSYLVANIA'S INJURY AND
11 HOW, AS A STATE, PENNSYLVANIA CAN BRING THIS ACTION. WE
12 THINK IT IS FAIRLY CLEAR THAT MASSACHUSETTS VS. EPA
13 CONTROLS AND ALLOWS THE COMMONWEALTH TO BRING AN ACTION
14 CHALLENGING THE DECISIONS HERE IN THE FEDERAL
15 GOVERNMENT. THE COURT POINTED OUT THAT THAT WAS THE
16 CASE INVOLVING INACTION RATHER THAN ACTION, BUT IN MANY
17 WAYS THIS CASE, ALTHOUGH IT IS CHALLENGING THE SPECIFIC
18 REGULATIONS THAT WERE ISSUED, ULTIMATELY IS ABOUT THE
19 GOVERNMENT CHOOSING NOT TO ENFORCE THE REQUIREMENTS OF
20 THE AFFORDABLE CARE ACT AND THE CONTRACEPTIVE MANDATE
21 AGAINST ENTITIES THAT OBJECT. AS A RESULT OF THESE
22 RULES, THOSE LAWS, THOSE REQUIREMENTS WILL NO LONGER BE
23 ENFORCED.

24 WHAT IS MORE, I DON'T THINK THAT FOR
25 STANDING ANALYSIS PURPOSES THERE IS A SIGNIFICANT

1 DIFFERENCE BETWEEN ACTION AND INACTION. EITHER WAY,
2 PENNSYLVANIA'S HARMED, PENNSYLVANIA'S RESIDENTS ARE
3 HARMED, THE COMMONWEALTH'S QUASI-SOVEREIGN INTEREST IN
4 PROTECTING THE HEALTH AND SAFETY OF ITS RESIDENTS IS
5 GOING TO BE HARMED, AND FOR ALL OF THOSE REASONS, WE
6 BELIEVE THAT THE COMMONWEALTH DOES HAVE STANDING IN THIS
7 CASE.

8
9 THE COURT: OKAY, I THINK YOUR COLLEAGUE
10 WANTS YOU TO TELL ME ONE MORE THING.

11 MR. FISCHER: YOUR HONOR, I APOLOGIZE. I
12 DO NOT BELIEVE I RESERVED ANY TIME FOR REBUTTAL. WOULD
13 THAT BE POSSIBLE? IF I HAVE TIME LEFT --

14 THE COURT: THAT IS FINE.

15 MR. FISCHER: OKAY.

16 THE COURT: AS I SAID, IT'S ME AND YOU.
17 THERE IS NO ONE HERE SO IT'S FINE. WE HAVE UNTIL
18 6 O'CLOCK SO LET'S --

19 MR. FISCHER: SO -- YEAH.

20 THE COURT: ARE YOU DONE NOW?

21 MR. FISCHER: I JUST HAVE ONE MORE --

22 THE COURT: GO AHEAD.

23 MR. FISCHER: ON THIS QUESTION OF WHETHER
24 THE COMMONWEALTH WILL BE HARMED, IT REALLY COMES DOWN TO
25 COMMON SENSE. WHAT THE GOVERNMENT IS SAYING IS THAT

1 DESPITE THESE SWEEPING NEW RULES THAT THEY ARGUE ARE SO
2 IMPORTANT THAT THEY HAVE TO BE IMPLEMENTED IMMEDIATELY
3 TO PROTECT PEOPLE THAT ARE SUFFERING, NEVERTHELESS,
4 NOBODY IN PENNSYLVANIA IS GOING TO BE HARMED BECAUSE NO
5 EMPLOYER IS GOING TO TAKE ADVANTAGE OF THEM.

6 NOW THAT JUST DEFIES LOGIC. IT IS FAIRLY
7 CLEAR THAT THERE WILL BE WOMEN ACROSS THE COUNTRY AND IN
8 PENNSYLVANIA, BASED ON THEIR OWN ESTIMATES, BASED ON
9 PRIOR LITIGATION, BASED ON SOME OF THE DOCUMENTS IN THE
10 RECORD, THERE WILL BE WOMEN WHO ARE HARMED. THAT WILL
11 CAUSE HARM TO THE COMMONWEALTH, AND CLEARLY WE BELIEVE
12 THAT THAT NOT ONLY GIVES US STANDING, BUT ALSO
13 ESTABLISHES INJURY FOR PURPOSES OF OUR INJUNCTION.

14 THANK YOU, YOUR HONOR.

15 THE COURT: THANK YOU.

16 WHO WILL BE ARGUING ON BEHALF OF THE
17 DEFENDANTS?

18 MR. DAVIS: I WILL, YOUR HONOR.

19 MAY I APPROACH, YOUR HONOR?

20 THE COURT: YOU MAY.

21 MR. DAVIS: IF YOUR HONOR WOULD INDULGE
22 ME AT THE BEGINNING, I WOULD LIKE TO MAKE A RECORD ON
23 CERTAIN EVIDENTIARY ISSUES. SPECIFICALLY WE WOULD LIKE
24 TO MOVE TO STRIKE THE TESTIMONY OF DRS. WEISMAN, BUTTS
25 AND CHUANG TO THE EXTENT THEY TESTIFIED ABOUT THE IMPACT

1 OF THE NEW RULES ON WOMEN'S ACCESS.

2 THE COURT: THE HORSE HAS LEFT THE BARN
3 ON THAT. YOU HAD AN OPPORTUNITY, YOU HAD A LAWYER WHO
4 WAS HANDLING THAT ISSUE. I RULED.

5 MR. DAVIS: YOUR HONOR, CERTAIN THINGS
6 CAME UP THROUGH THE TESTIMONY AFTER THE OBJECTION WAS
7 MADE THAT I'D JUST LIKE TO PUT ON THE RECORD, IF YOU
8 DON'T MIND.

9 THE COURT: I RULED AGAINST YOU. I DO
10 MIND. YOU DON'T GET TO HAVE A SECOND BITE AT THE APPLE.

11 GO AHEAD. THIS IS NOW THE CLOSING
12 ARGUMENT PORTION OF THE PROCEEDING.

13 MR. DAVIS: OKAY. ON STANDING, YOUR
14 HONOR, YOU HEARD FROM DRS. WEISMAN, BUTTS AND CHUANG
15 THAT THEY ARE NOT AWARE OF A SINGLE INDIVIDUAL WHO WILL
16 BE AFFECTED BY THE NEW RULES AND THEY ARE NOT AWARE OF A
17 SINGLE EMPLOYER WHO WILL BE TAKING ADVANTAGE OF THE NEW
18 RULES. I THINK IT WOULD BE EXTRAORDINARY TO GRANT AN
19 INJUNCTION THAT WOULD NOT BENEFIT A SINGLE IDENTIFIABLE
20 INDIVIDUAL. I THINK THAT TESTIMONY WAS VERY TELLING.

21 THE COURT: IF THEY HAD BEEN ABLE TO
22 IDENTIFY ONE PERSON, WOULD YOUR RESPONSE HAVE BEEN
23 DIFFERENT?

24 MR. DAVIS: YOUR HONOR, I THINK IT MIGHT
25 HAVE BEEN DIFFERENT WITH RESPECT TO STANDING BUT NOT

1 WITH RESPECT TO IRREPARABLE INJURY. I THINK IRREPARABLE
2 INJURY REQUIRES SOME SORT OF DAMAGE MORE THAN A MINOR
3 AMOUNT, AND IT WOULD NOT BE DIFFERENT IN A SENSE -- WITH
4 RESPECT TO STANDING, IN THE SENSE THAT THEY WOULD ALSO
5 HAVE TO SHOW THAT THAT EMPLOYEE WOULD ACTUALLY QUALIFY
6 FOR A STATE-FUNDED PROGRAM AND WOULD ACTUALLY GO SEEK
7 COVERAGE FROM THAT STATE-FUNDED PROGRAM. SO IF THEY
8 COULD SHOW ALL OF THAT, MAYBE IT WOULD CHANGE THE
9 STANDING ANALYSIS.

10 THE COURT: WELL, LET'S FOCUS IN ON
11 STANDING THEN.

12 SO I'M LOOKING AT FEDERAL REGISTER 82-197
13 AND THERE IS A SECTION, THE RELIGIOUS EXEMPTION. IT'S
14 THE DISCUSSION OF THE PEOPLE WHO WOULD BE IMPACTED OR
15 THE WOMEN WHO WOULD BE IMPACTED. IT SAYS: BASED ON OUR
16 LIMITED INFORMATION FROM THE LITIGATION AND
17 ACCOMMODATION NOTICES, WE EXPECT THAT THE OVERLAP IS
18 SIGNIFICANT. NEVERTHELESS, IN ORDER TO ESTIMATE THE
19 POSSIBLE EFFECTS OF THESE RULES WE ASSUME THERE IS NO
20 OVERLAP BETWEEN THESE TWO NUMBERS AND THEREFORE -- AND
21 HERE IS THE IMPORTANT PART -- THAT THESE INTERIM FINAL
22 RULES WOULD AFFECT THE CONTRACEPTIVE COSTS OF
23 APPROXIMATELY 31,700 WOMEN.

24 SO I THINK THAT YOUR RULES ALONE SUGGEST
25 THAT -- WELL, THEY DON'T SUGGEST, THEY SAY THAT 31,700

1 WOMEN WILL BE AFFECTED. AM I READING THAT CORRECTLY?

2 MR. DAVIS: YOUR HONOR, THE RULES

3 ESTIMATE THAT SOME WOMEN WILL BE AFFECTED BY THIS. THAT

4 ESTIMATE STANDARD IS LOWER THAN THE CERTAINLY IMPENDING

5 STANDARD NECESSARY TO SHOW STANDING. IN A COURTROOM, I

6 THINK THE STANDARD IS CERTAINLY IMPENDING, REASONABLY

7 CERTAIN, AND I THINK THAT IS WHAT THEY FAILED TO SHOW

8 HERE. AND AGAIN, YOU'D THINK THAT --

9 THE COURT: SO INSTEAD OF STEPPING AWAY

10 FROM MY QUESTION, ANSWER MY QUESTION. SO IN THE

11 REGULATIONS THERE IS A STATEMENT IS THAT THESE INTERIM

12 FINAL RULES WOULD AFFECT THE CONTRACEPTIVE COSTS OF

13 APPROXIMATELY 31,700 WOMEN. IS THAT A CORRECT STATEMENT

14 OF WHAT THE RULES SAY?

15 MR. DAVIS: YOUR HONOR, I DON'T HAVE THAT

16 STATEMENT RIGHT IN FRONT OF ME. I ASSUME YOUR HONOR IS

17 READING IT CORRECTLY.

18 THE COURT: SO GIVEN THE FACT THAT THE

19 RULES THEMSELVES HAVE SAID 31,700 WOMEN WILL BE -- THE

20 COST OF SEVEN -- 31,700 WOMEN WILL BE AFFECTED, HOW DOES

21 THAT IMPACT HERE ON THE STANDING ANALYSIS?

22 MR. DAVIS: AGAIN, YOUR HONOR, IN THE

23 CONTEXT OF THE RULES, THAT IS AN ESTIMATE. THAT IS NOT

24 A BLANKET STATEMENT THAT 31,000 WOMEN ARE DEFINITELY

25 GOING TO BE AFFECTED BY THESE RULES. I FUNDAMENTALLY

1 DISAGREE WITH THE IDEA THAT THAT IS AN IRONCLAD
2 PREDICTION OF WHAT WILL HAPPEN. THAT IS AN ESTIMATE.

3 THE RULES IN OTHER PLACES SAY THAT
4 THEY -- THAT IT'S -- THIS ENDEAVOR IS FRAUGHT WITH
5 UNCERTAINTY, IT'S NOT CLEAR WHAT EFFECT THESE WILL HAVE,
6 THAT MANY EMPLOYERS ARE ALREADY PROTECTED BY
7 INJUNCTIONS. I DON'T THINK THERE IS ANY WAY TO READ
8 THAT STATEMENT AS AN IRONCLAD PREDICTION THAT THIS IS
9 WHAT WILL HAPPEN.

10 THE COURT: GO AHEAD.

11 MR. DAVIS: I WOULD ALSO LIKE TO -- YOU
12 ALSO HEARD, ALSO ON THE STANDING QUESTION, YOUR HONOR,
13 YOU HEARD FROM THE WITNESSES THAT ACCESS TO
14 CONTRACEPTIVE COVERAGE HAS INCREASED IN THE YEAR AFTER
15 THE AFFORDABLE CARE ACT, THAT NO LONGER ARE THEY
16 BEING -- ARE DOCTORS BEING ASKED ABOUT COST-FREE
17 CONTRACEPTION. I JUST WANTED TO POINT OUT THAT THIS NEW
18 WORLD THAT THEY ARE TALKING ABOUT AFTER THE AFFORDABLE
19 CARE ACT IS A WORLD WHERE EVERY KNOWN RELIGIOUS OBJECTOR
20 WAS ALREADY EXEMPT. IT WAS ALREADY NOT PROVIDING
21 CONTRACEPTIVE COVERAGE, SO IT'S NOT CLEAR THEN WHY THESE
22 NEW RULES WOULD RETURN US BACK TO THE WORLD OF THE
23 PRE-ACA ERA.

24 I'D ALSO LIKE TO RETURN TO WHAT WE TALKED
25 ABOUT EARLIER THIS MORNING, YOUR HONOR, ON THE MORAL

1 OBJECTORS WHO COULD -- WHETHER OR NOT THERE IS A WAY TO
2 POLICE SINCERITY IN THAT CONTEXT. JUST TO ELABORATE ON
3 WHAT I SAID EARLIER, IT'S POSSIBLE FOR AN EMPLOYEE OF A
4 COMPANY WHO BELIEVES THAT HER EMPLOYER IS IMPROPERLY
5 ASSERTING A MORAL OBJECTION TO FILE A COMPLAINT UNDER
6 ERISA WITH THE DEPARTMENT OF LABOR. LABOR HAS THE
7 AUTHORITY TO ENFORCE UNDER ERISA.

8 LABOR ALSO HAS THE AUTHORITY TO REFER TO
9 THE TREASURY DEPARTMENT, FOR IRS TO INVESTIGATE THE
10 COMPANY FOR FAILING TO PAY EXCISE TAXES, IN OTHER WORDS
11 FOR FAILING TO COMPLY WITH THE MANDATE. AND SINCE
12 SINCERITY IS AN ELEMENT OF THE EXEMPTION, THAT WOULD BE
13 A LIVE ENFORCEMENT ISSUE IN THIS CONTEXT.

14 AND I ALSO ADD THAT AN EMPLOYEE IN THAT
15 CONTEXT WOULD CONCEIVABLY HAVE A TITLE VII REMEDY
16 AVAILABLE AGAINST HER EMPLOYER.

17 I WOULD ALSO, ALTHOUGH I KNOW YOUR HONOR
18 WAS NOT ENAMORED WITH THIS ARGUMENT, I WOULD JUST LIKE
19 TO ADD JUST A COUPLE OF QUICK WORDS ON THE RICCI VERSUS
20 DESTEFANO ARGUMENT. YOUR HONOR HAD EXPRESSED CONCERN
21 THAT THAT CASE WAS NOT SUFFICIENTLY ON ALL FOURS WITH
22 THIS CASE BECAUSE IT INVOLVED A CITY AND NOT THE FEDERAL
23 GOVERNMENT FOR OTHER REASONS. IF IT GIVES YOU ANY
24 SOLACE, YOUR HONOR, THERE ARE -- THERE IS AN ANALOGOUS
25 PRINCIPLE IN THE CONTEXT OF CHEVRON DEFERENCE THAT MAY

1 BE CLOSER TO THIS CASE.

2 AND THERE IS A SUPREME COURT CASE CALLED
3 SCIALABBA, S-C-I-A-L-A-B-B-A, VERSUS CUELLAR DE OSORIO,
4 C-U-E-L-L-A-R D-E O-S-O-R-I-O, 134 S.CT 2191: WHEN AN
5 AGENCY THUS RESOLVES STATUTORY TENSION, ORDINARY
6 PRINCIPLES OF ADMINISTRATIVE DEFERENCE REQUIRE US TO
7 DEFER.

8 ANOTHER CASE -- I WILL GIVE YOU THE CITE
9 IN A SECOND -- SAYS THAT WHEN A STATUTORY SCHEME
10 CONTAINS A FUNDAMENTAL AMBIGUITY ARISING FROM THE
11 DIFFERENT MANDATES OF TWO PROVISIONS, IT IS APPROPRIATE
12 TO LOOK TO THE IMPLEMENTING AGENCY'S EXPERT
13 INTERPRETATION.

14 SO I THINK THAT MIGHT BE CLOSER TO WHAT
15 YOUR HONOR WAS LOOKING FOR.

16 THE COURT: THAT IS BETTER.

17 MR. DAVIS: AND THAT CASE IS NATIONAL
18 ASSOCIATION OF HOMEBUILDERS VERSUS DEFENDERS OF
19 WILDLIFE. 551 U.S. 644-666.

20 THE COURT: SCIALABBA, WHAT YEAR WAS
21 SCIALABBA?

22 MR. DAVIS: I NEGLECTED TO WRITE DOWN THE
23 YEAR. I THOUGHT I HAD THAT.

24 ONE SECOND, YOUR HONOR. I WILL GET THAT
25 FOR YOU.

1 THE COURT: OKAY.

2 MR. DAVIS: 2014.

3 THE COURT: 2014.

4 MR. DAVIS: YES.

5 THE COURT: OKAY. I WILL TAKE A LOOK AT
6 THAT CASE.

7 MR. DAVIS: I WOULD LIKE TO RESPOND TO A
8 FEW THINGS THAT MY COLLEAGUE ON THE OTHER SIDE JUST
9 SAID. HE SUGGESTED THAT RECOGNITION OF MORAL OBJECTIONS
10 IS UNPRECEDENTED, IF I HEARD HIM CORRECTLY. THAT IS NOT
11 TRUE. MORAL OBJECTIONS HAVE BEEN STANDARD IN THE LAW
12 FOR QUITE A LONG TIME. IN FACT, PENNSYLVANIA HAS ITS
13 OWN CONSCIENCE CLAUSE PERMITTING MEDICAL PROFESSIONALS
14 TO OPT OUT OF PROVIDING ABORTIONS, FOR EXAMPLE, AND
15 THERE HAS BEEN THE CONSCIENCE CLAUSE EXEMPTING
16 CONSCIENTIOUS OBJECTORS FROM THE DRAFT.

17 I WOULD ALSO LIKE TO ADDRESS THE KING
18 VERSUS BURWELL ISSUE THAT CAME UP, YOUR HONOR, IN THE
19 CONTEXT OF WHETHER OR NOT THE AGENCY'S INTERPRETATION IS
20 ENTITLED TO -- OF THE AFFORDABLE CARE ACT IS ENTITLED TO
21 CHEVRON DEFERENCE. YOUR HONOR, IN KING VERSUS BURWELL
22 THE COURT HELD THAT WHETHER TAX CREDITS ARE AVAILABLE ON
23 FEDERAL EXCHANGES IS A MAJOR QUESTION, THAT IT WOULD BE
24 INCONCEIVABLE THAT CONGRESS WOULD HAVE DELEGATED THAT TO
25 THE -- IMPLICITLY DELEGATED THAT TO THE AGENCIES.

1 SO KING WAS ABOUT IMPLICIT DELEGATIONS
2 BUT THIS CASE IS ABOUT AN EXPLICIT DELEGATION OF
3 AUTHORITY AT 42 U.S.C. 300GG-13(A)(4).

4 ANOTHER POINT I'D LIKE TO CLARIFY THAT
5 CAME UP WAS THE QUESTION ABOUT WHETHER THE AGENCIES HAVE
6 AUTHORITY TO CREATE EXEMPTIONS FROM THE GUIDELINES,
7 WHICH WE DISCUSSED EARLIER. I JUST WANTED TO CLARIFY
8 THAT THE EXEMPTIONS THEMSELVES ARE IN THE HRSA
9 GUIDELINES, SO IT'S NOT LIKE THESE RULES ARE CREATING
10 EXEMPTIONS TO HRSA'S GUIDELINES; THE GUIDELINES
11 THEMSELVES SPELL OUT THE RELIGIOUS AND MORAL EXEMPTIONS.

12 AND THAT IS TRUE NOT ONLY OF THESE RULES
13 OF THE GUIDELINES IN 2016, IT'S ALSO TRUE OF THE
14 GUIDELINES IN 2011, WHEN THE LAST ADMINISTRATION DID THE
15 RELIGIOUS EMPLOYER EXEMPTION. THE HRSA GUIDELINES THERE
16 THEMSELVES INCORPORATED THE EXEMPTION, SO I DON'T THINK
17 THIS QUESTION ABOUT WHETHER AGENCIES CAN CREATE
18 EXCEPTIONS TO THE GUIDELINES IS REALLY PRESENTED HERE.

19 THERE WAS ALSO A REFERENCE TO ALL OF THE
20 PENNSYLVANIA ENTITIES THAT ARE USING THE ACCOMMODATION.
21 I JUST POINT OUT THERE, YOUR HONOR, THAT THERE IS NO
22 INDICATION THAT ANY OF THOSE ENTITIES ARE GOING TO
23 SWITCH FROM USING THE ACCOMMODATION TO USING THE
24 EXEMPTION. IT MAY BE, LIKE FOR MANY ENTITIES, THAT THE
25 ACCOMMODATION SATISFIES THEIR RELIGIOUS EXEMPTIONS AND

1 THEY WON'T SWITCH TO ANYTHING ELSE.

2 AND, FINALLY, YOUR HONOR, I THINK THIS
3 POINT ABOUT HOW -- ON IRREPARABLE INJURY, ABOUT HOW THE
4 EXCLUSION MUST BE CLEAR ON THE FACE OF THE PLAN DOCUMENT
5 AND THAT IS WHY MAYBE THESE WITNESSES DID NOT KNOW ABOUT
6 ANYONE WHO KNEW ABOUT ANYONE WHO WAS GOING TO LOSE
7 CONTRACEPTIVE COVERAGE, WELL, THERE IS ALSO A
8 REQUIREMENT THAT AN EMPLOYER WHO PLANS TO TAKE THIS
9 EXEMPTION NOTIFY ITS EMPLOYEES 30 DAYS BEFOREHAND AND
10 SEND OUT A PLAN DOCUMENT THAT -- WHERE THE EXCLUSION OF
11 COVERAGE IS APPARENT FROM THE FACE OF THE PLAN DOCUMENT.
12 AND WE HAVE HEARD NOTHING ABOUT ANY OF THOSE NOTICES
13 BEING SENT OUT. NO WITNESS HAS TESTIFIED THAT THEY ARE
14 AWARE OF ANY OF THOSE NOTICES. AND YOU WOULD THINK IF
15 THIS IMPACT WAS GOING TO BE AS WIDESPREAD AS THE
16 COMMONWEALTH SUGGESTS, WE WOULD HAVE HEARD SOME INKLING
17 OF THAT. AND THE FACT IS THAT WE HAVE NOT.

18 SO I JUST -- THE LAST POINT I WOULD JUST
19 LIKE TO MAKE, YOUR HONOR, IS THAT AGAIN, YOU ARE NOT
20 WRITING ON A BLANK SLATE HERE. THERE IS A LOT OF WATER
21 UNDER THE BRIDGE. THERE IS A LOT OF EXISTING
22 PRELIMINARY INJUNCTIONS AND PERMANENT INJUNCTIONS OUT
23 THERE THAT HAVE MEANT THAT THE STATE OF THE WORLD BEFORE
24 THESE NEW RULES CAME OUT WERE THAT MOST, MAYBE EVEN ALL
25 OF THE EMPLOYERS WHO OBJECTED TO PROVIDING CONTRACEPTIVE

1 COVERAGE WERE EXEMPT FROM THIS REQUIREMENT ALREADY. SO
2 THERE IS NOT -- IT'S NOT CLEAR WHAT IMPACT AN INJUNCTION
3 WOULD HAVE. AND IN THAT CIRCUMSTANCE, IT'S BLACK-LETTER
4 LAW THAT THE AGENCY SHOULD STAY ITS HAND -- OR THE COURT
5 SHOULD STAY ITS HAND. IT'S BLACK-LETTER LAW THAT THE
6 COURT SHOULD STAY ITS HAND.

7 YOUR HONOR, ON ONE MORE ISSUE, ON THE
8 APA, I JUST WOULD LIKE TO ADD THAT THIS CASE IS SUPPOSED
9 TO BE LIMITED TO THE ADMINISTRATIVE RECORD, AND THAT
10 WHILE I RECOGNIZE WHAT YOUR HONOR SAID ABOUT SOME OF
11 THESE WITNESSES' TESTIMONY --

12 THE COURT: I DON'T THINK THAT IS THE
13 CASE. IF YOU READ MY ORDER ON THE MOTION IN LIMINE,
14 THAT IS NOT THE CASE.

15 MR. DAVIS: WELL --

16 THE COURT: DID YOU READ THE ORDER ON
17 MOTION IN LIMINE?

18 MR. DAVIS: I DID, YOUR HONOR.

19 THE COURT: THEREFORE, THE CASE IS NOT
20 SUPPOSED TO BE DECIDED ON THE ADMINISTRATIVE RECORD
21 ONLY.

22 MR. DAVIS: YOUR HONOR, I'M RESPECTFULLY
23 DISAGREEING WITH YOUR HONOR'S MOTION.

24 THE COURT: YOU CAN SAY THAT YOU BELIEVE
25 THAT THAT IS THE CASE, BUT I DON'T THINK YOU CAN SAY

1 SUPPOSED TO, BECAUSE THERE IS AN ORDER OF THIS COURT
2 WHICH PARTICULARLY DESCRIBES WHAT RECORD THIS DECISION
3 IS BEING MADE ON. DO YOU UNDERSTAND THAT?

4 MR. DAVIS: FAIR ENOUGH, YOUR HONOR. I
5 WILL PHRASE IT DIFFERENTLY. I BELIEVE THAT THIS CASE
6 SHOULD BE DECIDED ON THE BASIS OF THE ADMINISTRATIVE
7 RECORD. I DON'T BELIEVE THAT THE COURT'S RULING ON THE
8 MOTION IN LIMINE WAS CORRECT. I THINK THAT THE WITNESS
9 TESTIMONY IN THIS CASE WENT FAR BEYOND THE
10 ADMINISTRATIVE RECORD. I THINK IT WENT INTO QUESTIONING
11 THE CORRECTNESS AND WISDOM OF THE AGENCY'S DECISION. I
12 THINK IT'S BLACK-LETTER LAW THAT THAT STUFF IS NOT
13 PROPER.

14 THE COURT: MOVE ON. THAT WAS ON A
15 MOTION IN LIMINE. WE ARE DOING THE CLOSING IN THIS CASE
16 RIGHT NOW.

17 MR. DAVIS: YOUR HONOR, THAT IS ALL I
18 HAVE, UNLESS YOU HAVE FURTHER QUESTIONS.

19 THE COURT: I HAVE NO FURTHER QUESTIONS.
20 REBUTTAL.

21 MR. FISCHER: THANK YOU, YOUR HONOR. I
22 WILL TRY TO KEEP THIS BRIEF.

23 THE DISCUSSION THAT WE ARE HAVING ABOUT
24 THE MORAL EXEMPTION I THINK IS A GOOD METAPHOR FOR ALL
25 THE PROBLEMS WITH BOTH RULES. THE FACT THAT WE ARE NOW

1 IN POSITION WHERE WE ARE HAVING A DEBATE ABOUT WHETHER
2 THE DEPARTMENT OF LABOR SHOULD BE INVESTIGATING WHETHER
3 EMPLOYERS' PROFESSED MORAL BELIEFS ARE SINCERE OR NOT,
4 AND THEY FEEL AN EMPLOYEE DENIED CONTRACEPTIVE COVERAGE
5 HAS TO FILE A TITLE VII CLAIM BECAUSE HER EMPLOYER, AS
6 THE COURT HYPOTHESIZED, MAY DECIDE THAT HE OBJECTS TO
7 WOMEN BEING IN THE WORKFORCE AND HE IS GOING TO DENY
8 CONTRACEPTIVE COVERAGE AS A RESULT OF THAT. I THINK
9 THAT IS A WORLD WE DON'T WANT TO BE IN.

10 THE RELIGIOUS FREEDOM RESTORATION ACT
11 ADDRESSED THE TENSION INHERENT IN THAT ISSUE IN THE
12 CONTEXT OF RELIGIOUS BELIEFS AND STRUCK A BALANCE WHERE
13 COURTS GENERALLY DO NOT GET INTO THE SINCERITY OF
14 BELIEFS, NOR SHOULD THEY. WHAT THEY CAN LOOK AT IS
15 WHETHER THOSE BELIEFS OR THE EXERCISE OF THOSE BELIEFS
16 IS SUBSTANTIALLY BURDENED BY GOVERNMENT PROGRAMS. THAT
17 IS WHERE RFRA STRUCK THE BALANCE. WHAT WE HAVE NOW IS
18 TWO RULES FROM THE GOVERNMENT THAT WOULD ESSENTIALLY
19 UPSET THAT BALANCE AND PUT EMPLOYEES AT THE WHIM OF THE
20 MORAL BELIEFS, WHATEVER THEY MAY BE, OF THEIR EMPLOYERS.
21 AND I THINK THE GOVERNMENT IS SUGGESTING AT LEAST THAT
22 AN EMPLOYER WHO HAD A MORAL BELIEF THAT WOMEN SHOULD NOT
23 BE IN THE WORKFORCE, THAT THAT WOULD NOT BE A
24 SINCERELY-HELD OR LEGITIMATE MORAL BELIEF. THERE IS
25 NOTHING IN THE RULES THAT SAYS THAT. THERE IS NOTHING

1 IN THE RULES THAT LIMITS THE TYPES OF MORAL BELIEFS THAT
2 AN ENTITY CAN PROFESS.

3 I WOULD LIKE TO THINK THAT HAD THIS GONE
4 THROUGH THE RIGHT PROCESS, THERE WOULD HAVE BEEN SOME
5 THOUGHT GIVEN TO THAT AND MAYBE THERE WOULD HAVE BEEN A
6 DIFFERENT RESULT AND WE WOULD NOT HAVE THIS SWEEPING
7 EXEMPTION, WE WOULD NOT HAVE THE PUBLICLY-TRADED COMPANY
8 OPTION UNDER THE RELIGIOUS EXEMPTION RULE, AND WE WOULD
9 NOT HAVE THE PROVISION MAKING THE ACCOMMODATION
10 OPTIONAL. I THINK IN SOME WAYS THOSE ARE ALL THE
11 RESULTS OF A FLAWED PROCESS AS I SAID THAT LED TO A
12 FLAWED RESULT, BUT I ALSO THINK THAT BECAUSE THE RESULT
13 IS SO FLAWED, IT IS IMPORTANT TO GET THAT ON THE RECORD
14 AND MAKE CLEAR THAT IF WE ARE FORTUNATE, IF THE COURT
15 DOES GRANT AN INJUNCTION AND THE GOVERNMENT GOES BACK TO
16 THE DRAWING BOARD, ONE WOULD HOPE THAT THEY WOULD COME
17 UP -- IF THEY DECIDE THERE'S A NEED FOR FURTHER RULE
18 MAKING, ONE WOULD HOPE THAT THEY WOULD COME UP WITH A
19 RULE THAT IS MUCH NARROWER THAN THIS, THAT DOES NOT
20 ALLOW FOR SUCH SWEEPING OBJECTIONS, THAT IS MUCH MORE
21 JUSTIFIABLE UNDER THE AFFORDABLE CARE ACT AND UNDER
22 RFRA.

23 THE GOVERNMENT SAID -- TURNING BRIEFLY TO
24 THE HARM, AGAIN, THE GOVERNMENT HAS SAID WELL, EVERY
25 KNOWN RELIGIOUS OBJECTOR IS EXEMPT. NOW, THAT IS SIMPLY

1 NOT THE CASE.

2 RELIGIOUS -- MANY RELIGIOUS OBJECTORS ARE
3 STILL OPERATING UNDER THE ACCOMMODATION PROCESS UNDER
4 WHICH THEIR EMPLOYEES DO GET HEALTH COVERAGE. AND, IN
5 FACT, EVEN IF YOU LOOK AT WHAT IS REFERRED TO AS THE
6 ZUBIK INJUNCTION, THE ORDER FROM THE SUPREME COURT, THE
7 COURT DID NOT SAY YOUR EMPLOYEES DO NOT GET COVERAGE.
8 WHAT THEY SAID IS, HHS NOW KNOWS BY VIRTUE OF THIS
9 LITIGATION YOU OBJECT, SO THEY CAN GO AHEAD AND ARRANGE
10 FOR COVERAGE, AND THEY CAN'T FINE YOU FOR NOT PROVIDING
11 THE NOTICE. NOW, SOME OF THOSE ENTITIES ARE COVERED BY
12 CHURCH PLANS, WHICH IS A SIDE ISSUE, AND THEIR
13 EMPLOYERS -- THEIR EMPLOYEES MAY NOT BE GETTING
14 COVERAGE. BUT CERTAINLY TO SAY THAT ALL KNOWN
15 RELIGIOUS OBJECTORS ARE EXEMPT IS NOT CONSISTENT WITH
16 THE RECORD IN THIS CASE.

17 YOUR HONOR, THE GOVERNMENT COUNSEL HAS
18 TALKED A LITTLE BIT ABOUT THE NEED TO DEFER TO THEIR
19 INTERPRETATION AND CITED THE TWO CASES. IN THOSE CASES
20 IT SOUNDS LIKE AT LEAST THERE WAS LEGITIMATE TENSION IN
21 ONE OR AMBIGUITY IN ANOTHER THAT ALLOWED THE GOVERNMENT
22 TO SAY WE ARE ADOPTING A REASONABLE INTERPRETATION.
23 HERE THERE SIMPLY ISN'T. THERE'S NOT A BASIS FOR
24 READING INTO THE WOMEN'S HEALTH AMENDMENT THIS BROAD
25 AUTHORITY TO CARVE OUT EXEMPTIONS FROM WHAT IS A CLEAR

1 MANDATORY OBLIGATION THAT CONGRESS PASSED THAT THESE
2 PLAN SPONSORS HAVE TO PROVIDE AND HAVE TO NOT IMPOSE
3 COST SHARING REQUIREMENTS FOR THE NECESSARY PREVENTIVE
4 MEDICINE AS DEFINED BY HRSA, THIS IDEA THAT HR -- THE
5 GUIDELINES INCLUDE THE EXEMPTIONS. WELL, THE AGENCIES
6 PROMULGATE THE EXEMPTIONS AND THEN THEY GIVE HRSA THE
7 AUTHORITY, AND THEY APPEAR ON THE WEB PAGE. SO I DON'T
8 THINK IT'S THE CASE THAT HRSA IS EXERCISING ITS
9 INDEPENDENT AUTHORITY TO IMPLEMENT THESE GUIDELINES --
10 OR IMPLEMENT THESE EXCEPTIONS.

11 YOUR HONOR, LET'S RETURN TO THE THREE
12 MOST PROBLEMATIC ASPECTS THAT I MENTIONED IN THE
13 BEGINNING. THE MORAL EXEMPTION RULE IS SIMPLY NOT
14 SUPPORTED BY THE RECORD. THIS EXPANSION OF PUBLICLY
15 TRADED COMPANY IS NOT SUPPORTED. AND THE RENDERING OF
16 THE ACCOMMODATION PROCESS OPTIONAL REALLY DOES THREATEN
17 TO TAKE AWAY COVERAGE FOR MANY WOMEN WHO WORK FOR
18 RELIGIOUS EMPLOYERS BUT WHO ARE NONETHELESS GETTING
19 CONTRACEPTIVE COVERAGE TODAY.

20 AND WITH RESPECT TO ALL OF THESE IN SOME
21 WAY, AT LEAST CERTAINLY THE MORAL EXEMPTION AND THE
22 PUBLIC-TRADED COMPANY EXPANSION, THE GOVERNMENT'S
23 RESPONSE IS, WELL, WE JUST DON'T THINK THAT MANY PEOPLE
24 ARE GOING TO TAKE ADVANTAGE OF IT. THAT IN SOME WAYS IS
25 KIND OF A PERFECT EXAMPLE OF ARBITRARY AND CAPRICIOUS

1 RULEMAKING. TO ALLOW FOR A SUCH SWEEPING EXEMPTION, BUT
2 THEN TO SAY WE ARE DOING THIS BECAUSE WE DON'T ACTUALLY
3 THINK THERE IS MUCH DEMAND FOR IT, WE DON'T THINK THERE
4 IS MUCH NEED FOR IT, THAT IS SIMPLY NOT HOW THE AGENCY
5 RULEMAKING PROCESS IS SUPPOSED TO WORK AND IT'S NOT THE
6 KIND OF RESULT THAT IS ENTITLED TO DEFERENCE OR ENTITLED
7 TO BE AFFIRMED BY A COURT.

8 AND FOR ALL OF THOSE REASONS WE BELIEVE
9 THE RULES ARE ILLEGAL, THAT THEY WILL CAUSE IRREPARABLE
10 HARM TO THE COMMONWEALTH, TO THE COMMONWEALTH'S
11 RESIDENTS. PUBLIC INTEREST STRONGLY FAVORS AN
12 INJUNCTION HERE, AND WE WOULD ASK THE COURT TO GRANT THE
13 COMMONWEALTH'S MOTION. THANK YOU.

14 THE COURT: OKAY. AS I SAID AT THE
15 BEGINNING OF THIS HEARING, I CONSIDERED ALL THE
16 BRIEFINGS SUBMITTED BY THE PARTIES WITH RESPECT TO THIS
17 PRELIMINARY INJUNCTION, INCLUDING THE COMMONWEALTH'S
18 MOTION FOR PRELIMINARY INJUNCTION AND ITS SUPPORTING
19 EXHIBITS, THE DEFENDANT'S RESPONSE IN OPPOSITION TO THE
20 MOTION FOR PRELIMINARY INJUNCTION, AND THE
21 COMMONWEALTH'S REPLY. I HAVE ALSO CONSIDERED THE
22 ADMINISTRATIVE RECORD SUBMITTED BY THE DEFENDANTS. I
23 ALSO WISH TO THANK THE AMICI FOR SUBMITTING THEIR
24 THOUGHTFUL BRIEFS IN THIS CASE.

25 BASED ON THESE DOCUMENTS AND AS WELL AS

1 THE DOCUMENTS I HAVE RECEIVED AT TODAY'S HEARING, THE
2 TESTIMONY I HAVE HEARD AT TODAY'S HEARING, AND THE
3 ARGUMENT I HAVE HEARD, I WILL BE ABLE TO ISSUE AN
4 OPINION IN THE TIME SCALE REQUESTED BY PENNSYLVANIA,
5 WHICH IS PRIOR TO THE BEGINNING OF THE YEAR, AND WILL
6 ENDEAVOR TO GET THAT OPINION OUT AS SOON AS POSSIBLE.

7 THANK YOU. ANYTHING ELSE?

8 MR. FISCHER: NOTHING FURTHER FROM THE
9 COMMONWEALTH, YOUR HONOR.

10 MR. DAVIS: NOTHING FURTHER, YOUR HONOR.

11 MR. GOLDMAN: YOUR HONOR, I'M SORRY. YOU
12 HAD SUGGESTED ON TUESDAY EVENING THAT YOU WANTED
13 FINDINGS OF FACT AND CONCLUSIONS OF LAW.

14 THE COURT: BASED ON WHAT I HAVE READ AND
15 WHAT I HAVE, I DON'T NEED YOU TO DO THAT. I WILL -- WE
16 WILL BE ABLE TO DO THAT INTERNALLY. I THINK YOU WERE
17 VERY CLEAR IN YOUR BRIEFS, AND I APPRECIATE THAT FROM
18 ALL SIDES. SO TO THE EXTENT THAT MY PREVIOUS ORDER
19 INDICATES A TIME FOR POST-HEARING BRIEFING AND
20 POST-HEARING SUBMISSION OF FINDINGS OF FACT, I'M
21 ABROGATING THAT PORTION IN MY ORDER. IT IS NOT
22 NECESSARY THAT YOU DO THAT. SO INSTEAD OF HAVING TO GO
23 HOME RIGHT NOW AND START WRITING, YOU CAN, I DON'T KNOW,
24 GO AND HAVE A DRINK OR SOMETHING.

25 ALL COUNSEL: THANK YOU, YOUR HONOR.

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(HEARING CONCLUDED.)

I CERTIFY THAT THE FOREGOING IS A CORRECT
TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.

DATE	OFFICIAL COURT REPORTER
	SUZANNE R. WHITE

1

INDEX PAGE

2

3

WITNESSES

DIRECT

CROSS

REDIRECT

RECROSS

4

CAROL WEISMAN

5

BY MR. GOLDMAN

55

--

105

--

6

BY MS. KADE

--

97

--

--

7

8

SAMANTHA BUTTS

9

BY MR. GOLDMAN

113

--

152

--

10

BY MS. KADE

--

146

--

--

11

12

CYNTHIA CHUANG

13

BY MS. BOLAND

165

--

--

--

14

BY MS. KOPPLIN

--

193

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XAVIER BECERRA, State Bar No. 118517
 Attorney General of California
 JULIE WENG-GUTIERREZ, State Bar No. 179277
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 Attorneys for Plaintiff State of California

[Additional counsel listed on next page]

IN THE UNITED STATES DISTRICT COURT
 FOR THE NORTHERN DISTRICT OF CALIFORNIA

**THE STATE OF CALIFORNIA; THE
 STATE OF DELAWARE; THE STATE OF
 MARYLAND; THE STATE OF NEW
 YORK; THE COMMONWEALTH OF
 VIRGINIA,**

Plaintiffs,

v.

**ERIC D. HARGAN, IN HIS OFFICIAL
 CAPACITY AS ACTING SECRETARY OF THE
 U.S. DEPARTMENT OF HEALTH & HUMAN
 SERVICES; U.S. DEPARTMENT OF
 HEALTH AND HUMAN SERVICES; R.
 ALEXANDER ACOSTA, IN HIS OFFICIAL
 CAPACITY AS SECRETARY OF THE U.S.
 DEPARTMENT OF LABOR; U.S.
 DEPARTMENT OF LABOR; STEVEN
 MNUCHIN, IN HIS OFFICIAL CAPACITY AS
 SECRETARY OF THE U.S. DEPARTMENT OF
 THE TREASURY; U.S. DEPARTMENT OF
 THE TREASURY; DOES 1-100,**

Defendants.

4:17-cv-05783-HSG

**DECLARATION OF SHARITA
 GRUBERG IN SUPPORT OF THE
 STATES' REPLY TO OPPOSITION TO
 MOTION FOR PRELIMINARY
 INJUNCTION**

ATTORNEYS FOR ADDITIONAL PLAINTIFFS

MATTHEW P. DENN
Attorney General of Delaware
AARON R. GOLDSTEIN*
State Solicitor
LAKRESHA S ROBERTS*
Chief Deputy Attorney General
JESSICA M. WILLEY*
Deputy Attorney General
Delaware Department of Justice
820 N. French Street
Wilmington, DE 19801

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KIMBERLY S. CAMMARATA*
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200 St. Paul Place
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LISA LANDAU*
Bureau Chief, Health Care Bureau
SARA MARK*
Special Counsel
ELIZABETH CHESLER*
Assistant Attorney General
120 Broadway
New York, NY 10271

MARK R. HERRING
Attorney General of Virginia
SAMUEL T. TOWELL*
Deputy Attorney General
202 North Ninth Street
Richmond, VA 23219

* Pro hac vice application forthcoming

1 I, Sharita Gruberg, declare as follows:

2 1. I am Associate Director of the LGBT Research and Communications Project at the
3 Center for American Progress (CAP). I am a lawyer with five years of experience filing Freedom
4 of Information Act requests.

5 2. On May 31, 2017, CAP submitted a Freedom of Information Act (FOIA) request to
6 the U.S. Department of Health and Human Services for all records of religious accommodation
7 requests submitted to the agency under the Affordable Care Act's contraceptive mandate. Records
8 were requested from when the Affordable Care Act went into effect to the date the FOIA request
9 was submitted and included filings made by requesting entities as well as the agency's responses.

10 3. We received 558 pages of documents from January 2014 to March 2016 in response
11 to our request. A true and correct copy of these documents is attached as Exhibit A.

12 I declare under penalty of perjury that the foregoing is true and correct of my own personal
13 knowledge.

14 Executed on December 6, 2017 in Washington, D.C.

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18 

19 Sharita Gruberg
20 Center for American Progress

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22 SA2017109209
23 52715008.docx
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28



Office of the President

September 10, 2014

Sylvia Mathews Burwell
Secretary of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room 739H
Via email to marketreform@cms.hhs.gov

Re: Valley Forge Christian College Objection to Health Care Mandate

To the Secretary of Health and Human Services:

Valley Forge Christian College has a religious objection to providing coverage of a subset of contraceptive services required to be covered under PHS Action Section 2713, as adopted by the Affordable Care Act, and incorporated under ERISA section 715 and Code section 9815.

The services for which this organization objects are the following:

We are requesting relief, based on our sincerely held religious beliefs, from the regulations issued under the Patient Protection and Affordable Care Act (PPACA) that force employers to provide, directly or indirectly, insurance plans that include potentially life threatening drugs and devices, which harm or terminate a fertilized human egg (the "Mandate"); including but not limited to:

- Ulipristal (aka Ella)
- Levonorgestrel (aka Plan B, Plan B One-Step, Next Choice)
- Intrauterine Devices (of any type)
- Abortion services except to save the life of the mother

Service Provider Information

(a) Plan Name	(b) Service Provider Name	(c) Service Provider Contact Information	(d) Service Provider Category	(e) Plan type if applicable
Valley Forge Christian College	Aetna	Karla Hellings Senior Account Manager-Established Business SEPA 980 Jolly Road U11E Blue Bell, PA 19422 215-775-7815 HellingsKJ@aetna.com	Issuer	N/A
Valley Forge Christian College	PrimePay	Brad Ramer Product Specialist/Channel Manager, HR & Benefit Services 1487 Dunwoody Drive, West Chester, PA 19335 484.913.3535 bramer@primepay.com	TPA	N/A

Information being submitted is:

☒ Original Information ☐ Updated

Contact Information: Kindly direct all correspondence related to this matter to

Don Meyer, Ph.D.
President
VALLEY FORGE CHRISTIAN COLLEGE
1401 Charlestown Road
Phoenixville, PA 19460
610.917.1402 (O)

Eligible Organization: Nonprofit entity – Christian college

VALLEY FORGE CHRISTIAN COLLEGE

By 
Don Meyer, Ph.D.
President



PH 800 230 7339
PH 717 941 2307

December 29, 2014

Honorable Sylvia Burwell
Secretary, Health & Human Services
The U.S. Department of Health and Human Services
c/o Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
Room 739H
200 Independence Avenue, SW
Washington, DC 20201

Notification of Objection

Dear Ms. Burwell:

DAS Companies, Inc. is a closely-held corporation organized in Pennsylvania. The sole shareholder of the corporation is a [REDACTED] and adheres to the tenets of his faith. As a closely-held family corporation with deep religious convictions and based on the United States Supreme Court's decision in Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (U.S. 2014), DAS objects to providing coverage of all contraceptive services required to be covered under PHS Act section 2713, as added by the Affordable Care Act, and incorporated into ERISA section 715 and Code section 9815.

DAS will continue to provide comprehensive health care plans for its employees. Based on its religious objections to the mandate to provide contraceptives, however, no form of contraceptives will be offered in the health care plans provided for its employees. The DAS health plan is the DAS Companies, Inc. PPO. It is administered by a Third Party Administrator: Highmark Blue Shield, 1800 Center Street, Camp Hill PA 17009.

Should you have any questions regarding this letter, please feel free to contact the undersigned.

[REDACTED]

Chief Financial Officer & Assistant Secretary

Corporate Office
2241 High Road
Parsippany, NJ 07054
www.das.com

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20001
Room 1381



VIA CERTIFIED MAIL & EMAIL
RETURN RECEIPT REQUESTED

March 03, 2016

Mary Hentosz
UPMC Health Plan
600 Grant Street
Pittsburgh, Pa. 15219

Re: Earth Sun Moon Trading Health Plan, Earth Sun Moon Trading Company, Inc.

Dear Ms. Hentosz,

This is to inform you that the Department of Health and Human Services (HHS) has received notice from Earth Sun Moon Trading Company, Inc. that it is an eligible organization as defined in 45 CFR 147.131(b) and that your organization is the issuer of its group health insurance coverage. Earth Sun Moon Trading Company, Inc. has notified HHS of its religious objection to the coverage of the following contraceptive services for its group health plan(s) Earth Sun Moon Trading Health Plan: "all contraceptive benefits".

As the issuer of the eligible organization's health insurance coverage your organization is responsible for complying with PHS Act section 2713(a)(4) and 45 CFR 147.131 with respect to coverage of such contraceptive services to which the eligible organization objects on religious grounds. As such, your organization is required to provide payments for such contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. You may not require any documentation or other information from the eligible organization.

Questions can be directed to marketreform@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Ackerman'.

Jacob Ackerman
Acting Director, Market-wide Regulation Division
Oversight Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room 7391



VIA CERTIFIED MAIL & EMAIL
RETURN RECEIPT REQUESTED

October 14, 2014

Andrea Meehan
Sr. Account Executive
Sales
3031C Walton Road, Ste. 201
Plymouth Meeting, PA 19462
Andrea.Meehan@ibx.com

Re: PAISBOA Plan & Trust, Holy Ghost Preparatory School

Dear Ms. Meehan,

This is to inform you that the Department of Health and Human Services has received notice from Holy Ghost Preparatory School that it is an eligible organization as defined in 45 CFR 147.131(b) and that your organization is the issuer of its group health insurance coverage. Holy Ghost Preparatory School has notified HHS of its religious objection to the coverage of all contraceptive services for its group health plan PAISBOA Plan & Trust.

As the issuer of the eligible organization's health insurance coverage your organization is responsible for complying with PHS Act section 2713(a)(4) and 45 CFR 147.131 with respect to coverage of such contraceptive services to which the eligible organization objects on religious grounds. As such, your organization is required to provide payments for such contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. You may not require any documentation or other information from the eligible organization.

Questions can be directed to marketreform@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'James Mayhew'.

James Mayhew
Director, Division of Regulations and Policy
Acting Director, Division of Compliance and Enforcement
Oversight Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room T19E



VIA OVERNIGHT MAIL & E-MAIL
RETURN RECEIPT REQUESTED

September 18, 2014

Karla Hellings
Senior Account Manager-Established Business SEPA
Actna
980 Jolly Road U11E
Blue Bell, PA 19422
215-775-7815
HellingsKJ@actna.com

Re: Valley Forge Christian College

Dear Ms. Hellings,

This is to inform you that the Department of Health and Human Services has received notice from Valley Forge Christian College that it is an eligible organization as defined in 45 CFR 147.131(b) and that your organization is the issuer of its group health insurance coverage. Valley Forge Christian College has notified HHS of its religious objection to the coverage of the following contraceptive services that for its group health plan Valley Forge Christian College: drugs and devices which harm or terminate a fertilized human egg, including but not limited to

- Ulipristal (aka Ella)
- Levonorgestrel (aka Plan B, Plan B One-Step, Next Choice)
- Intrauterine Devices (of any type)
- Abortion services except to save the life of the mother.

As the issuer of the eligible organization's health insurance coverage your organization is responsible for complying with PHS Act section 2713(a)(4) and 45 CFR 147.131 with respect to coverage of such contraceptive services to which the eligible organization objects on religious grounds. As such, your organization is required to provide payments for such contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. You may not require any documentation or other information from the eligible organization.

Questions can be directed to marketreform@cms.fhs.gov.

Sincerely,



James Mayhew
Director, Division of Regulations and Policy
Acting Director, Division of Compliance and Enforcement
Oversight Group



Office of the President

September 10, 2014

Sylvia Mathews Burwell
Secretary of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room 739H
Via email to marketreform@cms.hhs.gov

Re: Valley Forge Christian College Objection to Health Care Mandate

To the Secretary of Health and Human Services:

Valley Forge Christian College has a religious objection to providing coverage of a subset of contraceptive services required to be covered under PHS Action Section 2713, as adopted by the Affordable Care Act, and incorporated under ERISA section 715 and Code section 9815.

The services for which this organization objects are the following:

We are requesting relief, based on our sincerely held religious beliefs, from the regulations issued under the Patient Protection and Affordable Care Act (PPACA) that force employers to provide, directly or indirectly, insurance plans that include potentially life threatening drugs and devices, which harm or terminate a fertilized human egg (the "Mandate"); including but not limited to:

- Ulipristal (aka Ella)
- Levonorgestrel (aka Plan B, Plan B One-Step, Next Choice)
- Intrauterine Devices (of any type)
- Abortion services except to save the life of the mother

Service Provider Information

(a) Plan Name	(b) Service Provider Name	(c) Service Provider Contact Information	(d) Service Provider Category	(e) Plan type if applicable
Valley Forge Christian College	Aetna	Karla Hellings Senior Account Manager-Established Business SEPA 980 Jolly Road U11E Blue Bell, PA 19422 215-775-7815 HellingsKJ@aetna.com	Issuer	N/A
Valley Forge Christian College	PrimePay	Brad Ramer Product Specialist/Channel Manager, HR & Benefit Services 1487 Dunwoody Drive, West Chester, PA 19335 484.913.3535 bramer@primepay.com	TPA	N/A

Information being submitted is:

☒ Original Information ☐ Updated

Contact Information: Kindly direct all correspondence related to this matter to

Don Meyer, Ph.D.
President
VALLEY FORGE CHRISTIAN COLLEGE
1401 Charlestown Road
Phoenixville, PA 19460
610.917.1402 (O)

Eligible Organization: Nonprofit entity – Christian college

VALLEY FORGE CHRISTIAN COLLEGE

By 
Don Meyer, Ph.D.
President

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Boxen 71444



August 19, 2015

Michael Worrell
Director, Human Resources
Bingaman and Son Lumber Inc.
PO Box 247
1195 Creek Mountain Rd
Kremer, PA 17833
E-mail: mworrell@bingamanlumber.com

Re: Notification regarding religious objections to providing contraceptive coverage

Dear Mr. Worrell,

The Department of Health and Human Services (HHS) has received notice from your for-profit organization of its religious objection to the coverage of contraceptive services for its group health plan(s).

The Departments of the Treasury, Labor, and HHS recently published final rules titled "Coverage of Certain Preventive Services Under the Affordable Care Act" (July 14, 2015, 80 FR 41318), which expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services to include a closely held for-profit entity whose highest governing body has adopted a resolution or similar action under its applicable rules of governance and consistent with state law establishing that it objects to covering some or all contraceptive services on account of the owners' sincerely held religious beliefs. The regulations define a closely held for-profit entity as one that is not publicly traded and has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto. For purposes of determining ownership interests, an individual is considered to own the ownership interests owned by or for his or her family (brothers, sisters, half-brothers, half-sisters, spouse, ancestors, and lineal descendants). These family members count as a single owner. These final regulations are effective September 14, 2015 and are applicable beginning on the first day of the first plan year that begins on or after September 14, 2015.

If an organization satisfies the definition of an eligible organization as defined in 45 CFR 147.131(b), it may use EBSA Form 700 to notify the issuer or third-party administrator of its group health plan of its religious objections to coverage of all or a subset of contraceptive services. The EBSA Form 700 is accessible at:

<http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf>

Alternately, an eligible organization may notify HHS in writing of its religious objection to coverage of all or a subset of contraceptive services. The notice must include the following information, as required in 45 CFR 147.131(c): the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, including, if applicable, an identification of the subset of contraceptive services to which coverage the eligible organization objects; the plan name and type (i.e., whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. A model notice is available at

<http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Model-Notice-3-22-14.pdf>.

If your organization is eligible and would like to avail itself of the accommodation, please provide notification, using one of the two mechanisms described above, that your organization meets the definition of a closely held for-profit entity as set forth in 45 CFR 147.131(b) and include all the required information. If you have any questions regarding whether your organization qualifies for the accommodation, you may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. The rules cited above specify the process that will occur after HHS receives such a letter. Other questions can be directed to marketreform@cms.hhs.gov.

Sincerely,



Jacob Ackerman
Acting Director, Market Rules Division
Oversight Group



November 23, 2015

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue, SW
Room 739H
Washington, DC 20201

Re: Religious Objection to Providing Certain forms of Contraception

To the Secretary of Health and Human Services:

As you are well aware, Conestoga Wood Specialties, Corp., Conestoga Wood Transportation, Inc., and its owners, the Hahn family, have long objected to providing certain forms of contraception as part of their employer sponsored healthcare plan. See *Burwell v. Hobby Lobby Stores, Inc.*, 134 S.Ct. 2751 (2014) (which consolidated our appeal with that of Hobby Lobby and provided us injunctive relief from the relevant mandate). As our history in this subject demonstrates, we are an eligible, closely-held, for-profit corporation with a sincerely held religious belief. As such, we do not provide any of the hormonal drugs or IUDs but do provide barrier contraception and sterilization.

I can be reached at the address and phone number listed on this letterhead. Additionally, you can reach our Third Party Administrator for Conestoga Wood Specialties Employee Benefit Plan through Highmark Blue Shield, Attention: Jason Campbell, Lead Client Manager, 1000 Center Street 1A L4, Camp Hill, PA 17089-0089 (717) 302-2461.

Sincerely,

A handwritten signature in dark ink, appearing to read "Anthony Hahn".

Anthony Hahn
President and Chief Executive Officer

AH/mms

MODEL NOTICE

Date: 10/7/2014

To the Secretary of Health and Human Services:

The following eligible organization has a religious objection to providing coverage of ☐ all or ☒ a subset of contraceptive services required to be covered under PHS Act section 2713, as added by the Affordable Care Act, and incorporated into ERISA section 715 and Code section 9815. If the eligible organization objects to providing coverage of a subset of contraceptive services, insert a description of the services for which the eligible organization objects to providing coverage:

Plan B, which is one form of the morning-after pill.

Ella (the manufacturer uses a lower case "e") is another version of the morning-after pill.

Mirena, an IUD that changes cervical mucus.

ParaGard, which is a copper IUD.

(1) Name of eligible organization: Bingaman and Son Lumber Inc, Po Box 247 (1195 Creek Mountain rd) Kreamer PA 17833

Contact information: Michael Worrell, Director Human Resources, 570-374-1108
mworrell@bingamanlumber.com

Eligible organization is a: ☐ Non-profit entity; OR ☒ Other eligible organization

(2) Service provider information:

(a) Plan name	(b) Service provider name	(c) Service provider contact information	(d) Service provider category	(e) Plan type (if applicable)
Health America/ Health Assurance PPO \$5000 plan	PO Box 6506 Carol Stream IL 60197		☒ Employer or ☐ TPA	☐ Church plan ☐ Student plan
UPMC PPO \$5500 plan	One Chatham Center 112 Washington Place Pittsburgh PA 15219		☒ Employer or ☐ TPA	☐ Church plan ☐ Student plan

(3) Information being submitted is (check one):

☒ Original information; OR ☐ Updated information.

If updated information is being provided, specify the date upon which the updated information was, or will be, effective and what has changed:



Signature of authorized representative of eligible organization

10/7/2014

Date

Michael Worrell

10/7/2014

Typed name of authorized representative of eligible organization

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room T19H



August 19, 2015

Michael Worrell
Director, Human Resources
Bingaman and Son Lumber Inc.
PO Box 247
1195 Creek Mountain Rd
Kremer, PA 17833
E-mail: mworrell@bingamanlumber.com

Re: Notification regarding religious objections to providing contraceptive coverage

Dear Mr. Worrell,

The Department of Health and Human Services (HHS) has received notice from your for-profit organization of its religious objection to the coverage of contraceptive services for its group health plan(s).

The Departments of the Treasury, Labor, and HHS recently published final rules titled "Coverage of Certain Preventive Services Under the Affordable Care Act" (July 14, 2015, 80 FR 41318), which expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services to include a closely held for-profit entity whose highest governing body has adopted a resolution or similar action under its applicable rules of governance and consistent with state law establishing that it objects to covering some or all contraceptive services on account of the owners' sincerely held religious beliefs. The regulations define a closely held for-profit entity as one that is not publicly traded and has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto. For purposes of determining ownership interests, an individual is considered to own the ownership interests owned by or for his or her family (brothers, sisters, half-brothers, half-sisters, spouse, ancestors, and lineal descendants). These family members count as a single owner. These final regulations are effective September 14, 2015 and are applicable beginning on the first day of the first plan year that begins on or after September 14, 2015.

If an organization satisfies the definition of an eligible organization as defined in 45 CFR 147.131(b), it may use EBSA Form 700 to notify the issuer or third-party administrator of its group health plan of its religious objections to coverage of all or a subset of contraceptive services. The EBSA Form 700 is accessible at:

<http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf>

Alternately, an eligible organization may notify HHS in writing of its religious objection to coverage of all or a subset of contraceptive services. The notice must include the following information, as required in 45 CFR 147.131(e): the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, including, if applicable, an identification of the subset of contraceptive services to which coverage the eligible organization objects; the plan name and type (i.e., whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. A model notice is available at

<http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Model-Notice-8-22-14.pdf>.

If your organization is eligible and would like to avail itself of the accommodation, please provide notification, using one of the two mechanisms described above, that your organization meets the definition of a closely held for-profit entity as set forth in 45 CFR 147.131(b) and include all the required information. If you have any questions regarding whether your organization qualifies for the accommodation, you may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. The rules cited above specify the process that will occur after HHS receives such a letter. Other questions can be directed to marketreform@cms.hhs.gov.

Sincerely,



Jacob Ackerman
Acting Director, Market Rules Division
Oversight Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room 719H



August 19, 2015

John Borst
Chief Financial Officer & Assistant Secretary
DAS Companies, Inc.
724 Lawn Road,
Palmyra, PA 17078

Re: Notification regarding religious objections to providing contraceptive coverage

Dear Mr. Borst,

The Department of Health and Human Services (HHS) has received notice from your for-profit organization of its religious objection to the coverage of contraceptive services for its group health plan(s).

The Departments of the Treasury, Labor, and HHS recently published final rules titled "Coverage of Certain Preventive Services Under the Affordable Care Act" (July 14, 2015, 80 FR 41318), which expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services to include a closely held for-profit entity whose highest governing body has adopted a resolution or similar action under its applicable rules of governance and consistent with state law establishing that it objects to covering some or all contraceptive services on account of the owners' sincerely held religious beliefs. The regulations define a closely held for-profit entity as one that is not publicly traded and has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto. For purposes of determining ownership interests, an individual is considered to own the ownership interests owned by or for his or her family (brothers, sisters, half-brothers, half-sisters, spouse, ancestors, and lineal descendants). These family members count as a single owner. These final regulations are effective September 14, 2015 and are applicable beginning on the first day of the first plan year that begins on or after September 14, 2015.

If an organization satisfies the definition of an eligible organization as defined in 45 CFR 147.131(b), it may use EBSA Form 700 to notify the issuer or third-party administrator of its group health plan of its religious objections to coverage of all or a subset of contraceptive services. The EBSA Form 700 is accessible at:
<http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf>

Alternately, an eligible organization may notify HHS in writing of its religious objection to coverage of all or a subset of contraceptive services. The notice must include the following

information, as required in 45 CFR 147.131(c): the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, including, if applicable, an identification of the subset of contraceptive services to which coverage the eligible organization objects; the plan name and type (i.e., whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. A model notice is available at <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Model-Notice-8-22-14.pdf>.

If your organization is eligible and would like to avail itself of the accommodation, please provide notification, using one of the two mechanisms described above, that your organization meets the definition of a closely held for-profit entity as set forth in 45 CFR 147.131(b) and include all the required information. If you have any questions regarding whether your organization qualifies for the accommodation, you may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. The rules cited above specify the process that will occur after HHS receives such a letter. Other questions can be directed to marketreform@cms.hhs.gov.

Sincerely,



Jacob Ackerman
Acting Director, Market Rules Division
Oversight Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room 7341



VIA OVERNIGHT MAIL & E-MAIL
RETURN RECEIPT REQUESTED

September 18, 2014

Karla Hellings
Senior Account Manager-Established Business SEPA
Aetna
980 Jolly Road UIIE
Blue Bell, PA 19422
215-775-7815
HellingusKJ@aetna.com

Re: Valley Forge Christian College

Dear Ms. Hellings,

This is to inform you that the Department of Health and Human Services has received notice from Valley Forge Christian College that it is an eligible organization as defined in 45 CFR 147.131(b) and that your organization is the issuer of its group health insurance coverage. Valley Forge Christian College has notified HHS of its religious objection to the coverage of the following contraceptive services that for its group health plan Valley Forge Christian College: drugs and devices which harm or terminate a fertilized human egg, including but not limited to

- Ulipristal (aka Ella)
- Levonorgestrel (aka Plan B, Plan B One-Step, Next Choice)
- Intrauterine Devices (of any type)
- Abortion services except to save the life of the mother

As the issuer of the eligible organization's health insurance coverage your organization is responsible for complying with PHS Act section 2713(a)(4) and 45 CFR 147.131 with respect to coverage of such contraceptive services to which the eligible organization objects on religious grounds. As such, your organization is required to provide payments for such contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. You may not require any documentation or other information from the eligible organization.

Questions can be directed to marketreform@cms.fhs.gov.

Sincerely,



James Mayhew
Director, Division of Regulations and Policy
Acting Director, Division of Compliance and Enforcement
Oversight Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Center for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20260
Room 719H



VIA CERTIFIED MAIL & EMAIL
RETURN RECEIPT REQUESTED

October 14, 2014

Andrea Meehan
Sr. Account Executive
Sales
3031C Walton Road, Ste. 201
Plymouth Meeting, PA 19462
Andrea.Meehan@ibx.com

Re: PAISBOA Plan & Trust, Holy Ghost Preparatory School

Dear Ms. Meehan,

This is to inform you that the Department of Health and Human Services has received notice from Holy Ghost Preparatory School that it is an eligible organization as defined in 45 CFR 147.131(b) and that your organization is the issuer of its group health insurance coverage. Holy Ghost Preparatory School has notified HHS of its religious objection to the coverage of all contraceptive services for its group health plan PAISBOA Plan & Trust.

As the issuer of the eligible organization's health insurance coverage your organization is responsible for complying with PHS Act section 2713(a)(4) and 45 CFR 147.131 with respect to coverage of such contraceptive services to which the eligible organization objects on religious grounds. As such, your organization is required to provide payments for such contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. You may not require any documentation or other information from the eligible organization.

Questions can be directed to marketreform@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'James Mayhew'.

James Mayhew
Director, Division of Regulations and Policy
Acting Director, Division of Compliance and Enforcement
Oversight Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
110 Independence Avenue SW
Washington, DC 20201
Room T1911



VIA CERTIFIED MAIL & EMAIL
RETURN RECEIPT REQUESTED

October 17, 2014

Patricia Mayhall
United HealthCare
1110 Montlimar Drive
Suite 250
Mobile, AL 36609
Patricia_Mayhall@uhc.com

Re: Loyola University Core, Basic and Plus Plans (Policy Number 903297), Loyola University New Orleans

Dear Ms. Mayhall,

This is to inform you that the Department of Health and Human Services has received notice from Loyola University New Orleans that it is an eligible organization as defined in 45 CFR 147.131(b) and that your organization is the issuer of its group health insurance coverage. Loyola University New Orleans has notified HHS of its religious objection to the coverage of the following contraceptive services for its group health plans: Loyola University Core Plan (Policy Number 903297, Balanced - 40/1000/80% Plan 422 Modified), Loyola University Basic Plan (Policy Number 903297, Traditional with Deductible - 25/500/90% Plan 4Y4 Modified), and Loyola University Plus Plan (Policy Number 903297, Traditional with Deductible - 20/100% 3D1 Modified); all contraceptive benefits.

As the issuer of the eligible organization's health insurance coverage your organization is responsible for complying with PHS Act section 2713(a)(4) and 45 CFR 147.131 with respect to coverage of such contraceptive services to which the eligible organization objects on religious grounds. As such, your organization is required to provide payments for such contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. You may not require any documentation or other information from the eligible organization.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room 739H



VIA CERTIFIED MAIL & EMAIL
RETURN RECEIPT REQUESTED

March 03, 2016

Mary Hentosz
UPMC Health Plan
600 Grant Street
Pittsburgh, Pa. 15219

Re: Earth Sun Moon Trading Health Plan, Earth Sun Moon Trading Company, Inc.

Dear Ms. Hentosz,

This is to inform you that the Department of Health and Human Services (HHS) has received notice from Earth Sun Moon Trading Company, Inc. that it is an eligible organization as defined in 45 CFR 147.131(b) and that your organization is the issuer of its group health insurance coverage. Earth Sun Moon Trading Company, Inc. has notified HHS of its religious objection to the coverage of the following contraceptive services for its group health plan(s) Earth Sun Moon Trading Health Plan: "all contraceptive benefits".

As the issuer of the eligible organization's health insurance coverage your organization is responsible for complying with PHS Act section 2713(a)(4) and 45 CFR 147.131 with respect to coverage of such contraceptive services to which the eligible organization objects on religious grounds. As such, your organization is required to provide payments for such contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. You may not require any documentation or other information from the eligible organization.

Questions can be directed to marketreform@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Ackerman'.

Jacob Ackerman
Acting Director, Market-wide Regulation Division
Oversight Group



Office of the President

September 10, 2014

Sylvia Mathews Burwell
Secretary of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201
Room 739H
Via email to marketreform@cms.hhs.gov

Re: Valley Forge Christian College Objection to Health Care Mandate

To the Secretary of Health and Human Services:

Valley Forge Christian College has a religious objection to providing coverage of a subset of contraceptive services required to be covered under PHS Action Section 2713, as adopted by the Affordable Care Act, and incorporated under ERISA section 715 and Code section 9815.

The services for which this organization objects are the following:

We are requesting relief, based on our sincerely held religious beliefs, from the regulations issued under the Patient Protection and Affordable Care Act (PPACA) that force employers to provide, directly or indirectly, insurance plans that include potentially life threatening drugs and devices, which harm or terminate a fertilized human egg (the "Mandate"); including but not limited to:

- Ulipristal (aka Ella)
- Levonorgestrel (aka Plan B, Plan B One-Step, Next Choice)
- Intrauterine Devices (of any type)
- Abortion services except to save the life of the mother

Service Provider Information

(a) Plan Name	(b) Service Provider Name	(c) Service Provider Contact Information	(d) Service Provider Category	(e) Plan type if applicable
Valley Forge Christian College	Aetna	Karla Hellings Senior Account Manager-Established Business SEPA 980 Jolly Road U11E Blue Bell, PA 19422 215-775-7815 HellingsKJ@aetna.com	Issuer	N/A
Valley Forge Christian College	PrimePay	Brad Ramer Product Specialist/Channel Manager, HR & Benefit Services 1487 Dunwoody Drive, West Chester, PA 19335 484.913.3535 bramer@primepay.com	TPA	N/A

Information being submitted is:

☒ Original Information ☐ Updated

Contact Information: Kindly direct all correspondence related to this matter to

Don Meyer, Ph.D.
President
VALLEY FORGE CHRISTIAN COLLEGE
1401 Charlestown Road
Phoenixville, PA 19460
610.917.1402 (O)

Eligible Organization: Nonprofit entity – Christian college

VALLEY FORGE CHRISTIAN COLLEGE

By 
Don Meyer, Ph.D.
President

MODEL NOTICE

Date: 10/7/2014

To the Secretary of Health and Human Services:

The following eligible organization has a religious objection to providing coverage of ☐ all or ☒ a subset of contraceptive services required to be covered under PHS Act section 2713, as added by the Affordable Care Act, and incorporated into ERISA section 715 and Code section 9815. If the eligible organization objects to providing coverage of a subset of contraceptive services, insert a description of the services for which the eligible organization objects to providing coverage:

Plan B, which is one form of the morning-after pill.

Ella (the manufacturer uses a lower case 'e') is another version of the morning-after pill.

Mirena, an IUD that changes cervical mucus.

ParaGard, which is a copper IUD.

(1) Name of eligible organization: Bingaman and Son Lumber Inc. Po Box 247 1195 Creek Mountain rd) Kreamer PA 17833

Contact information: Michael Worrell, Director Human Resources 570-374-1108
mworrell@bingamanlumber.com

Eligible organization is a: ☐ Non-profit entity; OR ☒ Other eligible organization

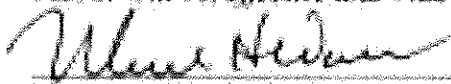
(2) Service provider information:

(a) Plan name	(b) Service provider name	(c) Service provider contact information	(d) Service provider category	(e) Plan type (if applicable)
Health America/ Health Assurance PPO \$5000 plan	PO Box 6506 Carol Stream IL 60197		☒ Employer or ☐ TPA	☐ Church plan ☐ Student plan
UPMC PPO \$5500 plan	One Chatham Center 112 Washington Place Pittsburgh PA 15219		☒ Employer or ☐ TPA	☐ Church plan ☐ Student plan

(3) Information being submitted is (check one):

☒ Original information; OR ☐ Updated information.

If updated information is being provided, specify the date upon which the updated information was, or will be, effective and what has changed.



Signature of authorized representative of eligible organization

10/7/2014

Date

Michael Worrell

Date 10/7/2014

Typed name of authorized representative of eligible organization

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF	:	CIVIL ACTION
PENNSYLVANIA, et al.,	:	
	:	
Plaintiffs,	:	
	:	
vs.	:	
	:	
DONALD J. TRUMP, et al.,	:	NO. 17-4540
	:	
Defendants,	:	
	:	
LITTLE SISTERS OF THE POOR	:	
SAINT PETER AND PAUL HOME	:	
	:	
Intervenor-Defendant.	:	

PHILADELPHIA, PA

JANUARY 10, 2019

BEFORE: THE HONORABLE WENDY BEETLESTONE, J.

ORAL ARGUMENT

APPEARANCES:

OFFICE OF THE ATTORNEY GENERAL
COMMONWEALTH OF PENNSYLVANIA
BY: MICHAEL J. FISCHER, ESQUIRE
Chief Deputy Attorney General
AIMEE D. THOMSON, ESQUIRE
Deputy Attorney General
1600 Arch Street, Suite 300
Philadelphia, PA 19103
For the Commonwealth of Pennsylvania

(CONT.)

1 APPEARANCES: (CONT.)

2
3 ATTORNEY GENERAL STATE OF NEW JERSEY
4 DEPARTMENT OF LAW AND PUBLIC SAFETY
5 BY: GLENN J. MORAMARCO, ESQUIRE
6 Assistant Attorney General
7 R.J. Hughes Justice Complex
8 25 Market St. P.O. Box 112
9 Trenton, NJ 08625-0112
10 For the State of NJ
11

12
13 U.S. DEPARTMENT OF JUSTICE
14 BY: JUSTIN MICHAEL SANDBERG, ESQUIRE
15 REBECCA M. KOPPLIN, ESQUIRE
16 20 Massachusetts Avenue NW
17 Room 7302
18 Washington, DC 20530
19 For the Federal Defendants
20

21
22 BECKET FUND FOR RELIGIOUS LIBERTY
23 BY: MARK RIENZI, ESQUIRE
24 President
25 LORI WINDHAM, ESQUIRE
Senior Counsel
1200 New Hampshire Ave. NW, Suite 700
Washington, DC 20036
For the Defendant Intervenor

18 KATHLEEN FELDMAN, CSR, CRR, RPR, CM
19 Official Court Reporter
20 Room 1234 - U.S. Courthouse
21 601 Market Street
22 Philadelphia, PA 19106
23 (215) 779-5578
24
25

(Transcript produced by machine shorthand via C.A.T.)

1 (Deputy Clerk opened court)

2 THE COURT: Good morning. Have a seat.

3 ALL COUNSEL: Good morning, Your Honor.

4 THE COURT: Okay, we're here in the Commonwealth of
5 Pennsylvania versus Trump, 17-4540, on the second motion for
6 preliminary injunction this time on the Final Rules.

7 Can I have some introductions on this side, please.

8 (Indicating)

9 MR. FISCHER: Good morning, Your Honor. Michael
10 Fischer for the Commonwealth of Pennsylvania.

11 MS. THOMSON: Aimee Thomson for the Commonwealth of
12 Pennsylvania.

13 MR. MORAMARCO: Glenn Moramarco for the State of New
14 Jersey.

15 THE COURT: Okay.

16 MR. SANDBERG: Good morning, Your Honor. Justin
17 Sandberg for the Federal Defendants.

18 MS. KOPPLIN: Rebecca Kopplin for the Federal
19 Defendants.

20 MR. RIENZI: Mark Rienzi for the Little Sisters of
21 the Poor.

22 MS. WINDHAM: Lori Windham for the Little Sisters of
23 the Poor.

24 THE COURT: Okay, I have Little Sisters of the Poor
25 or some members of the Little Sisters of the Poor in the

1 courtroom. I also have other people in the courtroom. Are
2 there any amici, other amici in the courtroom?

3 Okay, so who's taking the lead?

4 MR. FISCHER: Good morning, Your Honor. I will be
5 speaking first.

6 THE COURT: Fine.

7 MR. FISCHER: Your Honor, with the Court's
8 permission, we would like to divide the argument up on our
9 side.

10 Ms. Thomson will be speaking to issues arising out
11 of the Administrative Procedure Act, specifically, the
12 substantive and procedural violations that we allege.

13 I will be speaking to the remaining issues involving
14 standing, venue, and the scope of any injunction as well as
15 irreparable harm.

16 THE COURT: Okay.

17 MR. FISCHER: And before I begin, I would like to
18 acknowledge that the Third Circuit issued an order yesterday
19 relating to this case essentially staying the current appeal
20 while this Court resolved the pending injunction.

21 We don't think that necessarily changes anything.

22 The one aspect of the ruling that was perhaps
23 relevant is that it noted this Court could perhaps issue an
24 indicative ruling if it wished to modify the previous
25 injunction.

1 Given the timing, we do not think that is the best
2 approach. As the rules go into effect on Monday, the
3 indicative ruling takes some time, has to go back to the Court
4 of Appeals, come back here, and we would prefer just a new
5 injunction which is what we moved for.

6 THE COURT: I will be issuing a ruling.

7 I also note that the Honorable Judge Krause
8 indicated that she trusts that I will resolve Pennsylvania's
9 second motion for a preliminary injunction expeditiously and I
10 intend to do that.

11 MR. FISCHER: Yes, thank you very much, Your Honor.

12 We're here, as the Court indicated, because we have
13 filed a new injunction motion to challenge the Final Rules.

14 Approximately one year ago, this Court entered an
15 injunction blocking the Interim Final Rules, the IFRs in this
16 case, on the ground that they violated both the procedural
17 aspects of the APA and the substantive aspects of the APA and,
18 in particular, that they were inconsistent with the Women's
19 Health Amendment of the Affordable Care Act.

20 Since that time, the Agencies have issued Final
21 Rules that comport to, in their words, finalize the IFRs, but
22 very little has changed in other respects.

23 The harm that women of Pennsylvania, New Jersey, and
24 across the country will suffer remains the same. The
25 procedural and substantive infirmities of the Rules have not

1 been fixed. Pennsylvania and now New Jersey's standing is
2 very real. And for all of those reasons, we think that a
3 preliminary injunction of the Final Rules, like the one the
4 Court issued of the IFRs, is the only correct outcome of this
5 motion.

6 So I'd first like to talk about standing as well as
7 the issue of the irreparable harm that the states will suffer
8 because I think those two issues are inextricably linked in a
9 number of ways.

10 As I indicated at the beginning, not much has
11 changed since this Court's prior decision. There are,
12 however, a few relevant facts that have changed.

13 For one thing, New Jersey has now joined
14 Pennsylvania as a plaintiff in a lawsuit.

15 The second thing, we now have the benefit of the
16 Ninth Circuit's decision involving a similar challenge to the
17 Rules which held that the states there had standing, that
18 venue was proper, that the injunction was proper, although
19 limited in scope, which I will address later on.

20 And then finally, with respect to the Final Rules,
21 the Agencies have now found that their previous estimate of
22 the number of women who will be harmed was off by a factor of
23 over 100 percent.

24 As this Court noted originally, the Agencies
25 previously estimated that 31,700 women would be at risk. They

1 now estimate the number to be closer to 70,500.

2 Now, we think that goes to a number of issues that
3 are relevant to that case including the arbitrary nature of
4 the Rules, the failure to consider relevant background
5 information and to conduct a thorough investigation, but it
6 certainly more than anything shows that the states have
7 standing and the states will suffer irreparable injury in the
8 event these rules go into effect.

9 This Court previously found that the state has
10 standing. I won't belabor the arguments we made before, but
11 just to briefly summarize, we assert standing under two
12 theories.

13 The first is that women in Pennsylvania and New
14 Jersey and across the country will lose employer-sponsored
15 and, in some cases, college and university-sponsored
16 contraceptive coverage as a result of these rules. We don't
17 think there can be any real dispute about that given the
18 numbers the Defendants themselves have asserted, the numbers
19 of women they estimate will be at risk as a result.

20 Some number of those women will turn to
21 government-funded plans, whether they be Medicaid, whether
22 they be Family Planning Services Programs, or whether they be
23 Title X clinics. They'll turn to those programs in
24 Pennsylvania, New Jersey. And we submitted a number of
25 declarations from officials in both states outlining how those

1 plans work and the eligibility criteria and why it is
2 reasonable to expect that women who lose coverage under their
3 employer's plans will turn to the state-funded plans.

4 And then, finally, some number of women will be
5 forced to go without contraception entirely as we have argued
6 before and as our declarants, particularly, Professors Chuang
7 and Weisman, saying in declarations that for some women,
8 pregnancy is a life-threatening condition. For many, it's
9 contraindicated. For some, it is potentially life
10 threatening. So for them, acts of contraception is lifesaving
11 medical care.

12 But, in addition, for the women for whom pregnancy
13 is not necessarily life threatening, there will still be an
14 increase in unintended pregnancies as a result of these Rules.

15 The majority of unintended pregnancies in this
16 country, the costs are borne by public-funded programs, and,
17 in particular, I would direct the Court to the supplemental
18 declaration we submitted with our reply brief from the
19 Guttmacher Institute which goes down state by state and lists
20 the percentage of costs associated with unintended pregnancies
21 that are borne by state-funded programs in every single state.
22 And in virtually every state, the number is higher than
23 50 percent and in many states it's as high as 80 percent.

24 So if women lose coverage as a result of the Rules,
25 which we think is the inevitable result, we will see an

1 increase in unplanned pregnancies, many of those, the cost of
2 those pregnancies will be borne by Medicaid and other
3 state-funded programs that will cause harm to the states.

4 We think on that basis, both standing and the
5 existence of irreparable injury is clear.

6 THE COURT: Now, is it your position that if I
7 decide the issue in your favor on the direct injury theory of
8 standing, I don't have to address sovereign or parens patriae
9 standing?

10 MR. FISCHER: That is correct, Your Honor. And I
11 will say as the Court indicated in Your Honor's previous
12 opinion, there's this issue of special solicitude which arises
13 in Massachusetts v EPA which affects both direct standing and
14 parens patriae standing.

15 We think that direct standing in this case is very
16 clear. We also think parens patriae standing is very clear,
17 but it's not necessary to issue the second one, to address the
18 second issue particularly in light of the special solicitude
19 that the Supreme Court has directed courts to take into
20 account in addressing state standing.

21 So with that, I will now turn to the issue of venue
22 unless the Court has questions about standing.

23 THE COURT: No, that's fine.

24 MR. FISCHER: On the question of venue, the Ninth
25 Circuit reached the right result. It found that a state

1 resides everywhere throughout its borders. That's the only
2 natural understanding of the notion of state residency. Even
3 though it was a bit of an open question before the Ninth
4 Circuit ruled, we would submit that that is because there is
5 no other logical residency for a state other than across the
6 entirety of its borders.

7 As we noted in 2005, an Alabama court, the Northern
8 District of Alabama issued a ruling finding that common sense
9 dictates that a state resides throughout its sovereign
10 borders.

11 We think that makes sense and that because
12 Pennsylvania is the Plaintiff in this suit, it can file suit
13 in the Eastern District of Pennsylvania.

14 The Defendants argue that venue is not proper
15 because 28 U.S.C. § 1391 was subsequently amended with this
16 provision providing for entity residency for certain -- for
17 venue purposes.

18 The Ninth Circuit correctly rejected that argument,
19 finding that if you look at the legislative history, that that
20 provision was enacted to ensure that partnerships and similar
21 organizations were treated the same way as corporations.
22 Essentially, Congress wanted to correct this discrepancy that
23 some courts have found that partnerships -- that
24 unincorporated associations were treated differently.

25 There's nothing in the legislative history

1 indicating that that provision was intended to apply to the
2 states. And, frankly, common sense and principles of
3 federalism, which we think are at play here, would dictate
4 that it doesn't, that Congress cannot tell a state where it
5 resides. That would raise interesting constitutional
6 questions, but that, moreover, particularly without a clear
7 expression of Congressional intent, there's no reason to read
8 that statute as applying to the states. And the Ninth
9 Circuit, as I said, reached the right result on that decision.

10 As we've also argued, venue is proper because the
11 harm for the Rules will be felt in the states.

12 There are three avenues for venue against a suit
13 involving the Federal Government:

14 One, where the Plaintiffs resides.

15 Second, where the Defendant resides.

16 And then, third, where a substantial portion of the
17 events giving rise to the cause of action have occurred.

18 Because the harm will be felt in Pennsylvania, in
19 the Eastern District specifically, venue is proper in this
20 district.

21 In addition to being proper, it's because the
22 Plaintiff, Commonwealth of Pennsylvania, resides throughout
23 its borders.

24 And, finally, I would add that if the Federal
25 Government were correct that the narrow residency definition

1 under 1391 applies to the states, presumably it would also
2 apply to the United States, as well, and the United States
3 would be a resident of this district because under 1391,
4 Defendant residency is tied to personal jurisdiction in the
5 case at issue. Personal jurisdiction has not been challenged
6 here. So to the extent the United States asserts personal
7 jurisdiction of this Court, it would also be proper to assert
8 a venue under 1391(e)(1)(A).

9 That's not our primary argument. Our primary
10 argument is that the Plaintiff resides here, the Ninth Circuit
11 ruled correctly, but I think that it's worth considering that
12 if the Defendants arguably are correct, there would be this
13 anomaly where the United States would also be subject to the
14 same reasoning.

15 THE COURT: Okay.

16 MR. FISCHER: Your Honor, I'd also like to talk
17 about this issue of the scope of any injunction the Court
18 issues today.

19 I'm happy to do that now or to let Ms. Thomson
20 address the APA issues first if the Court has a preference.

21 THE COURT: I think that is an argument that should
22 be at the end.

23 MR. FISCHER: Okay.

24 THE COURT: I think it's a very important argument,
25 but why don't we turn now to the defense to address the

1 standing and the venue argument.

2 MR. FISCHER: Okay. Thank you, Your Honor.

3 THE COURT: Thank you.

4 MR. SANDBERG: Good morning, Your Honor.

5 THE COURT: Good morning.

6 MR. SANDBERG: I'll just state at the outset, and
7 then move to the specific questions the Court wanted us to
8 address, but, obviously, we think for a whole host of reasons
9 that the Court should deny the preliminary injunction in that
10 they can't establish the merits or any of the other factors
11 and I'll happily turn to the two issues the Court wanted me to
12 address.

13 As to standing, I think in the interest of brevity,
14 we're content to rest on our briefs. We continue to assert
15 and believe all the arguments in those briefs, but --

16 THE COURT: Why doesn't the law of the case apply
17 here?

18 MR. SANDBERG: Well, standing --

19 THE COURT: You're way beyond a motion for
20 reconsideration and the law of the case would generally say
21 that if I've decided the issue, absent extraordinary
22 circumstances, I shouldn't disturb that finding.

23 MR. SANDBERG: I don't think the law of the case
24 applies to the district court's rulings.

25 I think a couple of things.

1 One, it was decided at the preliminary injunction
2 stage. And courts ordinarily review the issues that they
3 decided at preliminary injunction because they're usually
4 decided in haste and there's much case law on that.

5 I'd say the second thing is jurisdiction is not
6 something that I think law of the case would normally apply to
7 because the Court is always obligated to reevaluate its
8 jurisdiction. So the Court can't say, Oh, I've decided
9 jurisdiction so I don't have to look at it again.

10 THE COURT: Okay.

11 MR. SANDBERG: Then, as I said, we're content to
12 rest on our briefs unless Your Honor -- with regard to
13 standing unless Your Honor has more specific questions.

14 THE COURT: No.

15 MR. SANDBERG: With regard to venue, I'll start with
16 the residency basis that the state alleges.

17 We think that's flawed. 1391(c)(2) states that an
18 entity, which the state certainly is, is a resident where its
19 principal place of business is when it's in the Plaintiff
20 capacity.

21 We think there's no doubt that the principal place
22 of business for the State of Pennsylvania is Harrisburg.
23 That's where the Governor sits, it's where the Legislature
24 meets, it's where many of the federal agencies are
25 headquartered. So we don't think there's any dispute about

1 that.

2 We don't think it's necessarily a matter of common
3 sense where the residency of a Plaintiff is for purposes of
4 federal venue. The venue statutes are devised for purposes of
5 a Defendant's fairness. So it's entirely in that vein, it's
6 entirely common sense to believe that it was limited. It
7 would limit Plaintiffs to its principal place of business and
8 not allow them to look around the state and pick whatever
9 venue they choose.

10 The Plaintiffs also argue in their brief that
11 permitting this argument would permit us to forum shop because
12 we could selectively assert or not assert a venue objection,
13 but that argument runs against any venue limitation, any venue
14 limitation is waived. So that would say there should be no
15 venue limitation because Defendants can always choose to waive
16 them or not waive them.

17 Clearly that's not the case. We have venue
18 limitations and it is waivable at the Defendants' discretion
19 and that's again because the venue statute is designed for the
20 fairness to Defendants.

21 And I'd like to quickly address a couple of the
22 arguments that they've raised here that I don't believe were
23 in their brief, frankly.

24 THE COURT: The federalism argument and the
25 1391(e) (1) (A) argument?

1 MR. SANDBERG: Correct.

2 THE COURT: Yes, I'd like to hear about that.

3 MR. SANDBERG: Yes. So my first objection would be
4 they don't raise those arguments in their brief.

5 My second would be -- certainly I think there's at
6 least the notion that the United States could not tell
7 Pennsylvania to move its capital. As a little physical
8 matter, it couldn't say, Pennsylvania, move your capital from
9 Harrisburg to Philadelphia. But venue is really controlled in
10 federal courts and what litigants can raise claims in what
11 federal courts. So certainly the Federal Government can
12 control sort of its federal courts.

13 And the second thing I would say is if that
14 argument's right, then if the Federal Government can't tell
15 the Plaintiff where it resides, then Pennsylvania in a case in
16 which California is not a Plaintiff could go up to San
17 Francisco and file suit saying, We reside here because the
18 Federal Government can't tell us where we reside and, you
19 know, we have -- there is somebody from the State of
20 Pennsylvania who, you know, is out in California who is an
21 emissary to the state and they do work out of here and,
22 therefore, Pennsylvania resides in California. That clearly
23 can't be the case so I think that argument fails.

24 As to the residency point, that the Federal
25 Government would be a resident, I would say there's a separate

1 statutory provision, 1391(e), that addresses the Federal
2 Government under the venue provision. There is no separate
3 provision that addresses states. And so I think for that
4 reason, I don't think it makes sense to assume that 1391(c)
5 defines necessarily where the Federal Government resides in
6 the Defendant capacity. But, again, this is an argument that
7 was not in their briefs and so if the Court would like further
8 briefing on that after we've had a chance to more fully
9 consider it, we'd be happy to provide it.

10 THE COURT: Okay. Where are we going next? Oh, I'm
11 sorry.

12 MR. RIENZI: Briefly on standing, Your Honor?

13 THE COURT: Yes. Go ahead.

14 MR. RIENZI: Thank you, Your Honor.

15 On the two issues you asked for, first, to be clear,
16 we take no position on the venue argument. That's between the
17 two sovereigns as they fight.

18 On Article III, I would just like to make a few
19 brief points since we weren't here to argue about it last
20 year.

21 The states are trying to enlist this Court in what
22 is essentially a political fight. It's a policy disagreement
23 between the states and the federal government about coverage
24 of contraception.

25 THE COURT: The courts have pretty much been

1 enlisted at this point. They've been enlisted for many years
2 so I --

3 MR. RIENZI: Well, yes, Your Honor, but I think it's
4 quite different.

5 Here there's a pretty extraordinary claim about the
6 impact on the states that is quite different from the first
7 five or six -- the first five or six years, there was no
8 standing challenge, there was no Article III question, no one
9 doubted it because the Little Sisters and other groups were
10 being directly commanded, You must do X.

11 Here the claim is, I would say, quite different.
12 The claim is that the states have the ability to enlist an
13 Article III Court to order the Federal Government to order
14 somebody else to indirectly provide contraceptives instead of
15 either the states doing it directly or the Federal Government
16 doing it directly. That's an odd proposition and it's one for
17 which they have not established the Article III standing that
18 they need.

19 And just a few brief points on why they don't have
20 the Article III standing that they need.

21 First, we're now 13 or 14 months into this case.
22 They still cannot find the first person or the first employer
23 who's planning to change their coverage based on this Final
24 Rule. That actually makes a lot of sense because the
25 religious objectors who had religious objections filed

1 lawsuits before. It's not that it's impossible that there
2 couldn't be some new religious entity that gets created or
3 something like that, but they ought to have to prove that
4 there's one. They can't find one.

5 To the extent that there are people who work for
6 these religious employers, for the most part, those employers
7 are already protected by injunctions. In other words, the
8 issuance of the Interim Rule or the Final Rule is not going to
9 suddenly yank away somebody's coverage that we need a
10 preliminary injunction if there were injunctions in place
11 before there were injunctions placed now. There's no sudden
12 rush of people who are going to show up on the state rolls.

13 The way that you know that that's true is that this
14 isn't the first time there's going to be a gap like this,
15 right. The contraceptive mandate doesn't cover -- the federal
16 contraceptive mandate doesn't cover every employer. It covers
17 the big ones. Those who have more than 50 employees are
18 required to provide this health care. It doesn't cover the
19 grandfather plans. It doesn't cover the religious employers
20 who met the Obama Administration's narrow definition of
21 religious employers. If those types of gaps were going to
22 lead to a bunch of people showing up on the state's rolls,
23 you'd see that in the declarations that are in front of you.
24 They submitted a stack of declarations that big (indicating),
25 but what they don't say and what they can't say is that as a

1 result of the injunction, Hobby Lobby, for example, they
2 suddenly had a new rush of people showing up on the rolls as
3 the result of the grandfather provision. If you like your
4 health plan, you can keep your health plan, right. That was,
5 you know, the big argument about the law over the line in the
6 first place. There's no argument that that -- even though
7 that covers millions and millions of people, no argument that
8 that landed people on the state rolls.

9 So the idea that suddenly putting into the Final
10 Rules this Religious Exemption is now -- this is the one thing
11 that's going to land people on the state rolls is farfetched
12 and the fact is they can't find a single employer, they can't
13 find a single employee. Even if they found one of those
14 things, they'd have to then connect the dots and say that
15 those people will end up on state aid programs, that they
16 qualify for state aid programs. If they have an unintended
17 pregnancy, even though these are people who, by supposition,
18 have full health coverage, we're supposed to assume that they
19 have full health insurance, but they're going to turn to the
20 state to finance their unintended pregnancy and their
21 childbirth. That's a pretty out-there kind of suggestion.
22 They ought to be required to show some proof and I'd suggest
23 they've shown no proof even though they've had lots of other
24 situations where people could have been in that position.

25 THE COURT: You talk about the Religious Exemption.

1 MR. RIENZI: Yes.

2 THE COURT: You have yet to refer to the Moral
3 Exemption.

4 Do your clients take any position with respect to
5 the Moral Exemption?

6 MR. RIENZI: Very narrowly to this extent, Your
7 Honor. If the Court were to say that the Moral Exemption is
8 valid and the Religious Exemption is invalid, then my clients
9 would show up and say, Okay, well, we also have a moral
10 objection. It's religious and moral.

11 We're not here principally to defend the moral
12 objection. I will say that we've had six or seven years of
13 this mandate so we have some pretty good evidence of the scope
14 of how many moral objectors there are out there. And to my
15 knowledge, I think there are only two in the whole United
16 States. There may be three. And I think it's one or two
17 pro-life pregnancy centers that are nonreligious pro-life
18 centers and the March for Life. That's it. In other words,
19 there is no other group.

20 On the religious side, there were dozens, if not
21 more than 100, lawsuits and probably several hundred
22 Plaintiffs in those cases nationwide. We know they're
23 religious objectors.

24 Moral objectors who aren't religious, really, really
25 narrow category we know from experience, and it's essentially

1 only openly pro-life groups.

2 So I would just say that it's presented as a very,
3 very big exemption. I would suggest to you that all the
4 experience we have shows it's going to be extremely tiny and
5 for validly pro-life groups.

6 The last one I would make on the standing and this
7 will eventually get more to the merits and I'll talk about it
8 more later, but Mr. Fischer said not much has changed in the
9 past year.

10 One thing that's changed is there have been either
11 10 or 12 additional Final Orders from other federal judges
12 across the country telling the Government that their old rule
13 violates RFRA.

14 So after Your Honor's injunction put the IFR, you
15 know, on hold so the IFR was invalid and couldn't be enforced,
16 though the Rule that took its place, the Rule I think the
17 states are going to continue arguing for today, is the older
18 Interim Final Rules and Rules from the Obama Administration.

19 What happened --

20 THE COURT: So lower courts have said that. The
21 Supreme Court has not.

22 MR. RIENZI: The Supreme Court has not, I agree.

23 THE COURT: Is there anything before the Supreme
24 Court addressing any of those cases?

25 MR. RIENZI: Not at present, no, Your Honor.

1 THE COURT: Any cert petitions? Any cert granted?

2 MR. RIENZI: No. There's no cert displayed because
3 we've won them all. In other words, there's really nothing to
4 fight about. The government -- Federal Government now admits
5 it violates RFRA. Federal judges across the country have
6 repeatedly found that there is a substantial burden, that the
7 Government has other ways to do this.

8 And I would just suggest that the more and more
9 injunctions shows there is less and less likelihood that
10 anybody is suddenly turning to the states because of the Final
11 Rule. If they're turning to the states, they'd be turning to
12 the states because there's grandfathering because the
13 contraceptive mandate doesn't cover everybody because there's
14 injunctions. They don't make any claim that any of that has
15 happened. The idea that there's somebody who slips through
16 the gap now and they are going to show up on the state rolls
17 is farfetched and I would say they have not proven it.

18 Let me stop there. I think the rest of what I have
19 to say is more merit based.

20 So if Your Honor has no questions --

21 THE COURT: I just need you to put a final point on
22 your point about the other cases have ruled that -- you said
23 prior Rules violate RFRA.

24 MR. RIENZI: Yes.

25 THE COURT: Can you describe, when you say prior

1 Rules --

2 MR. RIENZI: Sure.

3 THE COURT: -- there are many.

4 MR. RIENZI: Understood, Your Honor. I've been
5 living with the prior Rules for a very long time.

6 THE COURT: Yes. Just tell me which ones you're
7 talking about.

8 MR. RIENZI: Sure. The Rules that the IFR
9 changed -- that is the best way.

10 So the accommodation. What was at issue in Geneva
11 College. What was at issue in Geneva College.

12 THE COURT: Okay, the accommodation.

13 MR. RIENZI: The accommodation, that that set of
14 Rules was invalid, was --

15 THE COURT: For various reasons.

16 MR. RIENZI: All for the same reasons, really. All
17 for the violation of RFRA.

18 THE COURT: Okay. No, but I mean the violation of
19 RFRA was premised on different components of what one had to
20 do under the Rules.

21 MR. RIENZI: Yes. I would say the Hobby Lobby era
22 of cases for the for-profit employers was one version of it
23 and the accommodation --

24 THE COURT: And Wheaton was another and Zubik was
25 don't think about it.

1 MR. RIENZI: Yes. Everything I'm telling you about,
2 Your Honor, there's certainly plenty before Zubik, but when I
3 say 10 or 12 new ones, I'm talking about since your injunction
4 like a year ago, 10 or 12 new ones. So those were all post
5 Zubik. Essentially, there's no court in the country that
6 after the Federal Government admitted the things it admitted
7 in Zubik, there's no court in the country that has not found a
8 RFRA violation.

9 THE COURT: All right. Okay.

10 MR. RIENZI: Thank you, Your Honor.

11 MR. SANDBERG: Your Honor, I neglected in my
12 excitement to talk about residency, to discuss the substantial
13 part of the acts and omissions part of venue.

14 Could I briefly address that?

15 THE COURT: Okay. This is the last time you get
16 grace and favor, though.

17 MR. SANDBERG: Okay. Maybe I shouldn't use it now.
18 It's like a coach's challenge in football.

19 I will say that in their reply brief, the Plaintiff
20 cited a number of cases saying that where the effects are felt
21 provides a basis for a venue under the substantial part of
22 events giving rise to the claim aspect of the statute, and
23 they cite a number of cases in their reply brief, but I think
24 it's notable they don't cite any cases from this district and
25 that's because this district, the courts have repeatedly found

1 that where an effect is felt is not a sufficient basis for
2 standing under the acts and omissions part of the statute.

3 And I'm happy to provide a cite if the Court would
4 like it, but --

5 THE COURT: Okay, thank you.

6 MR. SANDBERG: -- that's my moment for grace.

7 THE COURT: Okay. So what are we moving to now?

8 MR. FISCHER: Your Honor, Ms. Thomson is going to
9 address the APA violations.

10 THE COURT: The APA violations?

11 MR. FISCHER: Yes.

12 THE COURT: And you're starting with process and
13 moving to substance, is that -- or what are we doing?

14 MS. THOMSON: Good morning, Your Honor. I'm happy
15 to go in whatever order you prefer. I was going to start with
16 the procedural violations and then turn to the substantive
17 violations.

18 THE COURT: Let's do that.

19 MS. THOMSON: Great.

20 So we believe that there are many reasons why the
21 Final Exemption Rules are unlawful and should be enjoined.
22 We're going to focus in this oral argument and we focused in
23 our motion on the APA violation, but we also retain our other
24 claims as well.

25 First of all, the Final Exemption Rule violates the

1 APA's procedural requirements because they were promulgated to
2 finalize IFRs that Your Honor previously found to violate the
3 APA. You previously held the Agency has lacked authority to
4 issue -- to bypass the APA's notice and comment requirements.
5 They were not authorized under the APA to do so, HIPPA did not
6 provide them express or implied authority, and they lacked
7 good cause.

8 Now, the APA requires in almost all circumstances
9 for Agencies to put forward proposals to the public for
10 comments, not final decisions, and this is -- and the only
11 narrow exceptions that allow an Agency to go around it are the
12 ones I just mentioned, either express statutory authority or
13 good cause, which this Court has already found the Agencies
14 lacked to issue the IFRs.

15 THE COURT: Let me just sort of set the stage
16 briefly here. I just want to clear away some brush.

17 Your argument is that the Agencies failed to respond
18 to significant comments adequately, correct?

19 MS. THOMSON: That's our second procedural argument,
20 Your Honor.

21 THE COURT: Okay.

22 MS. THOMSON: We raised two procedural arguments.

23 THE COURT: But there's no challenge to the notice
24 or any other -- or to the actual notice itself?

25 MS. THOMSON: We would argue we think that the IFRs

1 were issued without regard to notice and comment and that is
2 the law of the case as Your Honor held previously.

3 We're not challenging the specific notice aspect as
4 it relates to the comment. What we do believe, though, is
5 that the Final Rules were functionally issued in violation of
6 the APA because they did not take notice and comment as the
7 APA requires. Because what they put forward to the public was
8 a Final Decision for comment, not a proposal for comment.

9 So as you had previously held or as you recognized
10 in your prior opinion, the reason why the APA requires
11 Agencies to put forward proposals is because participants are
12 less likely to influence Agencies' thinking later in the
13 decision-making process.

14 So the APA requires Agencies to have an open mind,
15 they must put forward their thinking, take public comment, and
16 then issue a Final Decision.

17 But what happened here is the Agencies took public
18 comment on a Final Decision. As a result, the public,
19 including the Commonwealth, approached the Agencies hat in
20 hand and basically asked them to reconsider something that
21 they had already decided.

22 And I'd note that also during that time, the
23 Agencies were actually litigating in defense of the IFRs. So
24 they particularly lacked the open mind that the APA requires
25 when considering public comments.

1 Now, we think that there are several points of
2 authority that support the unlawfulness of the Final Rules.
3 Particularly, the Third Circuit case, NRDC v. EPA, in which
4 the Third Circuit functionally found that Final Rules that
5 were issued after unlawfully-issued -- not Interim Final
6 Rules, but an order issued in the absence of notice and
7 comment did not cure that violation. And the remedy that the
8 Third Circuit ordered in NRDC v. EPA wasn't -- required that
9 the Final Rule was invalidated. And we think the same
10 circumstance of NRDC v. EPA also applies here.

11 Here the Agencies issued a Final Decision, took
12 public comment on that Final Decision, and then issued a
13 second Final Decision. And that second Final Decision, which
14 we are challenging here, is still procedurally invalid under
15 the APA.

16 And, in fact, as the Third Circuit recognized in
17 NRDC v. EPA, this actually speaks to the function of what the
18 APA is supposed to do. A contrary holding here would allow
19 any Agency to issue a Final Rule in every case, take comment
20 on that Final Rule, and then -- or on whether that action
21 should continue and then issue a second Final Rule that cures
22 the process because they have taken public comment.

23 As you recognized a year ago in your prior opinion,
24 permitting post issuance commentary carte blanche would simply
25 write the notice and comment requirements out of the APA and

1 that is what we are concerned about here. So, for that
2 reason, we believe that the Final Rules are procedurally
3 improper, first, because they did not take notice and comment
4 as required by the APA.

5 We also have, as Your Honor mentioned, a second
6 procedural claim which has to do with the adequacy of their
7 consideration of public comment.

8 Now, the APA required Agencies to respond to
9 significant comments, to consider comments are all vital
10 questions of cogent materiality, to remain open-minded, and
11 engage with the substantive responses.

12 We just got the administrative record last night,
13 but we still think that there are several things on the face
14 of the Final Rules themselves that evidence the failure to
15 comply with the APA requirement.

16 Amongst other things, the Commonwealth in its
17 comments that it submitted discussed, along with many other
18 commentators, how pregnancy is contraindicated and, in fact,
19 can be fatal for some women and the Final Rules failed to at
20 all address this point.

21 More broadly, they -- the number of commentators,
22 including the Commonwealth and others, discussed how the Final
23 Rules would have a negative impact on women, whether women
24 would lose access to contraceptive coverage, and instead the
25 Final -- instead of actually engaging with the loss that women

1 will have -- that some women, at least 70,000, if not more,
2 certainly more -- they simply either minimize it by saying
3 that those women constitute simply .01 percent of the
4 nation's population or they say those women aren't actually
5 using anything. There's actually no burden on them at all.
6 It's really about relieving a burden on employers.

7 So that to us demonstrates a failure to really
8 engage with the substance of what will happen if these women
9 lose access to contraception.

10 So now those are our two procedural points. Unless
11 Your Honor has any more questions, I'll move on to the
12 substantive.

13 To Your Honor's substantive point, first and
14 foremost, the Final Exemption Rules are unlawful because they
15 violate the Women's Health Amendment of the Affordable Care
16 Act.

17 As Your Honor ruled a year ago, the ACA contains no
18 statutory authority allowing the Agencies to create sweeping
19 exemptions to the requirements to cover preventive services.

20 THE COURT: Okay, let me stop you right there
21 because this is puzzling me.

22 So on August the 1st, 2011, the Agencies issued an
23 IFR with respect to Religious Employer Exemptions, and then on
24 July 2nd, 2013, they issued the Final Rule. And there was
25 litigation about those Rules. So what you're asking me to do

1 right now is to say that there is no authority of the Agencies
2 to develop exemptions, but they've already been doing that for
3 many years and there's been a lot of litigation. So what is
4 different about this case? Has this issue been addressed
5 before by another court? Has it been decided before? You
6 know, if I write an opinion just on -- like a match to the
7 Chevron analysis and ignore everything that has gone before,
8 how does that play out in this context?

9 MS. THOMSON: Certainly I think I have two responses
10 to that, Your Honor.

11 First, this case is not about those prior
12 exemptions. I realize that that --

13 THE COURT: Well, that wouldn't really help me.

14 MS. THOMSON: Yes, I understand, but to the extent
15 that there is nothing that -- there's no order that you could
16 issue that would invalidate the prior exemptions because the
17 only thing that we are challenging are the Final Religious and
18 Moral Exemptions.

19 But more broadly we believe, as I think you found a
20 year ago, those Initial Religious Exemptions are required
21 under RFRA and so the Agencies had authority to issue those
22 exemptions from RFRA.

23 THE COURT: And those exemptions were specifically
24 made under RFRA? They were not made under any other
25 authority?

1 Was that a specific finding of the Agencies in
2 issuing the August 1st, 2011 IFRs and the July 2nd, 2013 Final
3 Rules?

4 MS. THOMSON: I can't answer that question, Your
5 Honor.

6 THE COURT: That's an important question.

7 MS. THOMSON: Certainly.

8 THE COURT: So I need someone to think about that
9 question and come up with the answer before we end here today.

10 MS. THOMSON: Okay, we'll get back to you on that.

11 THE COURT: Okay.

12 MS. THOMSON: But as to the authority of -- I'm
13 sorry, as to -- I would say that what the Supreme Court
14 recognized in Hobby Lobby is that there are certain things
15 that the Agencies are required to do.

16 I think it's reasonable to conclude that the
17 Agencies lack a compelling or have a less-than-compelling
18 interest with regard to women who work for churches. I
19 believe what they found in the original issuance of the
20 Final -- of those Final Religious Exemptions is that it's very
21 likely that women who work for churches and their integrated
22 auxiliaries are likely to share the religious views of their
23 employers.

24 I think that's a far cry from what we have here
25 where the exemptions extend to publicly-traded corporations

1 and so it is much less likely to think that women who work for
2 a publicly-traded corporation share the religious views of
3 their employers and I believe that informed the decision
4 making about the original Religious Exemption and differs from
5 the circumstance here and that differs in -- and that changes
6 the analysis which is always a case-specific situation.

7 I can continue with the discussion with the Women's
8 Health Amendment.

9 THE COURT: Go ahead.

10 MS. THOMSON: But I believe it's -- what we believe
11 is that Your Honor ruled correctly a year ago and the
12 reasoning that applied to the IFRs applies equally to the
13 Final Rules here for all the reasons that were identified
14 before that the Agencies lack authority to issue them.

15 Turning to RFRA, though, which is really, I think,
16 the crux of the Government's case here --

17 THE COURT: Well, let me talk about the -- I'm going
18 back a little bit about the taint issue.

19 Is it your understanding that no Third Circuit case
20 has presented the question of whether the procedural defect
21 that taints the original Interim Final Rule carries over to
22 the succeeding Final Rule as squarely as this one does?

23 MS. THOMSON: As squarely as NRDC does or as
24 squarely as --

25 THE COURT: As this one does. NRDC addresses it,

1 but is that the closest case or is there a closer case than
2 NRDC?

3 MS. THOMSON: I believe NRDC is what we believe is
4 our strongest authority on this point and I do think that the
5 Third Circuit was not exactly explicit, but their remedy is
6 absolutely consistent with the continuing existence of the
7 Final Rule in that case because the Final Rule that was issued
8 after taking public comment required that some amendments
9 would go into effect at a date later in time than when they
10 were supposed to and some other amendments would be
11 continually -- or further postponed.

12 What the Third Circuit ordered was that all of the
13 amendments would go into effect as of their original March 30,
14 1981 date and that is absolutely inconsistent with the
15 continued existence of the Final Rule that the EPA issued
16 there. So, by necessity, the Third Circuit invalidated the
17 Final Rule in that case.

18 THE COURT: Okay.

19 MS. THOMSON: If Your Honor has any more questions
20 about our initial argument, I can turn to RFRA.

21 THE COURT: All right. Actually, let's put RFRA on
22 hold for now. Let's go over to the defense.

23 MS. THOMSON: Absolutely. Thank you, Your Honor.

24 THE COURT: Mr. Sandberg.

25 MR. SANDBERG: So I'll start with the procedural APA

1 argument.

2 The Plaintiffs here raise a challenge under 553 that
3 they lack notice and comment. They clearly had notice. In
4 fact, the State of Pennsylvania provided a comment.

5 They argue that that notice is somehow infirm and
6 one of the things they say is that the Agency is less likely
7 to change its mind.

8 On that score, it's not clear how the Interim Final
9 Rule here and a Notice of Proposed Rulemaking differ.

10 Now, maybe if the Interim Final Rule hadn't been
11 enjoined, you could say, well, there's sort of a bureaucratic
12 inertia and reliance is built up so the Agency's going to be
13 reluctant to walk back from that.

14 Here, of course, the Interim Final Rule was enjoined
15 nearly at the outset so there's no reason to believe that the
16 Interim Final Rule here -- for some reason, the Agency is
17 going to be any less willing to change from the Interim Final
18 Rule than it would be from a Notice of Proposed Rulemaking.

19 THE COURT: Well, how do you respond to the point
20 that defense were fighting, that they went to the Third
21 Circuit, and so how could you fight a Rule and at the same
22 time remain open-minded?

23 MR. SANDBERG: Well, I will say this. To me, that's
24 akin to an argument that you sometimes see in cases about
25 whether a Plaintiff has to exhaust administrative remedies

1 before the Federal Government. And Plaintiffs have
2 occasionally, before they finished exhausting, have filed
3 cases in court and the Government's defended and the
4 Plaintiffs have said, See, the exhaustion was futile because
5 the Government rejected my argument.

6 And my understanding of those cases is that on the
7 whole, they've said you can't sort of invite the Federal
8 Government into court and then when it naturally defends
9 itself say, See, you had a closed mind and you were never
10 willing to consider my comment.

11 We can provide you in a subsequent briefing with
12 information about those cases, but my understanding is that
13 it's akin to that argument that you can't sort of drag the
14 Government into federal court and then say, See, you had a
15 closed mind because you defended against our federal court
16 too. I don't think that's true. In any case, the Rule itself
17 demonstrates that the Agency considered the comments, and this
18 gets more to the second part of their APA claim, which I'll
19 get to, to let them bleed into each other right now. The Rule
20 itself demonstrates that they considered the comments. They
21 didn't just say, We rejected this in federal court so we're
22 rejecting it here. They gave their reasoned basis for
23 rejecting the comments.

24 I'd like to next turn to the NRDC case, which is
25 obviously central to the Court's inquiry into Plaintiffs'

1 argument.

2 In NRDC, there were a number of Rules that were
3 postponed, but there were four that are essentially the heart
4 of the case because they continued to be postponed.

5 In that case, the NRDC issued an Interim Final Rule
6 and it postponed these four Rules. It then accepted comment
7 about whether these four Rules should continue to be
8 postponed. And then it issued a Final Rule saying, Yes, we're
9 going to continue to postpone these Rules. And what the Third
10 Circuit said was that was invalid because you were asking the
11 wrong question. You were asking about whether the Rule should
12 continue to be postponed, whereas if you had asked the right
13 question, if you had done this properly, the right question
14 would be should these Rules be postponed at all. So, in
15 essence, what the Agency had done is again injected reliance
16 interests into the decision in the way it otherwise wouldn't
17 have been. If the Rules had been allowed to go into effect as
18 they appropriately should have according to the Third Circuit,
19 they would have been in effect for several years and reliance
20 interests would have been built up and that would have
21 affected the analysis. Because they had postponed them, they
22 never -- those reliance interests never built up and so the
23 Agency was, in effect, answering a different question than it
24 would have had it done it appropriately the first time.

25 That's not the case here. As we've noted, the

1 Interim Final Rule asked for comment. It asked for comment on
2 the very same thing that -- what that issue in the Final Rule
3 was, whether there should be exemptions -- I'm sorry, whether
4 the Religious Exemptions should be expanded or whether there
5 should be a Moral Exemption. And there's no mismatch of
6 reliance interests for sort of the reasons I had referred to
7 earlier in that, you know, whether this ends up being an act
8 of grace or not, the Court had enjoined it so no reliance
9 interests had built up in favor of these IFRs that then put, I
10 guess in the view through the NRDC lens, an impermissible
11 thumb on the scale. If the Agency had sort of "done it right"
12 by issuing an NPRM and did it the way they did here, it would
13 have been the same thing. There was notice of the proposed
14 changes, they took comments, and then they made a decision,
15 and there were no sort of improper reliance interests that had
16 built up.

17 So as to the consideration of comments, unless Your
18 Honor has any further questions about this sort of notice
19 aspect, I would say that the Rule -- to take an example, they
20 say the Rule sort of doesn't address the impact on women and
21 there's several pages from, I think, 83 Fed. Reg. 57,555 to
22 556 or beyond where they address the sort of efficacy of the
23 mandate and what effect this will have they say more generally
24 on the women who would be subject -- who might be affected by
25 the exemption. So it's not something that wasn't addressed.

1 They clearly -- they took in the comments, they thought about
2 them, and the fact they didn't agree with the Pennsylvania
3 doesn't mean they didn't consider the comments.

4 And I think that's the strain of the argument that
5 runs through this, because they reached a different
6 conclusion, that means that they didn't adequately consider
7 the arguments, and clearly that's not what the law says.

8 Unless you have any further questions on that, I'm
9 happy to turn to the sort of substantive APA argument.

10 As to the substantive APA, I'll start with it's our
11 position that there were two bases for the enactment of the
12 extended Religious Exemption and Moral Exemption.

13 One is RFRA, which I guess we'll put off to the side
14 for now.

15 And the second is the discretion accorded to HRSA
16 through the ACA.

17 The statutory provision 42 U.S.C. § 300gg, I think
18 it's 13(a)(4), delegates, as the Supreme Court recognized in
19 Hobby Lobby, it delegates the important and sensitive task of
20 determining the scope of additional preventive care to HRSA,
21 and as we've talked about in previous briefing and the
22 hearing, it says, As provided for in guidelines supported by
23 HRSA.

24 THE COURT: Again, I just want to clear some brush
25 away here.

1 MR. SANDBERG: Sure.

2 THE COURT: It's the Defendants' position that the
3 Agency's authority to promulgate the Moral Exemption Rule
4 comes solely from the APA and not from RFRA, right?

5 MR. SANDBERG: Correct, Your Honor.

6 THE COURT: Okay.

7 MR. SANDBERG: So the Congress and the statute
8 delegated to HRSA to promulgate the Rule, and as Your Honor
9 noted, since 2011, the Agency has recognized a form of
10 Religious Exemption which has expanded over the years. And
11 the initial exemptions we cited, I think it's page 3 of our
12 brief, we cite a couple of places where the -- I think it's
13 the previous Administration created the original Religious
14 Exemption and then explained it and it did not rely on RFRA.

15 THE COURT: In any of the litigation -- I'll ask you
16 the same question I asked the Plaintiffs. Were there any
17 challenges brought under 7062(a) or 7062(c), the APA arbitrary
18 and capricious abuse of discretion? Were they all RFRA
19 challenges?

20 And, Mr. Rienzi, I know you know the answer to that.

21 I'm just asking everyone so I can get --

22 MR. SANDBERG: Can I call a friend?

23 My understanding is that they were RFRA challenges,
24 but I'm not certain about that.

25 THE COURT: Okay.

1 MR. SANDBERG: I am certain that the Agency did not
2 rely on RFRA when it enacted these original Religious
3 Exemptions.

4 As we cited in our brief, it relied on the
5 discretion afforded to it in the ACA and we, frankly, think
6 that there's no basis to distinguish in terms of the authority
7 between the authority to create the original Religious
8 Exemption and to create -- to extend this Religious Exemption
9 and create the Moral Exemption.

10 THE COURT: So the original, the August 1st, 2011
11 and the July 2, 2013 were not only RFRA, but also the
12 discretion, or just the discretion --

13 MR. SANDBERG: Just the discretion. They were not
14 RFRA.

15 THE COURT: Okay, and there was no challenge --
16 there was no legal challenge under the APA substantive
17 provisions?

18 MR. SANDBERG: That's the part I'm not certain
19 about.

20 THE COURT: Okay.

21 MR. SANDBERG: And it's entirely consistent with the
22 delegation that Congress gave the Agencies because, as the
23 Rules recite, Congress has a long history of recognizing
24 Religious and Moral Exemption in the field of health care.
25 This is something that Congress commonly does. So it's

1 entirely consistent with the delegation from Congress to make
2 regulations pertaining to health care, for the Agency to do
3 the same thing, for the Agency to recognize, you know, the
4 sort of special place that religion and objections of
5 conscience have in our country with respect to health care and
6 do the same thing.

7 And there is, frankly, no real principal basis in
8 our view to distinguish the Religious Rule exemption
9 previously granted and this one in terms of saying, Well, that
10 one was okay, but this one is not.

11 We certainly don't think, and the state doesn't
12 raise here now, we don't think there's a First Amendment basis
13 because the original one did not turn on whether any of the
14 Churches actually objected. So it couldn't -- there's no
15 plausible free exercise basis because it didn't turn on that
16 at all. And when you look to RFRA, we also don't think
17 there's a basis to distinguish between the two.

18 I think Plaintiffs here primarily relied on the
19 argument that women who work for Churches and integrated
20 auxiliaries are more likely to share the sort of religious
21 tenets of their employer than women covered by this exemption.
22 But as the Agency said in this rulemaking, they don't think
23 there's evidence to support that. The Agency looked at that
24 and concluded there isn't evidence to support that. And, you
25 know, anecdotally, you can think of religious broadcasters or

1 other entities like that which wouldn't have fallen within the
2 old exemption, but it surely seems logical to believe that
3 many of the women who worked for a small closely-held, you
4 know, religious -- for-profit religious broadcaster are going
5 to share their employer's views. So I don't think that's a
6 basis.

7 I don't think there's any basis on RFRA to say that
8 the compelling interest is different based on the likelihood
9 of shared beliefs. There's no evidence of that, certainly,
10 and the Agency found quite to the contrary.

11 So that I don't have to use grace again, I'm going
12 to turn to my colleague to make sure -- I'm told I didn't
13 screw up this time.

14 THE COURT: Mr. Rienzi, if you could answer that
15 second question I have first, that would be good.

16 MR. RIENZI: Yes.

17 THE COURT: The question is, one, the reliance of
18 the Agencies and, two, any challenges under the substantive
19 provisions of the APA.

20 MR. RIENZI: Yes. Sure.

21 So reliance of the Agency, I agree with Mr.
22 Sandberg, although I was just pulling it up on the computer
23 and it didn't get all the way there.

24 My memory of it also is that the Agencies said --
25 the Agencies did not say it would violate the free exercise

1 clause or it would violate RFRA if we applied this to churches
2 and integrated auxiliaries. Instead, they said, Well,
3 HRSA's understanding -- the one quote I have is, "In the
4 Department's view, it is appropriate that HRSA issuing
5 guidelines takes into account the effects on the religious
6 beliefs of certain religious employers." And that's 76 Fed.
7 Reg. 46,623. I believe that's from the 2011 Rule.

8 THE COURT: So they just said it's just the
9 authority that's delegated to us. We have the authority to do
10 this.

11 MR. RIENZI: Yes, and I think they were doing that
12 against the backdrop where HRSA had the discretion to not put
13 contraceptives in the basket at all. I mean, the entire
14 question was left to HRSA. So I think their view was
15 HRSA's allowed to come up with guidelines about how we're
16 going to do this, but it was completely discretionary. It
17 still remains completely discretionary what HRSA does with
18 that. I would point out, actually, HRSA's inclusion of
19 contraceptives was never the subject -- I mean, forget Interim
20 Final Rules. It was never the subject of any rulemaking.
21 It's posted on a website. That's what it was back in 2011.
22 That's what it remains today.

23 THE COURT: And so is it your position that at any
24 point, the Agency could take contraceptive services out of the
25 definition of preventive care?

1 MR. RIENZI: Yes, absolutely. I mean, I think
2 that's both straight from the ACA. That's from Hobby Lobby.
3 Your Honor's opinion from last year acknowledges that the
4 discretion was granted to HRSA to decide this.

5 They could act, for example, like Pennsylvania.
6 Pennsylvania doesn't have a contraceptive mandate for
7 employers. The Federal Government could decide, well, we have
8 lots of other ways to do this. We do it through Title X, we
9 do it through our exchanges where people can go get health
10 care. There's nothing that says the world must be the way
11 that the last Administration decided to make it in 2012 or
12 2013. They have complete discretion to do that.

13 THE COURT: Okay, so have there been any legal
14 challenges to the Rules other than on a RFRA basis?

15 MR. RIENZI: So, yes. Let me tell you what I know
16 and then be clear about what I do not know.

17 THE COURT: Yes.

18 MR. RIENZI: So the only APA decision -- at least
19 the only APA decision from a Court of Appeals that I know of
20 is the Priest for Life decision from the D.C. Circuit in
21 2000 -- probably late 2014 or it might be late 2015, actually,
22 but in the Priest for Life decision, the D.C. Circuit said
23 that third Interim Final Rule, which is the one after the
24 Wheaton College decision of the Supreme Court, they said that
25 one was fine. And I believe that was the subject of -- I

1 believe that would have been in the briefing before Your Honor
2 last year on the Interim Final Rule question.

3 THE COURT: So was there an analysis of the APA
4 substantive --

5 MR. RIENZI: Yes, but it was not -- yes. So it was
6 not on the substantive point to my knowledge. It was only on
7 is there good cause, is it a procedural cause?

8 THE COURT: Right. So as far as you're aware, there
9 has been no challenge under the substantive provisions of the
10 APA?

11 MR. RIENZI: So I'm not aware of any rulings by
12 courts on the substantive provisions. I will say that the
13 Complaints challenging those Rules tend to be long Complaints
14 with a dozen counts. They were all litigated essentially as
15 RFRA free exercise cases.

16 THE COURT: Right, but no analysis by any court on
17 that particular point?

18 MR. RIENZI: Not that I can recall.

19 THE COURT: Okay. That's what I think, but I just
20 wanted to make sure.

21 MR. RIENZI: Yes. So far as I know, no.

22 So if I can start with the -- follow the pattern
23 you've been doing, start with the procedural issues.

24 THE COURT: Go ahead.

25 MR. RIENZI: Then do the substance and then save

1 RFRA for -- it sounds like the final round.

2 THE COURT: Yes.

3 MR. RIENZI: First, let me just make a point about
4 the procedural questions before Your Honor. Does the IFR
5 taint everything after? Was it good enough looking at
6 comments and so forth?

7 Just as a threshold point, and I said a version of
8 this at the status conference, but just to reiterate it, I'm
9 obviously going to take my best run at convincing you that the
10 substantive ruling Your Honor entered last year about the IFR
11 isn't right, frankly, and shouldn't be applied here. So I'm
12 certainly going to make that argument. But if I don't change
13 your mind, if nobody changes your mind and you come away
14 firmly convinced that what you already decided is that this is
15 substantively invalid under the APA, it can't happen, can I
16 just suggest one possible path for Your Honor is to say that
17 the procedural stuff is stuff that in some ways then would
18 almost be advisory. In other words, if you've already reached
19 a conclusion that the states are entitled to an injunction
20 based on the substantive invalidity and if they're asking you
21 to reach out to relatively new, relatively unclear areas of
22 procedural law, one possible path for the Court is to say,
23 Well, based on the substantive invalidity that I already found
24 before and that I'm still convinced of, and I hope you're not,
25 but if you are, that that would be a ground to not reach out

1 and do the procedural stuff.

2 THE COURT: You've never been subject to the Third
3 Circuit's searing analysis of one of your opinions, obviously.

4 MR. RIENZI: I have not, Your Honor.

5 THE COURT: Okay.

6 MR. RIENZI: On the procedural claims, first, just a
7 note about terminology in the briefs. The states repeatedly
8 talk about post promulgation notice and comment and they cite
9 some cases that talk about post promulgation.

10 I'll just point out, I think that's a confusing term
11 in this context because if you look at the cases, what I think
12 the cases are saying, and NRDC versus EPA, I agree, is sort of
13 the outlier of the bunch, but, generally speaking, I think
14 what the cases the state cites are saying is that the post IFR
15 notice and comment doesn't make the IFR okay. In other words,
16 that the comment after the fact doesn't make the old thing
17 okay. That's what I think when courts are talking about the
18 post promulgation is not good enough, I think they're talking
19 about it's not good enough to revive the old IFR.

20 Here it's a different question because what we're
21 talking about is a comment that was after the IFR, but is
22 before the Final Rule, right?

23 So if we're looking at the Final Rule, this is not
24 post promulgation notice and comment. It's notice and comment
25 that came before a Final Rule.

1 As to the argument about how the Court should think
2 about that, I would suggest that, and you raised this a little
3 bit, if you go back and look at the transcript of everything
4 the state argued about why this Final Rule is invalid, it
5 would also invalidate the contraceptive mandate and the
6 accommodation. In other words, all of the analysis is the
7 same. You had IFRs. Those went into effect right away. They
8 were challenged in court. The Government took comments after
9 the IFRs and then said, Yes, we finalized the IFR. The Rule
10 was still effective immediately. The Government was still
11 litigating it. We, the Little Sisters, my clients, were
12 showing up hat in hand saying, Hey, guys, you issued this
13 Rule, but it's wrong. You should do something different.

14 So if that's really the Rule of Law, and I don't
15 think it is, but if that were really the Rule of Law, I don't
16 see how as the Court sitting in equity you could possibly
17 enter a ruling that says, Well, the new Rule that did that is
18 invalid and, therefore, Federal Government, I order you to
19 operate under the old Rule that came into effect by the exact
20 same process. If that process is no good, then the whole
21 thing is no good and then we've got to go back to start. But
22 it can't possibly be the case that when you're putting in a
23 contraceptive mandate, you can have IFR comment and finalizing
24 and, Hey, that's fine, but when you want to tweak it and
25 create a Religious Exemption to it, now that process is no

1 good so we're going to enforce it.

2 THE COURT: Well, but the court is a court of
3 limited jurisdiction. We deal with cases that are presented
4 to us. So if no one was presented with the earlier case --

5 MR. RIENZI: Well, I mean, I'm presenting it to you
6 now, Your Honor. You're a court of equity and they're asking
7 you to enforce that Rule.

8 THE COURT: Right, you're presenting an argument.
9 The issue of the validity of the earlier IFR is not in front
10 of me or whether the contraceptive mandate should be in or out
11 should be included in the definition of preventive services,
12 that's not in front of me, and I think that it has not been
13 challenged in this litigation.

14 I understand your clients take a different position,
15 but just maybe give me a guess from all the parties, that is
16 not at issue in this litigation?

17 MR. RIENZI: I'll just say no to the extent I'm
18 being asked -- and I'm happy to explain why I think it is at
19 issue.

20 THE COURT: Okay. Yes. Okay.

21 MR. RIENZI: I don't want to interrupt your poll.

22 MR. FISCHER: Yes, from the Commonwealth.

23 THE COURT: Right.

24 MR. SANDBERG: Just to be clear, the question is
25 whether the previous Rules not in the Complaint are at issue

1 in this case?

2 THE COURT: Correct.

3 MR. SANDBERG: Yes, our position is you'd be
4 correct, those Rules are not at issue.

5 THE COURT: They're not at issue in this case, okay.

6 So, Mr. Rienzi, you're arguing that they are and I
7 understand why. I mean, if you wanted to give me a legal
8 theory as to why --

9 MR. RIENZI: Sure.

10 THE COURT: -- an Intervenor can assert its view of
11 what the Complaint is on the Plaintiff and the Defendant, I'm
12 happy to listen.

13 MR. RIENZI: Sure, and I don't think I'm actually
14 asserting my view of what the Complaint is.

15 The Complaint asks you to reinstate a set of Rules.
16 If you don't reinstate the old set of Rules, right, if you
17 don't reinstate the old set of Rules, they don't get the
18 relief that they want.

19 The only way they get the relief that they want is
20 if you reinstate Rules that were superseded by the IFR and now
21 the Final Rules.

22 So they're asking you to enter an injunction that
23 makes the Federal Government operate by a set of Rules. I'm
24 saying that the set of Rules that they're asking you to tell
25 the Federal Government to follow is subject to all the same

1 criticisms that they're making to get you to issue that
2 ruling.

3 THE COURT: Well, I am under the impression they are
4 not asking me to issue a mandatory injunction, they're asking
5 me to issue a protective injunction. So you're reading it
6 entirely different than I am. They're saying, Stop these
7 Rules. As I understand it, they're not saying, Reimpose these
8 Rules, they're just saying, Stop these Rules.

9 MR. RIENZI: So at least as I understand it, I don't
10 think they could possibly get the relief that they're telling
11 you is irreparable, the stuff that they need done. I don't
12 think that could happen unless your order to the Federal
13 Government reinstated those Rules.

14 So I think you're sitting in equity, you're being
15 asked to issue an injunction. I don't see how you can write
16 an opinion that says, IFR Final Rules, no good, therefore, I'm
17 going to reinstate a set of Rules as IFR by filing my Final
18 Rules. I think -- I'm not sure how that works.

19 Ultimately, I would say the state's problems -- you
20 know, they say the Federal Government didn't consider the
21 comments and, again, I think the answer is the Federal
22 Government obviously considered them. They came to a
23 different conclusion than Pennsylvania in this litigation.
24 I'd say they came to a more pro-contraceptive conclusion than
25 Pennsylvania in terms of their own policies. Again, the

1 Federal Government chose to keep in place a contraceptive
2 mandate as to 99 percent of the employers in the country.
3 They could have said, Oh, the heck with it, no contraceptive
4 mandate at all. They didn't. They kept the contraceptive
5 mandate in place for 99-plus percent of employers. They did
6 create a Religious Exemption that matches a bunch of
7 injunctions that they're subject to, but the idea that that's
8 not permissible consideration out of the mouths of states, you
9 know, New Jersey does have a contraceptive mandate, but they
10 also have a Religious Exemption in their contraceptive
11 mandate. So the idea that the Plaintiffs can argue to you
12 that that sort of consideration, it could never possibly be
13 right, when they're doing it themselves strikes me as tough to
14 swallow.

15 The states also can't, on their procedural argument,
16 they can't explain how any error that they're complaining
17 about isn't harmless.

18 There's two versions of their argument, one of which
19 I'll suggest I should probably save.

20 But, first, they don't explain how the world would
21 really be different if the Government had issued a Notice of
22 Proposed Rulemaking.

23 In other words, the Federal Government has received
24 like a million comments by now on what should the scope of
25 Religious Employer Exemption be. Right, it is maybe slightly

1 off, maybe 8 or 900,000, but it is a lot of comments over the
2 past six or seven years. They've litigated the thing coast to
3 coast multiple times to the Supreme Court and never winning
4 their argument at the Supreme Court. The idea that something
5 would be different if they slapped the title Notice of
6 Proposed Rulemaking instead of IFR on the top of it doesn't
7 make any sense. They commented, everybody else commented,
8 there were comments on things the Agencies have heard a long
9 time. This is probably one of the most commented-on issues
10 any of us will ever see.

11 The argument that they are presenting that the IFR
12 taints everything that comes after would invalidate -- you
13 know, would be a very far-reaching argument. So they say you
14 can look at NRDC versus EPA and you can sort of assume that
15 what they must have been doing is killing the Final Rule. And
16 I would just say if you read it that way, then you have to
17 deal with the SORNA cases, too, Reynolds and the cases that
18 come after it, the sex offender registration cases, Reynolds
19 and the other SORNA cases that come after it, where in
20 Reynolds, the Third Circuit says, Well, the Interim Final
21 Rule, that was invalid. But then there's a bunch of cases
22 after Reynolds in which the Third Circuit upholds SORNA
23 convictions based on the Final Rule that issues after the
24 Interim Final Rule. And so that's the SORNA litigation, the
25 Reynolds case that they cite, and the ones that follow it.

1 It's also the contraceptive mandate that they are asking to
2 have reinstated here, right? It was the same thing. It was
3 Interim Final Rules finalized later. It's also, according to
4 the Government Accountability Office, about 35 percent of the
5 major regulations in the Code of Federal Regulations. In
6 other words, Agencies do this quite regularly where they do
7 Interim Final Rule, take comments, and then they finalize it.
8 If the Court were to issue a ruling that says that is invalid,
9 that would end up being a pretty far-reaching ruling. They
10 don't have anything directly that says that and that's a
11 little bit odd given how often the Federal Government does it.
12 I would suggest that that means it's probably not the Rule.
13 And, again, I don't see how we could get to a ruling that says
14 it's the Rule for parts of the contraceptive mandate, but not
15 other parts.

16 On the NRDC case, if I could just suggest two
17 distinctions from that case, two reasons why I don't think it
18 applies here. I think that was a pretty unique specific
19 situation the Court was dealing with in that case.

20 First, the time lag, and Mr. Sandberg got to this a
21 little bit, but the time lag there was really different. In
22 this case, Your Honor enjoined the IFRs I think probably
23 before they affected a single person's insurance plan. You
24 did it very promptly when the states came in and asked -- you
25 did it before January 1st which is when the plan years for

1 most people turn over. And so that interim, the effectiveness
2 of that was taken away immediately.

3 In the NRDC case, the Rules were supposed to take
4 effect in January of 1981. The Interim Final Rule on that
5 wasn't invalidated until 18 months later in July 1982 and they
6 didn't even ask for comments until like October 1981. So
7 there was a much longer period of time in which the effect of
8 these things were felt and in which they were built up and
9 ongoing in a way that's not the case here because of Your
10 Honor's swift action the last time.

11 But two other differences that the Court in the NRDC
12 case talked about that I think matter here.

13 One is in NRDC versus EPA, it was a complete
14 reversal. It was a complete reversal of policy. In other
15 words, the Rule's going to go into effect and they pulled it
16 out entirely, right, 100 percent we took away the old policy.

17 Here I would suggest that's not the case at all,
18 right? The main piece of the policy, Will contraceptive
19 coverage be required for most employers covered by this
20 mandate? Yes. They kept it in place. They kept 99 point
21 something percent of this policy in place. They did create
22 Religious Exemption, but it's nothing like the wholesale
23 taking out of another Rule that happened in NRDC and the Third
24 Circuit said that that was a reason for them to be extra --
25 I'm paraphrasing -- extra concerned or stare extra closely at

1 it because it's such a stark reversal.

2 Here I would suggest it's not a stark reversal on
3 the main policy. The main policy, they could have said no
4 contraceptive mandate, but they haven't said that. They kept
5 99 percent of it. They got the small Religious Exemption.

6 The second thing at issue in the NRDC case, there
7 was a mismatch between how the Rule got in and how the Rule
8 got out. In the NRDC case, you had a Rule that was fully
9 subject to notice and comment rulemaking and that they had
10 issued a Final Rule and it was almost at the effective date,
11 and then they killed a sort of full Notice and Comment Final
12 Rule with a quick Interim Final Rule. Right, so there was a
13 mismatch. You have something that really had been through the
14 process yanked out by something sort of quick and slapped at
15 you.

16 In this case, you have a contraceptive mandate that
17 was built on IFR after IFR after IFR, right, so you don't
18 really have that mismatch. That is the process by which the
19 thing came to be. And so the idea that the process by which
20 the thing came to be is insufficient to change it a little
21 bit, I don't think makes a lot of sense, and I think makes it
22 quite different from NRDC versus EPA.

23 And, again, I would just suggest that if the
24 Government's argument is right and the SORNA cases are wrong,
25 the contraceptive mandate itself is invalid. And even if Your

1 Honor doesn't think it's before the Court in this case, I
2 suppose we or somebody else will go bring that case here or
3 elsewhere, but it's quite an extraordinary claim by people
4 arguing that they want the federal contraceptive mandate to be
5 in place to say that you should issue a ruling that legally
6 would say that that one doesn't work either.

7 Let me pause there before moving on to the
8 substance. Is there anything else Your Honor would like me to
9 address on the procedure?

10 THE COURT: Go ahead.

11 MR. RIENZI: Okay, on the substance and, again, I
12 think I understood the Court to be saying you want us to leave
13 the RFRA arguments for the end? Okay.

14 The states have -- I'm sorry, the Federal Government
15 has discretion under the ACA. I read you that quote from the
16 Obama Administration before. 2011, '12, '13, '14. This is
17 not like a new Trump Administration invention. This is the
18 way people in the Agency on, you know, both pretty far sides
19 of the spectrum interpreting this have all understood that
20 they had some discretion to do that. They did not take the
21 view that the state said here that it was required by RFRA.
22 They didn't take the view that it was required by the free
23 exercise clause. They just said, Hey, Congress gave us
24 discretion. They said, We get to come up with the guidelines.
25 When we're doing that, we're going to take into account

1 important things. One of them is the impact on religions and
2 we're going to do that.

3 So that was sort of a unified position from Obama to
4 Trump that they had the authority to do that.

5 The idea that it would be required by something
6 else, Your Honor in your opinion last year, you said that you
7 thought it was required by the free exercise clause, that that
8 was what justified the original Religious Employer Exemption
9 that was part of the contraceptive mandate or the claim that
10 it's required by RFRA.

11 The problem with all those arguments -- I actually,
12 to be clear, I actually agree that RFRA requires these things.
13 Free exercise clause requires them not just for those
14 employers, for my clients as well. I think they require them
15 for everybody. But what you can't get to is a view of RFRA
16 and the free exercise clause that require them for integrated
17 auxiliaries and houses of worship, but not for the Little
18 Sisters and other religious employers who weren't covered and
19 here's why.

20 The argument that the free exercise clause requires
21 it is based on the idea there's some burden that the
22 Government is lifting. Well, if it were really true that the
23 accommodation is no burden at all, there would be nothing to
24 lift, right, and if it were really true that the accommodation
25 is no substantial burden at all, I don't understand how the

1 state could have the view that RFRA requires exempting
2 somebody else from it.

3 In other words, if the accommodation's no big deal,
4 you just fill out a form, Sister, hand it to somebody else,
5 and it's not your plan, right -- I don't think that's
6 accurate, but that's how it was proposed for a long time. If
7 that's not a burden, well, it's not a burden on anybody.
8 Anybody else could do the same thing. If you can't do that,
9 that's a burden for some, but not for others, depending on how
10 you're financed or how you're organized. That doesn't make
11 sense.

12 The Obama Administration's argument from the
13 beginning I think is clearly right. I think -- there's more I
14 would say, but it's clearly right that they had the
15 discretion. And the Agency here is dealing with a situation
16 -- I'll table most of this for the RFRA argument -- they're
17 dealing with a situation where they've got a discretionary
18 thing which is, Are we going to include contraceptives, on one
19 hand, and a mandatory thing, RFRA, on the other hand. And the
20 question that they have to wrestle with in this Rule is how am
21 I going to balance those two things? And the current
22 Administration has come up with what they think is the right
23 balance, which is, I'll require contraceptives for almost
24 everybody, but for people who have a valid RFRA claim, I'm not
25 going to do that, right. So their view is that instead of

1 losing these cases court by court and case by case all across
2 the country, we're just going to say people who have got a
3 religious objection don't have to do that.

4 I would say in terms of, Is that a valid way to
5 respond to comments -- I think absolutely. I think that
6 actually they had to do it, right? So I think this is the
7 other reason, it's procedurally valid.

8 Whatever you might think of any of these procedural
9 arguments, at the end of the analysis, the answer I think is
10 that RFRA required this. And since RFRA required it, you'd
11 have whatever process you want.

12 THE COURT: Don't go into RFRA.

13 MR. RIENZI: Yes. My point is just to --

14 THE COURT: I understand.

15 MR. RIENZI: -- draw the connection that --

16 THE COURT: I understand.

17 MR. RIENZI: -- the substantive argument bolsters
18 the procedural one at hand.

19 Thank you, Your Honor.

20 THE COURT: Okay, quick response from Plaintiff.

21 MS. THOMSON: Okay, Your Honor, I'll just first --
22 we've done some preliminary research into looking into the
23 2011 and 2013 in response to your question.

24 My understanding is in 2013, they did a search that
25 was not based on RFRA. In 2011, it appears to be as the

1 intervenors.

2 We would need -- if you would like a greater
3 discussion of this, we'd request the opportunity to file a
4 short supplemental brief that discusses it. However, I do not
5 think that it is necessary to your decision or really
6 necessary to the holding to the RFRA resolution in this case
7 for several reasons.

8 One, as I stated before, we're not challenging the
9 prior Religious Exemption or the accommodation. We are
10 challenging the current Moral and Religious Exemption. So
11 nothing that Your Honor can do can affect -- can order those
12 to be invalidated in any way. That's for a future lawsuit, if
13 one at all.

14 Second, Agencies assert authority all the time in
15 the things that they issue, and as you've observed and as
16 appears to be the case, no one has ever challenged a prior
17 Religious Exemption for an excess -- for being outside of the
18 Agency's statutory authority. So whether or not they claimed
19 that authority in the regulations is not necessarily
20 indicative of whether they actually had the authority because
21 no Court has ruled that they had or did not have the
22 authority.

23 However, it seems clear from the Supreme Court in
24 Hobby Lobby that RFRA does require the Agencies to take steps
25 where -- because the mandate imposed a substantial burden on

1 certain religious objectors, to seek out the least restrictive
2 means of satisfying a compelling Government interest.

3 For most people, the Government decided that was the
4 accommodation. For churches and their integrated auxiliaries,
5 the exemption seemed to be the choice that they made.

6 However, we're not here to defend those choices because we're
7 here to challenge the decision made by the current
8 Administration to issue the Religious and Moral Exemption.

9 So although we're happy to brief those things --

10 THE COURT: No, I don't need any briefing on it.

11 MS. THOMSON: Okay.

12 THE COURT: Because I agree, it's the elephant in
13 the room and I just have to understand it.

14 MS. THOMSON: Absolutely.

15 Second, so speaking to the numerous points made by
16 the defense intervenors about the NRDC opinion, I would first
17 note that we are not asserting that all IFRs are per se
18 invalid. We're saying that IFRs that are issued that do
19 not -- either in the absence of statutory authority or the
20 absence of good cause would therefore impermissibly taint a
21 Final Rule. However, impermissibly tainting a Final Rule is
22 also one way of looking at it. We're challenging the Final
23 Rules from the point that the Final Rules fail to go through
24 the notice and comment procedure required by the APA, which is
25 that an Agency put forward a proposal, accept comment, and

1 then issue a Final Rule. So it's not simply that they took
2 comment. What they take comment on has to be something about
3 which the Agency has an open mind because it's a proposed
4 change.

5 And I would note here, as you observed a year ago,
6 the Final Rules like the IFRs are a sweeping change compared
7 to what had existed previously. There had -- yes, there were
8 hundreds of thousands of comments on Religious Exemptions
9 before, but nowhere had the Federal Defendants previously
10 indicated that they planned to exempt for-profit
11 publicly-traded companies, for example, or that they planned
12 to create a Moral Exemption. They instead dropped that in
13 October 2017 without a chance for comment and those went into
14 effect immediately. And those Interim Final Rules were in
15 effect for about three months until you enjoined them. That
16 was for almost the entire duration of the comment period. The
17 entire time the public approached the Agencies to issue
18 comment, the Rules were in effect and that's really what the
19 Third Circuit in NRDC was concerned about. They were
20 concerned about writing the notice of comment provision out of
21 the APA because the APA envisioned giving the public an
22 opportunity to approach an Agency that hasn't yet made up its
23 mind. And here by issuing an IFR and not taking comment, the
24 public was deprived of that opportunity and the Final Rules,
25 by finalizing that, did not follow the process.

1 I think that actually -- unless you have any further
2 questions.

3 THE COURT: No, I'm fine.

4 Okay, so what we're going to do, we've been going
5 for about an hour and 20 minutes. We're going to take a
6 ten-minute break.

7 When we come back, we'll talk about RFRA, we'll talk
8 about the remedy, the national injunction, the scope of the
9 injunction, and if you want to talk about irreparable harm,
10 balance of the equities and public interest, that's fine, but
11 my focus is going to be on RFRA and the scope of the
12 injunction.

13 (After recess:)

14 THE DEPUTY CLERK: All rise.

15 THE COURT: Have a seat. Okay, let's move to RFRA.

16 Before we get there, I have just one
17 clearing-the-brush question.

18 Ms. Thomson, in Count Two of your Complaint, you
19 allege the Rules violate Title VII of the Civil Rights Act and
20 the Pregnancy Discrimination Act. In your briefing, though,
21 you argue, "Because the Rule authorized illegal conduct,
22 meaning conduct that violates Title VII and the PDA, the Rules
23 are not in accordance with law and they must be held unlawful
24 and set aside," and then you cite the APA.

25 Is Count Two then an independent cause of action

1 under Title VII or the PDA or an alternative argument as to
2 why the Rule violates the APA, or both?

3 MR. FISCHER: Your Honor, if I may respond to that?

4 THE COURT: Yes.

5 MR. FISCHER: It is an independent count. We have
6 today focused on other counts, the two primary counts being
7 our procedural APA count and then our substantive count as it
8 relates to authority to issue the injunction -- I'm sorry, the
9 authority to issue the exception as well as to the arbitrary
10 nature of some of the changes.

11 We have not focused on that. We did include it in
12 our earlier briefing. And, again, as we indicated at the
13 prior hearing, we don't believe it's necessary to get into the
14 constitutional or, in that case, the Title VII claim if the
15 Court focuses on the two primary --

16 THE COURT: Okay, but you do in your briefing
17 suggest that it adds weight to your argument.

18 MR. FISCHER: Yes. Absolutely.

19 THE COURT: Okay. Okay.

20 MR. FISCHER: Thank you, Your Honor.

21 THE COURT: Go ahead.

22 I notice my sign was not up so you probably had no
23 idea who you were speaking to.

24 Go ahead.

25 MS. THOMSON: Thank you, Your Honor.

1 So as the Government has admitted, only the
2 Religious Exemption Rule can be justified by RFRA. However,
3 RFRA provides no support because the Final Religious Rule is
4 neither required nor authorized by RFRA.

5 Now, in Hobby Lobby, the Supreme Court held that the
6 contraceptive mandate violates RFRA only because it is not the
7 least -- it was not the least restrictive means of
8 accomplishing a compelling Government interest and Justice
9 Alito in that opinion looked to the accommodation as a lesser
10 restrictive means that satisfied the compelling Government
11 interest, but also would have not been as burdensome on the
12 religious objections of the Plaintiffs in that case.

13 Now, the Agencies up until the issuance of the IFRs
14 had consistently concluded that the accommodation did not
15 impose a substantial burden at all on religious practice.

16 Eight out of nine Courts of Appeal had agreed with
17 them, including the Third Circuit in Geneva College, and
18 although that opinion was vacated, it was not vacated on the
19 merits, and the reasoning of that opinion I think is
20 persuasive as to why the accommodation, which simply requires
21 an entity to say, I am not going to provide coverage, does not
22 actually involve a burden, much less a substantial burden.

23 However, in issuing the Final Rule, the Agencies
24 reversed their position and determined -- and concluded that
25 the accommodation does now pose a substantial burden under

1 RFRA.

2 Now, we have agreed Agencies are allowed to change
3 their policy position, however, the Supreme Court has held in
4 Navarro and Fox Television Stations that the APA requires the
5 Agency to give good reason to do so, and when there are
6 reliance issues engendered by the prior policy position, the
7 Agency must give an even more reasoned explanation.

8 Here, pursuant to the Final Rules, more than half a
9 million women were working for entities that used the
10 accommodation in 2017. That is a significant reliance
11 interest. So they're required to provide not simply an
12 explanation, but a more reasoned one. However, in the Final
13 Rules, they provide no explanation at all. They simply say
14 that because some people have a sincerely-held religious
15 objection to the accommodation, that is per se a substantial
16 burden. However, this -- the Third Circuit has held in Geneva
17 College, but also in Real Alternatives, which is still binding
18 on this Court, that whether or not something is a substantial
19 burden is a question of law. And in Geneva College, it spoke
20 whether or not it's a burden and whether that burden is
21 substantial. These are both questions of law.

22 And while the Court must defer to the sincerity of
23 someone, of an entity to religious beliefs, they do not have
24 to defer to that entity's claims that the burden exists or is
25 substantial. That requires an objective analysis of the

1 nature of the burden.

2 The Agencies in reversing their position made no
3 attempt to engage at all with that position to engage with the
4 analysis that Geneva College and eight of the nine other
5 Courts of Appeals had done in determining that the
6 accommodation was not a substantial burden. And so as a
7 result, under Navarro, I think is the most on point, because
8 they reversed their position so abruptly without any
9 explanation, that invalidates the Final Rule. They have to
10 provide something to do that.

11 However, we also believe that they reversed their
12 position -- they also reversed their position on whether or
13 not they had a compelling interest to enforce the mandate.
14 They did provide reasons, however, the reasons don't match up
15 with what it is that they reversed their position on. They
16 say they actually haven't reversed position on whether the
17 entire mandate generally is a compelling Government interest,
18 but simply on whether they have a compelling interest in
19 enforcing the mandate against objecting entities. However,
20 none of the reasons that they offer, that HRSA has discretion
21 or that there were prior gaps, et cetera, none of those match
22 on to why a lack of compelling interest in enforcing the
23 mandate against objecting entities and why the women who work
24 for those objecting entities, which, again, can be a
25 publicly-traded corporation or an organization that has a

1 moral objection, why those women do not deserve access to
2 federally-mandated preventive health care or should not get
3 access to federally-mandated necessary preventive health care.
4 And so their failure to offer reasons on that reversal is also
5 a violation of the APA substantive requirements and also shows
6 that their invocation of RFRA generally is arbitrary and
7 capricious. And we would note that contrary to what the
8 Intervenor said earlier, the Agencies were not faced with a
9 choice between whether to cover contraception and whether to
10 respect the religious views of objectors.

11 HRSA has included contraception in its Guidelines
12 since 2011. They reaffirmed that in 2016. Contraceptive
13 coverage is the law. It is required.

14 In Zubik, the Supreme Court in Zubik recognized this
15 when they ordered the Agencies to come to a solution that both
16 tried to accommodate the religious objections of the lawyers
17 and also ensure that women had access to full and equal health
18 coverage including contraceptive care.

19 The Agencies here in issuing the moral religious
20 Final Rules have claimed RFRA, but they have done so only
21 taking -- only following one side of the Supreme
22 Court's order. They have completely issued any opportunity to
23 try to ensure that the women who work for objecting entities,
24 who will claim the religious objection, will have any access
25 to contraceptive coverage as required by the Women's Health

1 Amendment.

2 So, for that reason, we believe that -- for those
3 reasons, we believe the Agencies' attempt to justify the
4 Religious Exemption Rule with RFRA is invalid.

5 THE COURT: Okay. Let me hear from the Government
6 on RFRA, and before you start, I have a question designed to
7 try to understand what the baseline for the Government's
8 position is.

9 Is it Defendants' position that RFRA is an
10 affirmative grant of authority to Agencies to promulgate
11 generally applicable regulations such as the Final Rules?

12 MR. SANDBERG: Let me think of the best way to
13 answer that.

14 I think the best way to answer that is that RFRA is,
15 in a sense, integrated into all federal statutes. Congress
16 had -- the way Congress enacted RFRA was that it applied
17 unless specifically exempted.

18 So you can think of RFRA as a part of every federal
19 statute that the Agencies have to comply with. Just like when
20 they issue a Rule, they can't violate the First Amendment or
21 the Fourth Amendment or the Sixth Amendment. It's a
22 background norm that the Agencies have to comply with.

23 It's not our position that RFRA independently gives
24 an Agency the ability to necessarily make Rules, but that in
25 making the Rules that it's authorized to do so, it has to

1 comply with RFRA, like I said, just like it has to comply with
2 the Constitution or any other sort of federal statutes that
3 there are like RFRA that may sort of be background norms, for
4 lack of a better term.

5 THE COURT: Okay, so RFRA speaks explicitly in terms
6 of being a judicial remedy. So given that it speaks in terms
7 of judicial remedy, I would at least on the surface read that
8 as if an entity has a concern with an Agency Rule, it would
9 seek a judicial remedy in order to change that Rule.

10 So given that reading, and I'm not suggesting that
11 that is the final reading that I will reach, it's just a
12 possible reading, if that were the reading, where is the
13 authority for regulatory bodies to issue Rules based on RFRA?

14 MR. SANDBERG: Well, I mean, if -- like to the
15 extent that assumes the conclusion, if you're going to say
16 RFRA only allows courts to do something and doesn't allow --

17 THE COURT: Well, I'm just looking at the language
18 of RFRA.

19 MR. SANDBERG: Yes.

20 THE COURT: It speaks explicitly in terms of a
21 judicial remedy. So that would suggest that rather than it be
22 a grant of authority to the Agencies, it is a remedial statute
23 which can be taken advantage of if someone objects to a
24 particular Agency Rule.

25 MR. SANDBERG: It certainly is that, but I guess our

1 position is it's not only that. We don't think that
2 Agencies -- that it makes sense that Agencies should be able
3 to issue or should go around issuing regulations without
4 considering RFRA, thinking, Oh, I'll wait until someone sues
5 me under RFRA.

6 We do think that RFRA provides Agencies the
7 authority to certainly -- and requires them to take it into
8 consideration and to not impose regulations that, you know,
9 impose a substantial burden unless the other two parts of the
10 RFRA analysis are met.

11 THE COURT: Okay. So let's keep along this pathway.
12 If Agencies are required to take into account the RFRA rubric,
13 at some point presumably there has to be an analysis of
14 whether a RFRA violation has occurred or an analysis of how to
15 draft a particular Rule in order to avoid a RFRA violation.
16 Is that fair to say?

17 MR. SANDBERG: Yeah, I mean it's fair to say if
18 you're going to consider RFRA, you have to consider RFRA.

19 THE COURT: Right. So as a court, I must take into
20 account an Agency's expertise in determining how to view a
21 particular Agency Rule. But what expertise do any of the
22 Agencies here have on RFRA?

23 MR. SANDBERG: Well, I mean, on that score, I don't
24 know that any Agency -- I mean, that would be an argument that
25 every Agency should go around, you know, ignoring RFRA.

1 There may be some. There may be some sort of small
2 agencies, you know, designed for the point of their religious
3 fluidity. But on that score, there would be definitely scores
4 of Agencies that would be, I guess, empowered or designated to
5 go around violating RFRA. I mean, if you think about the
6 Constitutional backdrop, like presumably Agencies can't issue
7 Rules that violate the Constitution. Like are these Agencies
8 experts in the Constitution.

9 THE COURT: Well, I accept that --

10 MR. SANDBERG: That's --

11 THE COURT: -- yes, that's a different issue.

12 MR. SANDBERG: I don't know that it is. I mean, the
13 Constitution, the First Amendment, raises speech issues,
14 religion issues. I don't know that it is a different issue
15 to the extent RFRA is written in by Congress as a background
16 norm that Agencies have to consider.

17 And Agencies, of course, have many lawyers and
18 access to the Department of Justice so I don't think that it
19 makes sense to say -- especially in the realm of health care,
20 frankly, where Congress has recognized that it raises -- that
21 it repeatedly recognizes it raises religious and moral issues
22 and has created exemptions. So I don't think it's in any way
23 anomalous to say that HHS, which is obviously charged with
24 making recommendations about vast swatches of this
25 nation's health care system, sort of lacks the necessary

1 expertise to consider those kinds of issues.

2 THE COURT: So let's say tomorrow the EPA issued an
3 exemption to the Clean Air Act, which is based solely on RFRA,
4 because they determined that climate change is something that
5 is a God-ordained situation, and that for the Rule, they're
6 going to take into account the fact that it is God either
7 showing us a different way or punishing us for whatever we
8 have done. Would that be appropriate?

9 MR. SANDBERG: Well, you'd have to -- as you said,
10 if you're going to consider RFRA, you have to consider RFRA.

11 So if there were a reason to believe that there were
12 individuals whose religious beliefs had been substantially
13 burdened as a result of some government action or some
14 government program, then you would move through the next steps
15 of the analysis.

16 So, you know, I can't say in the abstract whether --
17 I can't say in the abstract the EPA can never issue a Rule
18 that, you know, creates an exemption, for lack of a better
19 term, on the basis of RFRA.

20 THE COURT: So let me just get the terms right.
21 It's either a background norm or -- RFRA is either a
22 background norm or an affirmative grant of authority.

23 Is it -- and, well, let's put that on a continuum.

24 Let's put on one end of the continuum the background
25 norm and on the other end of the continuum affirmative grant

1 of authority.

2 Where in your view does RFRA fall?

3 MR. SANDBERG: Well, I -- and I use background norms
4 just to the extent that I mean it's sort of woven into the
5 fabric of every statute given that Congress says it applies
6 unless it is specifically exempted by that statute.

7 And as to affirmative grant of authority, I think
8 it's an affirmative grant to the authority to the extent an
9 Agency issuing a Rule certainly can consider its obligations
10 under RFRA and what could occur under RFRA.

11 I don't take the position that it independently
12 authorizes rulemaking.

13 I mean, here the Agencies have authority to
14 implement the ACA and part of implementing the ACA was
15 devising the meaning of preventive, additional preventive
16 services. So certainly they have the authority to promulgate
17 Rules about the meaning of additional preventive services.
18 And so our position is simply that given that they have that
19 authority to do that, it's entirely consistent with the way
20 RFRA is drafted and it's, in fact, their obligation to
21 consider the terms of RFRA and what it requires of Agencies.

22 THE COURT: Okay. So can the Agencies point to any
23 instance outside the Women's Health Amendment where an Agency
24 has relied on RFRA alone to issue a generally applicable
25 regulation?

1 MR. SANDBERG: Well, again, they don't rely on RFRA
2 alone despite the hypothetical. Again, they rely on the
3 rulemaking ability to --

4 THE COURT: Okay, well, thank you for that friendly
5 amendment.

6 Can you think of any instance where outside this,
7 the Women's Health Amendment and the regs, where an Agency has
8 relied on RFRA at least in part to issue a generally
9 applicable regulation?

10 MR. SANDBERG: I'm not -- but, again, two important
11 notes to that.

12 One is, as you know, the number of federal
13 regulations are copious and I'm not going to stand up here and
14 pretend to be an expert in every federal regulation that's
15 been issued.

16 And the second here is that the history of this case
17 gave them particularly good reason to do so. You know, the
18 original exemption was issued and then the accommodation and
19 then there was years of litigation about who the accommodation
20 would apply to. And, you know, Hobby Lobby comes down and
21 says it applies to closely held for-profit companies and then
22 there's more litigation and dispute about how that
23 accommodation should work and whether folks should have to
24 send their sort of notices directly to the Government or
25 whether they have to send it to insurers or they have to send

1 it to the Government. So there's litigation about that. And
2 there's more litigation about are people substantially
3 burdened by the accommodation itself, which we think they are,
4 but then there was litigation about that which resulted in the
5 Zubik case and the related cases.

6 So here there was, I mean, special reason for the
7 Agency to do that and I'm not aware of any instance -- it
8 doesn't mean it hasn't happened before and that if it hasn't
9 happened before doesn't mean it's appropriate. I mean, I
10 think this case demonstrates why it's appropriate.

11 And just a note on the Zubik order, the Zubik order,
12 I think contrary to the suggestion of counsel on the other
13 side, did not dictate any results on the merits. It didn't
14 say that, you know, any broader exemption was inappropriate.
15 It was a remand to try to get the -- in the hopes that the
16 parties could find an accommodation that would work for sort
17 of everyone, for lack of a better term.

18 And as this Court I'm sure knows, in January 2017,
19 the previous Administration essentially said, you know, We
20 thought about this. We tried really hard. We're not aware of
21 any other accommodation that's going to suit everyone's needs.

22 And so I think that goes a long way to supporting
23 our argument that RFRA authorizes what happened here. If it
24 doesn't, you have Agencies in this untenable position where
25 they have to try to hit the exact right target and then face

1 years of litigation as they try to find that exact right
2 target.

3 I know we had a colloquy about this at the last
4 hearing I recall extensively so I won't go too much into that,
5 but that's the very reason why the RFRA authorizes argument
6 makes sense.

7 As the Court recognized in Ricci, and I remember
8 there was an extended colloquy about the applicability of
9 Ricci, but we think that the Court recognized in Ricci that
10 entities should have some leeway in determining the best way
11 out of navigating these conflicting legal obligations and they
12 would be conflicting here if the Court rejected our argument
13 that the ACA gave the authority for HRSA to create the
14 exemption just purely out of delegation and there would be
15 this conflict between what the ACA requires and, in our view,
16 what RFRA requires. And the Court said for that framework to
17 apply, you have to have at least a strong basis in evidence to
18 believe in this case that you'd be subject to liability under
19 RFRA.

20 And we think that certainly is the case here as to
21 substantial burden. There is one Court of Appeals certainly
22 that has found it a substantial burden, and while that opinion
23 was vacated on -- for reasons other than the merits, certainly
24 there's a reason to believe at least in those seven or eight
25 states in the Eighth Circuit the Government would face

1 liability and we think that's more than enough to say that
2 there's a strong basis or at least there would be substantial
3 burden. We think that's more than enough reason to believe
4 that they have a strong basis to believe that they face
5 liability under RFRA.

6 And an additional fact is if you look at the
7 reasoning of Hobby Lobby, there was an argument there about
8 whether the Plaintiffs there were properly understanding the
9 religion in terms of innocent -- whether acts are innocent and
10 when they're complicit in bad behavior. And the Court said,
11 Hey, it's not our job to draw that line to determine, you
12 know, when people are appropriately drawing the line between
13 innocent acts and acts that enmesh them, make them complicit
14 in behavior they think violates their religious tenets.

15 So given that line of reasoning which, contrary to
16 my friend's argument, is certainly in the Rule -- and I want
17 to mention as an aside, that argument backs a little more into
18 APA arguments about whether the Agency sort of had properly
19 addressed certain comments or made certain findings. We
20 certainly think they had so I'm trying to focus more here
21 specifically on the RFRA sort of as an objective matter and
22 not on the extent to which the Agency made the necessary
23 findings for RFRA. We think they did and I'm happy to address
24 that, that sort of aspect.

25 So that goes to the substantial burden point and

1 that applies both -- you know, we think there's a strong basis
2 in evidence with a substantial burden which relates to our
3 RFRA authorizes argument.

4 As to our RFRA requires argument, we think, in fact,
5 there is a substantial burden for the reasons I've said.

6 And then the other portion of our analysis is that
7 the Agency concluded that there was no compelling interest in
8 applying the mandate to this -- to these objecting religious
9 employers. And I think a key component of that analysis is
10 the number of exemptions that already exist to contraceptive
11 coverage under the Affordable Care Act.

12 The Affordable Care Act did not require
13 contraceptive grandfathered plans to cover contraceptive
14 coverage, and I don't know exact numbers, but based on the
15 Rule suggests that there's millions -- there's millions of
16 women covered by plans that do not require contraceptive
17 coverage.

18 The ACA still doesn't require it and I will back
19 step and say the ACA did, however, require grandfather plans
20 to cover certain other aspects of reform that it thought were
21 particularly important, but it did not include concept of
22 coverage as one of those sort of reform provisions that needed
23 to be included in grandfathered plans.

24 There's also a small employer exemption. So if
25 there's a woman who works for an employer with less than 50

1 employees that does not offer health care coverage, and
2 they're not obligated to offer health care coverage, then that
3 woman also does not have contraceptive coverage.

4 And then the Rules refer to basically an indirect
5 exemption, which is if they're self-insured church plans, they
6 -- so called self-insured church plans that use the
7 accommodation, the only way to enforce the accommodation is
8 under ERISA, and under ERISA, self-insured church plans are
9 sort of exempt from that.

10 So there was, in a sense, no way to enforce the
11 accommodation against self-insured church plans so they had
12 sort of a de facto exemption.

13 So there's just a number of -- there's a number of
14 categories in which women aren't covered, which the estimate
15 is probably that covers millions of women. Millions. Those
16 exemptions cover millions of women. So there's millions of
17 women who are not covered by the contraceptive coverage
18 mandate. And the Supreme Court has recognized that when
19 there's a supposedly compelling interest, you have to look at
20 the scope of that coverage and whether there are significant
21 swatches of behavior of people that are not covered. And here
22 having millions of women covered certainly makes it --
23 certainly we think decimates the argument that there's a
24 compelling interest.

25 The Agency laid out other bases for its conclusion

1 that there's no compelling interest.

2 Congress, as I said, did not obligate HRSA to cover
3 contraceptives. It did not state explicitly that
4 contraceptives need to be covered.

5 And then the Agency evaluated evidence and
6 determined, based on its review of evidence, that there was no
7 compelling evidence to require the coverage of contraceptives
8 and that it was a compelling interest with regard to these
9 objecting employers.

10 And the last point I would make, hopefully at my
11 colleague's suggestion, is that we're not aware of any Court
12 that has found a compelling interest when the Government has
13 not articulated a compelling interest in the case.

14 If the Court has no further questions.

15 THE COURT: Okay.

16 Mr. Rienzi.

17 MR. RIENZI: Thank you, Your Honor.

18 If I could just work backwards from a couple of
19 things that came up in your questioning of the two lawyers for
20 the different governments.

21 One, on what RFRA says, Your Honor's correct that in
22 2000bb-1(c), there's a provision for judicial relief, but I
23 don't think there is any way you could read the statute to
24 only be about the judicial relief.

25 Section (a) of that says, Government shall not

1 substantially burden the person's exercise of religion even if
2 it's from a rule of general applicability. And then in the
3 next part of the definitions, it defines Government to include
4 a branch, department, agency, instrumentality or official.

5 So I think the best reading of RFRA and the one that
6 I believe the Federal Government, again, across
7 Administrations on all sides of the spectrum has always had is
8 that RFRA is Congress telling the Agencies there are certain
9 things you can't do. You have to avoid doing these things.
10 And that's an affirmative obligation that they have and I
11 would say whether it's EPA -- I think your hypothetical about
12 the climate change thing I think is pretty unlikely to happen,
13 but you can imagine the EPA having some regulation of a piece
14 of land that, you know, someone could point to a cathedral is
15 on and there would be some question of that. All right, so I
16 don't know that that's happened. I would assume it's
17 happened. I would say it certainly probably happens in prison
18 contexts.

19 It happens with RLUIPA, right, which is the prison
20 equivalent of RFRA.

21 I'm sure it happens in the drug context. If you
22 think about a case like *O Centro*. Both before and after
23 *Gonzales v. O Centro*, the Federal Government created Religious
24 Exemptions for certain drug use because, obviously, RFRA was,
25 in part, designed to overturn *Smith*.

1 I don't think there's any RFRA requirement or much
2 sense in the idea that under RFRA, the Federal Government is
3 just supposed to keep running into RFRA violations, wait until
4 they get sued and lose, and kind of lose them retail all
5 across the country instead of fixing it wholesale and just not
6 burdening the religion. The command from Congress is don't do
7 that and I think they have an obligation to not do that.

8 THE COURT: Okay.

9 MR. RIENZI: There's also a brief mention of Title
10 VII which, for the most part, I'm happy to stand on what we
11 said about it in the briefs, but I would simply say to the
12 extent that it's Title VII as an APA argument, which is what I
13 think I heard the state to be saying, well, this violates
14 Title VII because it authorizes illegal conduct, again, I
15 would just suggest it's pretty hard to believe that the states
16 actually think that's true given that Pennsylvania doesn't
17 have a contraceptive mandate. So is Pennsylvania authorizing
18 illegal conduct?

19 New Jersey has a broader Religious Exemption than
20 the one they're saying the Feds can have here. Is New Jersey
21 authorizing illegal conduct? New Jersey's mandate only works
22 if you've already covered prescriptions and it doesn't cover
23 sterilization. And it's not no costs, it involves costs
24 sharing. Are they engaged in illegal behavior? I don't think
25 they really think that.

1 And so the only federal court to ever consider the
2 Title VII question is the Eighth Circuit one that we cited to
3 Your Honor, but it's a pretty farfetched argument to say that
4 having a Religious Exemption here is sex discrimination
5 against women. If that were true, then Hobby Lobby, for
6 example, the Supreme Court's decision in Hobby Lobby would be
7 sex discrimination against women. None of the nine Justices
8 suggested that it was.

9 Okay, on to RFRA. RFRA, as Your Honor knows, says
10 that if there is a -- the Government cannot impose a
11 substantial burden on religion. Most of the litigation over
12 the many years has been over is there a substantial burden on
13 religion imposed by the mandate and then by the accommodation.

14 What Hobby Lobby said in 2014 is that it is a
15 substantial burden on someone's religion to tell them that
16 they have to give out a health plan that includes things that
17 violate their religion. That was Hobby Lobby.

18 There was a short period of time in 2014 and '15
19 when the Government had a particular argument that it no
20 longer has where it said, Well, the accommodation is not like
21 Hobby Lobby because you don't have to give somebody a plan
22 that comes with the stuff that violates your religion.
23 Somebody else is going to give that out and it's not your
24 plan.

25 So if you look at the cases, the words that are all

1 over it are separate, independent, elsewhere. We cited the
2 ones that were used in the Geneva College briefing in our
3 brief to Your Honor.

4 But the point is that the argument at the time was,
5 the reason this is not Hobby Lobby, the reason Hobby Lobby
6 didn't end the whole thing is that for the religious
7 nonprofits, we've got this accommodation, and under the
8 accommodation, you don't have to give somebody the plan that
9 comes with the stuff that violates religion because that's
10 happening someplace else. And that was the state of the
11 Federal Government's argument at the time of Geneva College.

12 What happened after Geneva College, though, is
13 really important, which is in the Zubik litigation, the
14 Government acknowledged, in fact, that it is the same plan.
15 And as Mr. Sandberg said -- well, Mr. Sandberg said that ERISA
16 is necessary to make the system work in a lot of contexts and
17 it has to be the same plan for ERISA to control it. And the
18 Government admitted that and this is not a Trump versus Obama
19 thing. The Obama Administration admitted that to the Supreme
20 Court in 2015 and 2016 that it actually is the same plan.

21 Well, once they did that, they could never win
22 another RFRA claim, and actually once they did that, there's
23 not a court in the country anyplace who said they could win a
24 RFRA claim. Why? Because the whole basis of the Geneva
25 College opinion was, in fact, this claim that under the

1 accommodation, it's not the Hobby Lobby thing where you've got
2 to give a plan and this is part of the plan. It's different.
3 You give your plan over here and it's not part of your plan
4 and it's something else that happens over there. That was a
5 fiction and the Federal Government eventually admitted it
6 wasn't so. The Federal Government eventually admitted it's
7 actually the same plan.

8 So that the Sisters and all the other religious
9 nonprofits actually are being asked by the old version of the
10 mandate to give out a plan that will include the things that
11 violate their religion.

12 Under Hobby Lobby, that's a substantial burden.

13 And once the Government had acknowledged that, they
14 could never win another case. It was over. And, in fact,
15 that's been borne out.

16 And in every case where it's been litigated since
17 Zubik and every Court to consider the issue since Zubik, every
18 single one of them has found that the accommodation imposes a
19 substantial burden.

20 Now, Your Honor pointed out before, and this is
21 true, that those were all district courts and I agree with
22 that. They're all district courts. There's no split.
23 There's no Court of Appeals or Supreme Court decision on it.

24 But I would suggest that if you were the Agency and
25 you're making Rules, you have to care what other Article III

1 Courts say. In other words, I don't think the Agency can just
2 say, Oh, well, it was just district court that told me I was
3 wrong, therefore, I'm just going to forge ahead. That's not
4 really a government of laws and it's not a very good
5 government of laws to just say that we don't care what federal
6 judges have told us because they sit in Oklahoma or Colorado
7 or Chicago or Philly -- they apparently want to sit in
8 D.C. -- so I'm going to ignore them.

9 That's not the way I think we expect the Federal
10 Government to act. To their credit, it's not the way the
11 Federal Government acted here. What they've said here is now
12 that they have acknowledged that it really is the same plan,
13 well, then the "accomodation" doesn't solve anybody's problem
14 because you're still telling the Little Sisters you have to
15 give out a plan that includes the things that violate your
16 beliefs.

17 Under Hobby Lobby, the substantial burden question
18 is over. It's done. That is a substantial burden. The
19 Supreme Court already decided it. It's binding on HHS. It's
20 binding on lower courts. It's done.

21 And so, one, it's after those concessions, after
22 they acknowledge that fact -- which is different from what
23 they told the Third Circuit in Geneva College. Once they
24 acknowledged that fact, they couldn't win a RFRA case, right.

25 So what could they do? Well, they could either do

1 what they've done for the past year, which is go on and just
2 keep losing RFRA cases, right, and that's kind of fun for me
3 and I'll sue them everyplace else and my clients will keep
4 winning.

5 But that's no way to make law, right? That's not
6 what Congress told them. Congress told them don't
7 substantially burden religion.

8 One, two, three, four -- ten courts now have said
9 this substantially burdens religion. Was the Agency really
10 supposed to say, I don't care. I'm going to keep doing it
11 anyway. I'll keep getting sued. I'll just keep losing. I
12 don't have the authority to fix it. Or should they say, Well,
13 enough courts have told me I'm violating people's federal
14 civil rights. I'll obey the law and I'm going to fix it.

15 And that's what they did and I'd say that's the
16 right thing to do. I would say that's the only option they
17 had. In other words, I don't think legally they had the
18 option to say, I don't care that everyone keeps saying this
19 was a substantial burden on religion, I'm going to keep doing
20 it anyway.

21 RFRA says, Government shall not do that. They're
22 the Government. They are duty bound to obey RFRA. They're
23 not free to just say, I'd rather not, right? That's not one
24 of the choices that they had.

25 And so the choice the states want to put them to is

1 a mandate that applies to people like the Little Sisters of
2 the Poor, which the Government has now conceded violates RFRA,
3 and lots of courts have found that, or, frankly, no mandate at
4 all, right, because those are the two choices they're being
5 given.

6 The states are saying you can't possibly have a
7 mandate that applies to just about everybody on the planet,
8 but exempts the people who beat you under RFRA.

9 I don't think there's anything in the law that tells
10 the Government to behave that way. I think it's pretty
11 bizarre to think that the APA or that Congress intends for the
12 Agencies to just forge right ahead losing the cases and that
13 they can't fix what they've done. They can't stop losing the
14 cases by just changing the Rule. What benefit is there to
15 having them lose each of these cases retail, to make the
16 religious nonprofits go get lawyers and show up in court and
17 drag the DOJ lawyers who, I think, right now aren't even
18 getting paid, right, drag these people around court to court
19 for losing these cases. For what? There's no benefit. No
20 one benefits from that.

21 And so the state's argument, I would say, requires
22 you to ignore the fact that the Agencies face these
23 injunctions. It's not clear what they should have done with
24 that. It's not clear what the states think they should do
25 with that. But it would be odd, I think, for one Article III

1 Court to say, Oh, Agency, what you really should have done is
2 stop caring so much about those other ten judges who said that
3 it was a substantial burden and you should just forge ahead
4 with the reg. I think that would be odd. I'm not aware of
5 other courts who have said things like that.

6 At times I read the state's briefs to be saying that
7 RFRA perhaps authorizes one and only one solution and you can
8 go for that one solution, but anything else, RFRA doesn't
9 authorize it.

10 I don't think that's right. I think that's a
11 particularly bizarre way to read RFRA. You can't reconcile it
12 with Hobby Lobby, right? Hobby Lobby, the Court said, There's
13 a substantial burden. And then the Court says, Let me think
14 about a few less restrictive alternatives you could use.

15 Right, they start with what they say was the "most
16 straightforward" thing, which is, Hey, Government, if you want
17 to get everybody free contraceptives, I've got an idea, why
18 don't you give people free contraceptives instead of making
19 other people give people free contraceptives. The Federal
20 Government, if that's important to you, you can do it
21 yourself. That's the most straightforward way. And the Court
22 said that that was obviously less restrictive, a less
23 restrictive alternative that they could have tried under RFRA.

24 Then the Court went on to talk about the
25 accommodation as it was presented to them then, that it's some

1 separate plan, and they said, Well, that looks less
2 restrictive too. Right? If RFRA was -- there was only one
3 possible solution, you can do that one and otherwise you lose,
4 that type of approach from the Court doesn't make sense.

5 And RFRA is designed to be very protective of
6 religion. That's the whole point of RFRA. To look at RFRA
7 and say that, Well, RFRA's going to say you'd better hit --
8 you'd better get the bulls eye. You'd better get it exactly
9 right. If you get it exactly right, fine. If you get it at
10 all wrong in one direction, you'll go lose a bunch of RFRA
11 cases. And if you overshoot the mark by being a little too
12 protective of religion, nationwide injunctions are against
13 you.

14 That's a pretty strict way to read RFRA and it's not
15 a terribly protective-of-religion way.

16 I would say the better way and the way the Supreme
17 Court was discussing in Hobby Lobby is to say, Well, under
18 RFRA, when you're imposing a substantial burden, you've got to
19 go do something else and the Court threw out a couple of
20 different possibilities. I think it's pretty odd to look at
21 this world -- like this particular set of accommodations,
22 right? So, no, we don't cover grandfathers, it's only for
23 people under 50. I think the state still wants the Obama-era
24 Religious Exemption. So an accommodation with the Obama-era
25 Religious Exemption that doesn't work for anybody on church

1 plans that requires this handoff of the piece of paper, that's
2 the one thing RFRA allows.

3 That's weirdly path dependent, Your Honor. That's
4 strangely path dependent to say that's the one.

5 That's the one that the Obama Administration came
6 upon and perhaps in entirely good faith, right, in 2013.
7 That's what they came up with.

8 But the idea that that's the only thing? That's the
9 only way the Federal Government could decide to get people
10 contraceptives that would comply with their obligations under
11 RFRA? That's odd.

12 The Supreme Court again didn't think Hobby Lobby
13 when they said there was a different more straightforward way.

14 Again, the obligation of RFRA is mandatory. It's
15 not discretionary. Putting contraceptives into the preventive
16 services mandate, that is discretionary. That's just done on
17 a website.

18 RFRA is a statute. RFRA binds them. They have no
19 choice but to follow it. They have to follow it. Federal
20 civil rights laws are obligatory.

21 In Your Honor's 2017 opinion, you addressed RFRA
22 and, you know, we certainly were in front of you to make the
23 arguments we're making, so I don't feel like I'm presenting
24 something new to you, but when you addressed RFRA, you did it
25 through the lens of Geneva College and Real Alternatives.

1 We laid out in the brief and I'd just like to spend
2 a couple of minutes explaining why I don't think those cases
3 can actually resolve the RFRA claim.

4 Geneva College, as Your Honor pointed out, that's
5 been vacated.

6 Real Alternatives specifically said that they
7 weren't saying Geneva College was binding. So Real
8 Alternatives did not revive Geneva College. Certainly not for
9 this particular claim, the employer's claim.

10 In other words, in Real Alternatives, the only RFRA
11 claim on the table was whether an employee has a RFRA claim to
12 not have to have an insurance policy that gives them access to
13 something else. There was no religious employer claim at
14 issue in Real Alternatives.

15 So Geneva College, you know, is vacated, was not
16 revived by Real Alternatives. You know, to just give you one
17 data point, the Geneva College case itself is one in which the
18 trial judge has since entered a RFRA injunction saying that
19 there's a substantial burden on religion. So in Geneva
20 College, Geneva College is not even law of the case. I mean,
21 in that case, the trial judge went back and said, Oh, based on
22 what's presented to me now, yes, that is a substantial burden.
23 So I don't think Geneva College is in any way binding on this
24 Court. It's also not persuasive in light of what the
25 Government has conceded since then and we lay out what they

1 claimed in their briefs to the Court and what the Court had
2 found in Geneva College. But, again, Geneva College is based
3 on the fiction that it's not your plan and the reality which
4 they have since conceded is that, in fact, it is your plan.
5 And once they conceded that reality, I don't see how you can
6 say Geneva College is persuasive authority because Geneva
7 College is analyzing a state of facts that I don't think
8 anybody in the courtroom now can claim is true. Nobody can
9 say it's not your plan because what they eventually had to
10 acknowledge is that, well, to make the thing work, we need
11 ERISA and we need to order your plan administrator to
12 administer the plan in a certain way. And so once they did
13 that, they had to acknowledge it was the same plan. To their
14 credit, they told the truth, they said it was the same plan.
15 But once they did that, the RFRA case was sealed. And, again,
16 every Court considering it since then has found that it was a
17 RFRA violation.

18 The states argued that there was no reasoned
19 explanation for why the Agencies have switched their position.
20 They didn't explain why they now do think it's a substantial
21 burden. In the IFR, and I believe they incorporated the IFR
22 by reference in the Final Rules, they do say, Now that we have
23 acknowledged that it is the same plan, we realize that it
24 actually wasn't accommodating anybody's religion and it's
25 still a substantial burden. So they do explain why that's so.

1 Again, it's very public record. They've done it in
2 open court. There's no mystery as to what happened. They've
3 explained that it's the same plan. Once you do that, they've
4 lost that argument.

5 Two last points and I'll sit down, Your Honor.

6 One, the states, again, as I heard them, were making
7 the argument that they think the Obama-era Religious Employer
8 Exemption was required by RFRA. If it's required by RFRA,
9 it's because there is a burden. And it can't be that there's
10 a burden on those employers, but not on these. So if you
11 think that it's RFRA, the free exercise clause that requires
12 it, it's because you think there's a burden. There's no world
13 in which you can say RFRA and free exercise required this
14 thing that I like because I don't really want to say I'm going
15 after churches, but they don't impose a burden on these other
16 people. Like either there's a burden here to fill out the
17 form and hand it to somebody or there's not. I think the
18 answer pretty clearly is, yes, there is, because it means your
19 plan is covering something that you have religious objection
20 to and Hobby Lobby already answered that question.

21 And then, lastly, I would just make a brief plea to
22 the Court, which is, this has been a long and, frankly,
23 unnecessary fight. There are a lot of ways to get people
24 contraceptives.

25 The Federal Government's pretty good at it. State

1 governments are actually pretty good at it too. They all do
2 it. The idea that these two governments should be fighting
3 over whether the Constitution or federal law requires the
4 Federal Government to indirectly make nuns or somebody else do
5 it as opposed to these two governments doing it themselves
6 doesn't make a whole lot of sense. And RFRA, frankly, exists
7 to say, Hey, guys, if you all can do it yourselves, you can't
8 go burden somebody else. That's precisely what we've got
9 here.

10 All of the state's declarations talk about all of
11 the great programs that they have to do this. Well, given
12 that they all have all these great programs to do it, it can
13 never be this compelling interest in dragging nuns into the
14 process.

15 So we'd ask Your Honor to rule against the state's
16 motion for an injunction and hopefully put us on the path of
17 being done with this unnecessary fight.

18 Thank you, Your Honor.

19 THE COURT: Response briefly.

20 MS. THOMSON: Thank you, Your Honor. A few brief
21 points.

22 First of all, I would note that the law under the
23 ACA Women's Health Amendment as implemented by HRSA is that
24 all employers must include contraceptive services and
25 counseling in their insurance program. So that is the law

1 that exists. This idea of a tortured path dependence thing is
2 I think not relevant because the law is that. This is what
3 insurance employers -- employers must provide to their
4 insurees.

5 All RFRA does is prevent the Government from
6 enforcing the law against certain people where there's not a
7 least restrictive means to further the compelling Government
8 interests.

9 So with regards to what Hobby Lobby held and with
10 regards to Geneva College, there is a difference between
11 whether someone's religious objections are sincere and whether
12 they do impose a substantial burden.

13 With regards to whether Geneva College was procured
14 on false pretenses, I would point that the law under Third
15 Circuit and under RFRA is that a Court must look to what the
16 parties actually are obligated to do, not what third parties
17 are obligated to do.

18 So what the Third Circuit held in Geneva College is
19 that the actual people who were claiming this a burden were
20 not -- were only obligated to say they were not going to cover
21 contraception. That was it. The fact that the law stepped in
22 and required third parties to follow the law and provide
23 federally-mandated contraceptive services to other third
24 parties, the employees of the objecting entities, was not
25 something that could constitute a burden because the only

1 burden is on the action that the actual objecting person is
2 seeking. So the logic of Geneva College still controls.

3 I would note that all of the Courts to consider the
4 accommodation post this purported concession in Zubik have
5 been uncontested decisions, at least the ones in the district
6 court, and I would note that the Supreme Court in Zubik did
7 not actually find that the accommodation violated RFRA or make
8 any decision about the accommodation. So there is actually
9 no -- that Court, despite this purported concession, did not
10 recognize that it was somehow a fatal flaw to the
11 accommodation. And every Court to look at it after has been
12 looking at uncontested circumstances, about whether or not the
13 accommodation posed a substantial burden.

14 Finally, I would note that with regards to
15 Government providing services, there's been talk in the
16 briefing about Title X and an issue with the Government
17 potentially allowing women whose employers claim the exemption
18 to go to a Title X clinic to get access to those
19 federally-mandated contraceptive services.

20 I would note that simultaneously, the Government is
21 promulgating a new Rule to be issued in their Notice of
22 Proposed Rulemaking and they're actually set probably to issue
23 the Final Rule any day now which will substantially limit
24 funding for Title X clinics. It's also not clear how exactly
25 this would function because all it says in the Title X Rule is

1 that women whose employers claim the exemption will be
2 considered low income families for the purposes of Title X
3 clinics. But given that employers don't have to actually do
4 anything affirmative to claim the exemption, it's not at all
5 clear how this would function in reality. And, moreover, this
6 is not a solution to the real issue which is -- the real
7 interests which is giving women seamless access to
8 contraception as part of all of their other services because
9 contraception is, at the end of the day, health care and it
10 should be included in all of women's other health care
11 services with their doctor instead of having to go to a
12 different place, go through a different process to get this
13 particular form of health care.

14 If Your Honor has no further questions.

15 THE COURT: No.

16 MS. THOMSON: Thank you.

17 THE COURT: Okay, we're going to move to national
18 injunction, but I have a series of questions that I just need
19 quick answers to.

20 Defendants, is it your position that the Final Rules
21 make no substantive changes to the IFRs? That is, the Final
22 Rules have the same substantive effect as would the IFRs had
23 they not been enjoined?

24 Put differently, are there any changes to the IFRs
25 embodied in the Final Rules? Are they all technical revisions

1 to clarify the meaning of the IFRs or is there anything that
2 makes substantive changes?

3 MR. SANDBERG: Would you like me to answer here or
4 there?

5 THE COURT: Yes.

6 MR. SANDBERG: So to avoid any confusion about
7 labels, I'll do the best I can to explain it.

8 I think the one that sort of might be termed
9 substantive change is that the Rule discusses the meaning as
10 supported by -- in the Women's Health Amendment in terms of
11 HRSA's delegation, which, to the extent the Agency therefore
12 adopts that rationale, that may factor into Chevron.

13 But in terms of --

14 THE COURT: Sorry, spell that out a bit more.

15 MR. SANDBERG: Yes, sure.

16 So the Agency sort of takes the position that
17 the -- which I don't recall that it did in the IFR -- that the
18 part of the ACA that says, you know, the additional preventive
19 service shall be those -- shall be required as provided by
20 guidelines supported by HRSA. The Rule goes into what the
21 Agency thinks "as provided by" means.

22 THE COURT: Ah, okay, so this is the "as", what does
23 "as" mean --

24 MR. SANDBERG: Correct.

25 THE COURT: Essentially, in the Rules, the Agency

1 has taken a position on what "as" means in a statute.

2 MR. SANDBERG: Correct.

3 THE COURT: Isn't that a judicial function? Quite
4 clearly a judicial function?

5 MR. SANDBERG: No, I mean, not if -- under Chevron
6 Step One, if Congress is clear, then the meaning is what
7 Congress says.

8 Under Step Two, if there's ambiguity, then you defer
9 to the Agency's reasonable interpretation.

10 THE COURT: Okay, where can I find that discussion
11 in the Final Rules?

12 MR. SANDBERG: I can get you that. Did you have any
13 other questions that you --

14 THE COURT: Well --

15 MR. SANDBERG: And just I think, I mean, otherwise,
16 generally, I would say the changes are sort of technical and
17 sort of housecleaning and clarifying things from the IFR.

18 There's a couple of places where the Agency says,
19 you know, We said this in the IFR. People asked what we
20 meant. What we meant was, you know, A, B, C.

21 So they don't say they're changing anything.
22 They're just clarifying what's in there.

23 THE COURT: Okay, so to keep on this line, you're
24 going to provide me with the "as" supported by a pinpoint
25 cite, but I do have a question about the change that the IFRs

1 and Final Rules make to the existing accommodation exemption
2 framework. That hasn't gotten much attention.

3 It's my understanding that the IFRs and now the
4 Final Rules changed the level at which the exemption is to be
5 applied. So whereas before, the availability of the exemption
6 was to be determined on an employer-by-employer basis, the
7 IFRs provide that the exemption will be determined on a plan
8 basis.

9 MR. SANDBERG: To my understanding, that's correct.

10 THE COURT: And do you have any information about
11 how often an insured's health care plan sponsor will be a
12 different entity than the insured's employer?

13 MR. SANDBERG: I don't standing up here. It's not
14 saying the Agency doesn't. I don't standing up here.

15 THE COURT: Okay. So we just got the administrative
16 record here. The fact that I just received the administrative
17 record, do you think that that makes any difference? Do you
18 think I need to -- that the Plaintiff should have another
19 opportunity to look at the administrative record? Do you
20 think that we need to -- is there anything that we need to do
21 here in this court with respect to that?

22 MR. SANDBERG: Well, I would say this. To the
23 extent the Court, which we would think is incorrect, would
24 say, I can look to these outside declarants, these people
25 outside the Agency to determine the correctness of what the

1 Agency did, we think the Court's previous ruling in our motion
2 in limine which said you could rely on sort of extra record
3 information for a limited purpose -- but that limited purpose
4 did not include assessing the correctness of what the Agency
5 did. So the only thing I would say would be if the Court were
6 inclined to say, Because I got the record just today or
7 yesterday, I'm going to rely on extra record evidence, we
8 think that would be incorrect and that, you know, if the Court
9 wants to take additional time or permit additional briefing on
10 what's in the record, we would prefer that certainly as
11 opposed to --

12 THE COURT: Well, yes, that wasn't the question.

13 The issue is -- well, I suppose it's for the
14 Plaintiff.

15 Have you had access to the administrative record
16 before yesterday or whatever?

17 MR. FISCHER: Your Honor, we received -- no, not
18 before. We received it by FedEx, I believe --

19 THE COURT: Do you think it makes a difference here?

20 MR. FISCHER: It does certainly because I think it
21 heightens the burden on Defendants to justify their reversals
22 of position here.

23 If they're relying on what's in the administrative
24 record to justify, for instance, their reinterpretation of the
25 word "as", the fact is we have not had the chance to go

1 through and analyze exactly what they relied on.

2 Now, the only thing we found related to that,
3 someone printed out the OED definition of the word "as" two
4 weeks after the Rules were issued and they threw it to us in
5 the record, but I think it makes the burden higher on
6 Defendants.

7 I also think it may inform -- regardless of what
8 happens today, it may inform how the case proceeds and I'll
9 talk about this a little bit more when we get into
10 injunctions, but perhaps it's an argument for all parties that
11 are moving expeditiously toward a final judgment. If there's
12 a preliminary injunction entered or if there is not, but one
13 that will give everybody the opportunity to take full account
14 of the administrative record rather than resting on a decision
15 on a PI that was the basis of a record that we have only had a
16 day to look at and not even a day, frankly --

17 THE COURT: So do you think I can make a decision
18 without any further briefing with respect to the
19 administrative record?

20 MR. FISCHER: Yes, I believe Your Honor can because
21 we think that the conclusions in the Rule are in many ways
22 arbitrary and capricious on their face. We think that, for
23 instance, the reversal on benefits of contraception, which is
24 justified by a statement that they've identified, one study
25 that's ambiguous on the benefits, that by itself simply

1 doesn't carry their burden. We think that there's enough in
2 there right now to show that the conclusions that the
3 Government's reaching are simply not justified. The same as I
4 think with this "as" issue.

5 There's been a lot of discussion about, you know,
6 does the ACA give the Agency the authority to create
7 exemptions. Well, they're resting the authority on the word
8 "as". But that's the only argument I've heard as to where
9 this authority comes from. They say, well, because it says as
10 provided for, HRSA can do more than just identify services
11 which is what HRSA did. They're saying HRSA -- which has no
12 expertise in religious exercise identifying a burden on
13 religious beliefs -- they're saying HRSA, nonetheless, has the
14 authority to create broad-sweeping exemptions and they're
15 resting all of that on the use of the word "as".

16 So, frankly, I think it's unlikely there's anything
17 in the history of the record that will show that to be
18 justified. On its face, I think it's, frankly, just wrong and
19 Your Honor could rule on that basis.

20 THE COURT: Okay. Have you got the "as" cite now?

21 MR. SANDBERG: Yes. The cites are the Religious
22 Rule. It's 83 Fed. Reg --

23 THE COURT: 83 Fed. Reg.

24 MR. SANDBERG: -- 57,540 to 41.

25 THE COURT: 57,540 to 41.

1 MR. SANDBERG: And the parallel citation in the
2 Moral Rule, would you like that?

3 THE COURT: Yes.

4 MR. SANDBERG: 83 Fed. Reg. 57,597 --

5 THE COURT: 57,597.

6 MR. SANDBERG: -- to 98.

7 THE COURT: Okay.

8 MR. SANDBERG: I do want to point out, our only
9 basis is not the word "as".

10 We've had argument here this morning, we've provided
11 other bases entirely tendentious to their only basis for --

12 THE COURT: I understand. I understand. I just
13 want to focus on the "as" argument.

14 MR. SANDBERG: And it's also entirely tendentious to
15 say that we rely on one study for the benefit. There's -- I
16 think there's four or five pages in the Federal Register
17 regarding sort of the Agency's assessment of the efficacy of
18 contraceptives and it doesn't rely on one study.

19 THE COURT: Okay, so let's now turn to the scope of
20 the remedy.

21 MR. SANDBERG: Okay.

22 MR. FISCHER: Thank you, Your Honor.

23 The states believe that the only remedy that will
24 fully address the harm that they and the residents are likely
25 to suffer is an injunction preventing the Agencies from

1 enforcing the Rules nationwide. That is what the Court issued
2 before and we believe it's also warranted under the facts of
3 the Final Rules.

4 Now, the question of what remedy is appropriate
5 depends on a variety of factors. It involves looking at the
6 nature of the violation, it involves looking at the nature of
7 the harm, it involves balancing the equities, looking at the
8 public interest. And I think the Supreme Court's decision in
9 the -- one of your early travel ban cases where the Court
10 granted a stay of a nationwide injunction in some respects,
11 but allowed the nationwide injunction to go forward in other
12 respects, particularly with individuals who were similarly
13 situated to the Plaintiffs in that case. So while the Court
14 stayed some aspects of the injunction, it did not say a
15 nationwide injunction was improper.

16 THE COURT: Well, Justice Thomas did.

17 MR. FISCHER: Justice Thomas did.

18 THE COURT: In his dissent, he put forth five
19 reasons why they were totally improper.

20 MR. FISCHER: Exactly. It was his dissent and I
21 believe he was writing for himself and either one or two
22 other Justices so it didn't carry the day. The remainder of
23 the Court felt that a nationwide injunction at least in some
24 respects was appropriate.

25 And, frankly, you're going to think if we look at

1 the concerns that Justice Thomas raised, they're not
2 appropriate in this case or they certainly are not a reason to
3 not issue an injunction which we think is necessary to give
4 the states the full relief that we believe they made a case
5 for. You know, Justice Thomas talks about issues need to
6 percolate among the circuits. This issue clearly is. There's
7 a case pending in California, there's a case pending in
8 Massachusetts where the Commonwealth of Massachusetts lost on
9 standing ground. It continued to press ahead with that case.
10 That's before the First Circuit. There are other cases
11 brought by private entities or organizations that are also
12 pending.

13 This issue will be addressed by a number of
14 circuits. So -- and, frankly, I think the fact of whether or
15 not Your Honor issues a nationwide injunction isn't going to
16 have much significant impact on whether those other cases
17 proceed. Those are decisions being made by the litigants in
18 those cases. So it's not as if the Supreme Court, if this
19 issue ultimately reaches the Court, will be deprived of the
20 benefit of many, many courts looking at this issue. In fact,
21 I think it's inevitable that many courts will have considered
22 this issue by the time that it comes before the Court.

23 I also think it's important to understand the harm
24 that we are asserting, which is that residents of Pennsylvania
25 and New Jersey will be deprived of contraceptive coverage and

1 will turn to state-funded plans.

2 Now, the Defendants have said Your Honor can just
3 issue an injunction that applies in Pennsylvania and New
4 Jersey. I don't really understand what that means.

5 When you've got a situation where college students
6 in Pennsylvania may be on a health plan from their parents,
7 that their parents pay for, the parents live across the
8 country, is that college student then allowed -- is that
9 parents' plan then required to cover contraception or are they
10 exempt from the injunction?

11 If the answer is because that plan is located in
12 another state, they're not required to cover contraception,
13 then that's a harm that Pennsylvania will suffer.

14 So given the highly integrated nature of insurance,
15 achieving full relief for the states will require an
16 injunction that goes well beyond our borders.

17 THE COURT: So in your brief, you talk about -- you
18 provide me with two categories of people who may come from
19 outside of Pennsylvania, but may use Pennsylvania's services.
20 One are the folks who commute into either New Jersey or
21 Pennsylvania. So I suppose there you would have the
22 neighboring or nearby states. So the question I would have
23 there is why would an injunction cover, let's say, New Mexico
24 when it's highly unlikely that someone is commuting to
25 Pennsylvania and New Jersey from New Mexico, but then I hear

1 you talk about students who come from around the country. Is
2 there any indication, do you have any evidence to suggest that
3 there are students in Pennsylvania from every state in the
4 union or any reason to believe that that is the case, any
5 evidence?

6 MR. FISCHER: I am fairly confident that is the
7 case. I can't point to specific, you know, pieces of evidence
8 in the record.

9 I'll note in the amicus brief that was submitted by
10 20 states and the District of Columbia, there's a reference to
11 Pennsylvania I think having the second highest number of
12 first-year students of any colleges -- of any --

13 THE COURT: This is the American Association of
14 College --

15 MR. FISCHER: No, this is the one from other states,
16 from the Commonwealth of Massachusetts and 19 other states as
17 well as D.C. I believe it's on page 14 of that brief.
18 There's a reference to, essentially, how significant a role
19 education plays in Pennsylvania, that Pennsylvania has a large
20 number of colleges and universities, and I'm confident that --
21 well, I'm reasonably confident that some individual college in
22 Pennsylvania could probably say they have students from every
23 state and certainly the state -- the Commonwealth as a whole,
24 I would be very surprised if that were not the case. I will
25 say that and I'm happy to submit something for the record

1 later.

2 This is sort of the complicated nature and this kind
3 of shows why this case is different from other cases where
4 courts have put the brakes on nationwide injunctions.

5 There's a citation to the Chicago case which
6 involved the dispute over so-called sanctuary cities laws.

7 Well, the issue there was whether the Justice
8 Department had to give grant money to states and to cities
9 that it was trying to withhold. Now, it's very easy to sever
10 Chicago's grant from Philadelphia's grant from your grant and
11 say, Okay, Chicago, you have shown you should prevail,
12 therefore, you get your grant money, but it doesn't matter
13 whether California, San Francisco, whether anybody else gets
14 the grant money to remedy the violation that you have alleged.

15 This is a very different situation here. Saying
16 that the Rules should not harm anybody in Pennsylvania or
17 should not cause injury in Pennsylvania or New Jersey requires
18 much broader relief than was available in that case and
19 requires broader relief than just simply an order saying the
20 Defendants may not enforce the injunction within the borders
21 of Pennsylvania or New Jersey. We believe that would prove to
22 be unworkable and that, therefore, something broader is
23 necessary in this case.

24 I also think it's relevant to the analysis, and this
25 is, again, I think the Court's -- the Supreme Court's decision

1 in the IRAP travel ban case touches on issues of public
2 interest and balance of equities. It's relevant that these
3 Rules are harming women across the country.

4 There's a great deal of evidence in the record on
5 this. We've submitted the supplemental declaration from Ms.
6 Kost from the Guttmacher Institute which breaks down per state
7 essentially the percentage of women who are -- who need
8 publicly-funded Family Planning benefits and who actually get
9 it and what that shows is there's a gap in every single state.
10 No state is able to meet all of the needs of women who need
11 Family Planning benefits. So that if the pool of women who
12 have to rely on the state is expanded, the burden on the
13 states everywhere is going to increase.

14 It also, as I mentioned earlier, noted the fact that
15 well over half of the unplanned pregnancies in this country
16 end up imposing costs on the states. That's true across the
17 board with the exception of a few states where the percentage
18 is just under 50 percent. But, regardless, increasing the
19 number of women who do not have access to contraception will
20 increase the number of unplanned pregnancies and will impose
21 costs on every state in the country.

22 These again are factors that go into the equities
23 that the Court should consider in fashioning appropriate
24 relief.

25 THE COURT: Do you think there's a perfect solution?

1 I mean, I sort of have to go between the concept of providing
2 complete relief, but also providing relief that is no broader
3 than necessary to provide full relief. So is there a perfect
4 solution here?

5 MR. FISCHER: Well, there is in that a nationwide
6 injunction is in many ways the least restrictive form of
7 relief that would give the states full relief for what harms
8 they've alleged. And, frankly, if the analysis were to be
9 more restrictive than that, the Supreme Court in the IRAP case
10 would have done something different and would have said we're
11 only allowing the injunction to move forward as to the named
12 Plaintiffs, not as to individuals who are similarly situated.

13 The Supreme Court considered issues like public
14 interest, balance of equities and said it was not an abuse of
15 discretion to allow that, to allow that class of individuals
16 the benefit of the injunction.

17 So I think where there may be some tension between
18 fashioning relief that gives the Plaintiffs, you know, full
19 remedy for their harms versus fashioning a relief that is
20 broader than necessary, the Third Circuit I think has made
21 clear that the injunction to be crafted must give the
22 Plaintiffs -- must address the Plaintiffs' injury that they
23 have alleged.

24 So that, therefore, to the extent what -- you know,
25 to the extent addressing the injury that Pennsylvania and New

1 Jersey have suffered requires nationwide injunction, that is
2 the least restrictive way of addressing this claim.

3 And I would also note I think it is relevant again
4 that other states have weighed in. There's an amicus brief
5 from 20 other states and D.C. that talk about the importance
6 of this issue to their states. It is not as if this is a harm
7 being felt in Pennsylvania and New Jersey alone and other
8 states do not have an interest in this. I think that goes to
9 some of these other issues that are relevant.

10 And then, finally, I think that the Court should
11 consider the sweeping nature of the Rule itself in fashioning
12 relief. You know, I think we sometimes -- I think the
13 arguments sort of drifted away from what's actually at issue
14 here.

15 We're not trying to reinstate the mandate on the
16 Little Sisters of the Poor. Let me make absolutely clear
17 about that. They are protected by an injunction from the
18 District Court of Colorado that says the Government cannot
19 require them to pay for contraception. We are in no way
20 challenging that. We're not challenging the earlier
21 exemption, we're not challenging the earlier accommodation.

22 We are challenging these Rules which allow for the
23 first time publicly-traded companies to opt out of the
24 exemption, which it's clear got opted out of the contraceptive
25 mandate, which completely do away with the accommodation and

1 render it totally optional even in the cases of the companies
2 that never asserted that it violated their religious beliefs
3 to fill out the form and send it to their insurance company.

4 And then, of course, there's the Moral Exemption
5 which, as Your Honor correctly held earlier, could allow a
6 company to say, It is our moral belief that women should not
7 be in the workplace and we're not going to offer
8 contraception.

9 Now, I was frankly surprised that in light of that
10 decision, the Agencies did not at least go back and say they
11 were going to withdraw this Rule, issue a new NPRM, go through
12 the process and try to address some of these concerns.

13 I don't see any real discussion of those concerns
14 and I think, as the earlier colloquy indicated, there's very
15 little substantively different about the Rules. They
16 essentially are the IFRs with a few tweaks and a few things
17 that were true earlier sort of explained a little better.

18 So I think with all of those factors considered,
19 that the scope of the Rules that we are challenging, the harm
20 to women across the country, the integrated nature of
21 insurance in this country, the difficulty of providing
22 complete relief for Pennsylvania and New Jersey without
23 imposing a nationwide injunction and, finally, the fact that
24 this issue is going to percolate, we think a nationwide
25 injunction is the only appropriate remedy.

1 And I also have just one final thing. I think the
2 Ninth Circuit, as Your Honor's aware, remanded that case for
3 consideration of the appropriateness of the nationwide
4 injunction. One of the factors that it turned on, which was
5 interesting, was that the case had been stayed after the
6 preliminary injunction was issued. We think that that perhaps
7 should inform how our case proceeds afterwards. And as I
8 indicated earlier, given the issue with the administrative
9 record, we likely would not agree to a further stay following
10 a preliminary injunction and we are certainly prepared to move
11 this case forward to a final remedy.

12 But in the interim, what is necessary to preserve
13 the status quo as it existed really prior to the IFRs on
14 October 5th, 2017, is a nationwide injunction that prevents
15 the Agencies from enforcing the Rule. Okay, that's what we
16 request.

17 THE COURT: Thank you. Just off the record for a
18 second.

19 (Recess taken)

20 (After recess:)

21 THE COURT: Okay. Have a seat. Okay, let's hear
22 from the defense on the nationwide injunction issue.

23 MR. SANDBERG: Thank you, Your Honor.

24 I think the well-understood backdrop to this is we
25 don't think an injunction is appropriate.

1 Forging on from there, our first argument is that
2 Plaintiffs need standing for every form of relief sought and
3 Plaintiffs do not have standing to seek relief for a state
4 just because of similarly situated and the sort of recent --
5 Supreme Court's recent decision in Gill versus Whitford, which
6 is admittedly a different context, it has to do with voting
7 rights, the Supreme Court there found that residents of one
8 district didn't have standing to challenge how the state had
9 set up other districts because they weren't injured by it. So
10 in terms of getting an injunction, getting an injunction that
11 covers the whole state, they could only get an injunction that
12 related to the districts they were in and that's because they
13 don't have standing under Article III.

14 We think the same law clearly applies here.

15 Another argument against a nationwide injunction is
16 the sort of traditional equitable limits of injunctions.

17 Injunction is an equitable remedy. And as a
18 traditional matter, injunctions were given only to the extent
19 necessary to provide the relief to Plaintiffs. And so unless
20 Plaintiffs can establish that a nationwide injunction is
21 necessary, and it's their burden as Plaintiff, I think, to
22 establish the scope of the necessary injunction, unless they
23 can establish a nationwide injunction is necessary, they
24 haven't met the threshold of that traditional equitable
25 principle and I'd like to pick up a little bit on the sort of

1 the college student example.

2 So if you have a college student from Idaho that
3 goes to Penn State and the idea is, well, maybe they're on
4 their parents' plan.

5 One question: Are they on their parents' plan?

6 Second question: You know, did their parents' plan
7 in Idaho, did it previously cover contraceptives?

8 Maybe; maybe not.

9 Are they now invoking the exemption?

10 Maybe; maybe not.

11 Are they invoking the exemption as to contraceptives
12 this college student uses because some employers and providers
13 are willing to cover certain things? So are they covering it
14 as to a contraceptive used by this woman?

15 Maybe; maybe not.

16 Will this woman then qualify for state coverage?

17 Maybe; maybe not.

18 Will she choose to use state coverage?

19 Maybe; maybe not.

20 So the fact that you have a student from Idaho,
21 certainly even if you had 1 or 10 or 20, that's not
22 dispositive of whether, in fact, the State of Pennsylvania is
23 going to be harmed because it relies on a long causal chain
24 and to just -- I think partly because, and I don't want to
25 devolve too much in that, but partly because their standing is

1 in the realm of maybes, now their injunction is in the realm
2 of maybe, too.

3 It's like, Well, because, you know, maybe this
4 person's harmed, maybe this will happen, maybe that will
5 happen, and then maybe we'll need a nationwide injunction.

6 So I certainly think that as an equitable matter,
7 there's no basis for a nationwide injunction based on a series
8 of maybes, a chain of reasoning that relies on many maybes
9 across many different potential individuals affected.

10 And as to the interference of development of law, I
11 think it's likely true unless, you know, this Court's decision
12 somehow stands in the way of Judge Gilliam in the Ninth
13 Circuit deciding something, that there at least will be a
14 couple of decisions on this, but I think in terms of the
15 percolation of issues and interference and development of law,
16 you have to look at the cases that aren't filed and decided as
17 well. You can't just say, Oh, there's two cases so it's not
18 going to interfere with the development of the law.

19 Well, maybe the issuance of a nationwide injunction
20 prevents other cases from being filed and decided.

21 And I think that's a key question when talking about
22 the interference of development of law.

23 And on this point, I would like to add, a nationwide
24 injunction would presumably extend to Massachusetts and I
25 believe Massachusetts has filed an amicus brief here.

1 Massachusetts, of course, lost their case in the District of
2 Massachusetts so I think that sort of brings into sharp relief
3 parts of the problem of issuing a nationwide injunction. And
4 this case includes potentially giving someone a win they
5 didn't get when they litigated in a court in their district.

6 I would like to cover a few other points somewhat
7 more briefly.

8 I think Plaintiffs are overreading the International
9 Refugee Assistance Plan case. That case certainly doesn't
10 squarely decide the scope of preliminary injunctions and when
11 national injunctions are appropriate. And, in particular,
12 Plaintiffs discuss language that the Court says that you have
13 to consider the overall public interest, and that's true, and
14 it's a long-held principle that when courts are issuing
15 injunctions, they consider it's a public interest. It's one
16 of the factors when the Court's balancing it, it balances the
17 parties' interest and then it also balances the public
18 interest. But I don't think that's ever, at least in my -- I
19 don't think that's appropriately understood as meaning you can
20 give the Plaintiff an injunction broader than that necessary
21 to provide them relief. So sort of, as I view it, when the
22 Court said consider the public interest, it meant something
23 like this: If the Government has a building project that's
24 going to impose irreparable harm of \$5,000 on a Plaintiff and,
25 you know, ceasing that project will impose some harm on the

1 Defendant, you consider that, but then you also consider maybe
2 that building project has brought 500 jobs to the area that
3 wouldn't otherwise be there. So if you grant the Plaintiff an
4 injunction that would be sort of necessary to provide them
5 relief, it would, you know, maybe cost those 500 jobs. So
6 that's the kind of public interest you consider. In the
7 course of granting an injunction of appropriate scope
8 sufficient to provide the Plaintiff relief, you consider the
9 public interest in that injunction. I don't think it means
10 anything more than that. I don't think it means, Oh, we can
11 consider whether there are other states that might be kind of
12 similar and therefore give Plaintiff a broader injunction than
13 is necessary to provide them the remedy they need. And I
14 certainly don't think that's what the Supreme Court was
15 saying.

16 There were a couple brief asides that I thought were
17 sort of tangentially related to the scope of the injunction.
18 I'd like to comment briefly on the publicly-traded companies
19 aspect.

20 As the Rule points out, it seems possible, but
21 unlikely, that there are going to be many publicly-traded
22 companies that will invoke the Religious -- that will invoke
23 the Religious or Moral Exemptions. They certainly created an
24 exemption for publicly-traded companies on the Religious Rule,
25 but the Rule itself says they think this is limited and

1 unlikely to occur. And, in fact, Hobby Lobby, I believe, the
2 Supreme Court said a similar thing about the likely effect of
3 publicly-traded companies getting exemptions and
4 accommodations.

5 And the other thing would be that the Moral
6 Exemption is some sort of open invitation to gender
7 discrimination. This was addressed, as I recall, in the last
8 hearing and I think we provided responses including there
9 might be other potential remedies.

10 But I would also like to say, as Mr. Rienzi has
11 pointed out, the states have their own exemptions and they
12 clearly don't think that the potential for some bad actors in
13 some small number of cases to misuse those exemptions is a
14 basis to not have Moral Exemptions to health care, otherwise
15 applicable health care law. They haven't seen this as an
16 insuperable barrier for their own exemptions. It's hard to
17 understand why the fact that there might be a few bad actors
18 through whom, as we say, there might be other remedies somehow
19 becomes an insuperable barrier to the basis of the Moral
20 Exemption here.

21 If the Court has no further questions.

22 THE COURT: Mr. Rienzi.

23 MR. RIENZI: Just three brief points for Your Honor.

24 One, on the publicly -- I'm sorry --

25 THE COURT: On the what, sir?

1 MR. RIENZI: On the publicly-traded point, I would
2 just point out that most of us were probably paying attention
3 when Hobby Lobby was litigated. And when the claim was, Oh,
4 if you let Hobby Lobby exercise religion, we're going to see a
5 rash of these claims of for-profit businesses coming in and
6 making all sorts of outlandish religious liberty claims. That
7 claim's getting kind of stale. Frankly, it's 2019. It was
8 four and a half years ago. It hasn't happened. There's no
9 reason to believe it will happen.

10 The reason the Rule has to cover publicly-traded is
11 the same reason in Hobby Lobby that they said you couldn't
12 exclude corporations generally, which the Dictionary Act says,
13 Person includes corporation. And so it's pretty farfetched,
14 it's pretty unlikely, we still haven't seen the first such
15 case, even though Hobby Lobby was almost five years ago, but
16 it certainly should make the Rules invalid. Congress said
17 person.

18 Secondly, you heard a bunch of times really, but, in
19 particular, the nationwide injunction argument references to
20 the sweeping nature of this Rule, to the great deal of
21 evidence of the problems. We heard about all the amici who
22 filed briefs and the 20-some states that filed briefs.

23 I would just point out the more you hear that, I
24 would just ask Your Honor to think about the fact that, Well,
25 gosh, it's pretty weird to have a sweeping, but imperceptible

1 Rule, right? Like it's sweeping, it covers all these people,
2 all these amici are in the case, the 20 states, everyone
3 showed up. Nobody can find a soul. Nobody can find one.
4 There's not one employer who said they're going to change.
5 There's not one employee who said they're going to lose it.
6 Maybe it's all fake.

7 I suggest to Your Honor it is all fake. There's
8 actually not some huge group of people who are about to lose
9 coverage. Why? Because the actual objectors have their RFRA
10 suits. Because the states and the feds have all of their
11 programs. From the modern era through 2013, women got
12 contraceptives through a zillion different programs and they
13 didn't need nuns.

14 And so the idea that this is going to cause some
15 huge problem is just really farfetched and the more you talk
16 about how sweeping the relief needs to be and all these people
17 who are showing up tell you, yes, it's a problem in my state,
18 too, the more you should pause and say, Gosh, and none of you
19 people can find a soul, not one? That's odd. That's
20 consistent with the fact that it's not really the big problem
21 that they're claiming it's going to be.

22 Lastly, Your Honor, you said, you know, you're
23 wondering if there's a perfect solution on the nationwide
24 injunction point. To be clear, The Little Sisters, we don't
25 take a position either way on scope of relief, on whether

1 nationwide injunctions are okay or not okay.

2 But I will say if you're looking for the perfect
3 solution, RFRA gave it to you. RFRA gives you the solution
4 that lets you have a contraceptive mandate and lets a small
5 number of religious objectors not do it and lets all the other
6 ways that people can get contraceptives continue forward,
7 including changing Title X to make them more accessible.
8 That's your perfect solution. Not a solution that instead
9 asks this Court to issue an order that puts the Administration
10 to an all-or-nothing choice, that either you have no
11 contraceptive mandate or you have one that gets Little Sisters
12 of the Poor. That is the furthest from perfect kind of
13 solution you can have.

14 So I would just suggest that the RFRA solution, the
15 live and let live solution that says, We're big enough to both
16 have a lot of people that want contraceptives and a pretty
17 small minority to say, Hey, I can't have something to do with
18 that, the Government's got to do it another way, that's the
19 RFRA solution. That's actually the perfect solution that
20 would get everything done.

21 Thank you, Your Honor.

22 THE COURT: Okay. Anything else from the
23 Plaintiffs?

24 MR. FISCHER: Real briefly, Your Honor?

25 THE COURT: Okay.

1 MR. FISCHER: Just to be clear, Mr. Rienzi just
2 acknowledged that many of the objectors are protected by
3 injunction. So if the Rule is not for the benefit of the
4 people who have objected, then whose benefit is it for?

5 To be clear, we do not know exactly how many women
6 will be affected because the way the Rule is written, the
7 notice provisions are almost seemingly designed to make it
8 difficult to figure out whether your employer is going to
9 withhold contraception. There is just simply no additional
10 notice is required beyond that which is required by ERISA. So
11 it's not like employers need to publicly announce that we are
12 not going to provide contraception any more.

13 I'm aware of a case where the college did publicly
14 announce, and it was met with significant backlash, and then
15 changed its mind which is probably a lesson to others that
16 perhaps they should not make a big deal out of the fact that
17 they're going to deny contraception. That's not to say that
18 there are not entities that are planning to do it.

19 Finally, just to the nationwide injunction point,
20 although there are certainly laws restricting insurance to --
21 you know, the interstate sale of insurance, there is still a
22 nationwide market for insurance. That's why ERISA exists.
23 There are companies that provide coverage for their employees
24 nationwide that are governed under ERISA. As we mentioned
25 earlier, there are students in Pennsylvania who receive

1 coverage from their parents' plans up until age 26. There's
2 just simply no clean way of carving out the harm to
3 Pennsylvania and New Jersey without leaving our states somehow
4 short of full relief than a nationwide injunction and that's
5 why we think it's appropriate here.

6 We think that the IRAP case does give some
7 direction.

8 I also would refer to the Texas versus United States
9 challenge to the DOPA Program which we discussed at length the
10 last time. Now, again, that was a 4 to 4 decision, but
11 obviously four Justices agreed on standing, on the merits, and
12 on relief. And the relief in that case was not limited to
13 Texas and the other Plaintiffs. The relief was to strike down
14 the DOPA Program nationwide. So four Justices of the Supreme
15 Court felt that was appropriate frankly on, I would submit,
16 much weaker evidence of harm. There the harm in Texas was the
17 cost of providing driver's licenses to undocumented immigrants
18 who would be allowed to stay in the states.

19 We would submit the harm here is much more
20 significant.

21 So, at the very least, four Justices of the Supreme
22 Court gave pretty clear direction.

23 So with that, Your Honor we would again repeat our
24 request for nationwide injunction.

25 THE COURT: Okay, thank you.

1 So the Final Rules are expected to go or scheduled
2 to go into effect on the 14th, is that correct?

3 MR. RIENZI: Correct, Your Honor.

4 THE COURT: Okay, I know you've told me before that
5 it doesn't really matter whether I rule before or after
6 because nothing's going to really happen for what, 30 to 60
7 days, but I am going to rule before the 14th or on the 14th.

8 So what is that? When is the 14th? Tuesday?

9 MR. FISCHER: Monday, Your Honor.

10 THE COURT: Monday. So I'll be working on Sunday.
11 Okay, anything else before I get off the bench?

12 MR. FISCHER: Nothing further, Your Honor.

13 MR. RIENZI: Nothing from us, Your Honor.

14 MR. SANDBERG: Nothing further, Your Honor.

15 THE COURT: Great. Thank you.

16 (Court adjourned)

17 C E R T I F I C A T E

18 I certify that the foregoing is a correct transcript
19 from the record of the proceedings in the above-entitled
20 matter.

21 _____
22 DATE: Kathleen Feldman, CSR, CRR, RPR, CM
 Official Court Reporter

23

24

25

CERTIFICATE OF SERVICE

I hereby certify that on February 15, 2019, I electronically filed the foregoing appendix with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Lowell V. Sturgill Jr.
Lowell V. Sturgill Jr.

Nos. 17-3752, 18-1253, 19-1129, and 19-1189

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY,

Plaintiffs-Appellees,

v.

PRESIDENT, UNITED STATES OF AMERICA; SECRETARY,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES;
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY,
U.S. DEPARTMENT OF THE TREASURY; U.S. DEPARTMENT OF THE
TREASURY; SECRETARY, U.S. DEPARTMENT OF LABOR; and
U.S. DEPARTMENT OF LABOR,

Defendants-Appellants,

and

LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME,

Intervenor-Defendant-Appellant.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania

**JOINT APPENDIX
Vol. 3 (pp. 804-1040)**

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TABLE OF CONTENTS

Volume 1

Notice of Appeal of the Federal Defendants (Case No. 18-1253) (dkt. no. 68)	1
Notice of Appeal of Defendant-Intervenor the Little Sisters of the Poor (Case No. 17-3752) (dkt. no. 61).....	4
Opinion (interim rules) (dkt. no. 59).....	7
Order (enjoining interim rules) (dkt. no. 60).....	51
Notice of Appeal of the Federal Defendants (Case No. 19-1189) (dkt. no. 139)	53
Notice of Appeal of Defendant-Intervenor the Little Sisters of the Poor (Case No. 19-1129) (dkt. no. 138).....	56
Opinion (final rules) (dkt. no. 136)	59
Order (enjoining final rules) (dkt. no. 135)	124

Volume 2

Docket Sheet	126
Complaint (dkt. no. 1).....	165
Amended Complaint (dkt. no. 89).....	198
Declaration of Kathryn Kost (dkt. no. 90-13).....	234
Declaration of Cynthia H. Chuang (dkt. no. 90-14)	267
Declaration of Carol S. Weisman (dkt. no. 90-15).....	277
Declaration of Samantha F. Butts (dkt. no 90-17).....	288

Declaration of Seth A. Mendelsohn (dkt. no 90-18)	297
Declaration of Leesa Allen (dkt. no 90-19)	301
Declaration of Dayle Steinberg (dkt. no 90-20)	307
Declaration of Sarah Adelman (dkt. no. 90-21).....	314
Declaration of Philip Gennace (dkt. no. 90-22)	319
Declaration of Elizabeth Coulter (dkt. no. 90-23)	324
Supplemental Declaration of Kathryn Kost (dkt. no. 118-3).....	331
Declaration of Mother Superior Marie Vincente (dkt. no. 19-2)	334
Spreadsheet from Administrative Record (Litigating Entities) (dkt. no. 90-24)	350
Spreadsheet from Administrative Record (Accommodation) (dkt. no. 90-25)	357
Spreadsheet from Administrative Record (Litigating Entities) (Bates nos. 00805059-00805065).....	384
Transcript of Preliminary-Injunction Hearing (interim rules) (dkt. no. 69)	391
Declaration and Excerpts from Exhibit to Declaration of Sharita Gruberg (ex. 20 at preliminary-injunction hearing)	645
Transcript of Preliminary-Injunction Hearing (final rules) (dkt. no. ____)	673

Volume 3

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017)*	804
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017)*	848
Comments on Interim Final Rules (dkt. no. 90-26)	873
Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018)	882
Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018)	937
Executive Order No. 13,798 (May 4, 2017) (dkt. no. 90-11)	977
Health Resources & Services Administration, Women’s Preventive Services Guidelines (2016) (dkt. no. 90-10)	979
Health Resources & Services Administration, Women’s Preventive Services Guidelines (2011) (dkt. no. 90-9)	984
Excerpts from Institute of Medicine, <i>Clinical Preventive Services for Women: Closing the Gaps</i> (2011) (dkt. no. 90-8)	987
Ashley H. Snyder et al., <i>The Impact of the Affordable Care Act on Contraceptive Use and Costs Among Privately Insured Women</i> (2018) (dkt. no. 90-16)	1036

* “Public inspection” copies of the interim final rules were attached to the complaint. For ease of reference and citation, we have included in the appendix the interim rules as published in the Federal Register.

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD-9827]

RIN 1545-BN92

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS-9940-IFC]

RIN 0938-AT20

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions. These interim final rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave the “accommodation” process in place as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These interim final rules and temporary regulations are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by “Preventive Services,” may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9940-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9940-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the

building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492-4305 or marketreform@cms.hhs.gov for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317-5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (www.dol.gov/ebsa).

Information from HHS on private health insurance coverage can be found on CMS's Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Congress has consistently sought to protect religious beliefs in the context of health care and human services, including health insurance, even as it has sought to promote access to health services.¹ Against that backdrop,

¹ See, for example, 42 U.S.C. 300a-7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their “religious beliefs or moral convictions”); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115-31 (protecting any “health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan” in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of “the provision of

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, “with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by” by HRSA (the “Guidelines”). Public Health Service Act section 2713(a)(4).

contraceptive coverage by health insurance plans” in the District of Columbia, “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions”); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their “religious or conscientious commitment to offer only natural family planning”); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on “religious beliefs or moral objections”); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on “conscience” as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on “religious beliefs or moral convictions”); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); also, see 8 U.S.C. 1182(g) (protecting vaccination objections by “aliens” due to “religious beliefs or moral convictions”); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on “moral or religious convictions”); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their “religious or moral objection”).

HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,² while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, “the Departments”³)—exercised the same discretion to allow exemptions to those requirements. Through rulemaking, including three interim final rules, the Departments allowed exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the “contraceptive Mandate,” or the “Mandate”) as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1. Much of that litigation continues to this day.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as the interests served by the existing Guidelines, regulations, and accommodation process;⁴ the extensive litigation; Executive Order 13798, “Promoting Free Speech and Religious Liberty” (May 4, 2017); protection of the free exercise of religion in the First Amendment and by Congress in the Religious Freedom Restoration Act of 1993; Congress’ history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under section 2713(a)(4) of the PHS Act; the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; the regulatory process and comments submitted in various requests for public comments (including in the Departments’ 2016 Request for Information).

In light of these factors, the Departments issue these new interim

final rules to better balance the Government’s interest in ensuring coverage for contraceptive and sterilization services in relation to the Government’s interests, including as reflected throughout Federal law, to provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, “[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact” and that “[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.”

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS Act requires coverage without cost sharing for “such additional” women’s preventive care and screenings “as provided for” and “supported by” guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

² This document’s references to “contraception,” “contraceptive,” “contraceptive coverage,” or “contraceptive services” generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

³ Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

⁴ In this document, we generally use “accommodation” and “accommodation process” interchangeably.

The Departments have consistently interpreted section 2714(a)(4) PHS Act's grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act's reference to "comprehensive guidelines supported by HRSA for purposes of this paragraph" to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines "supported by HRSA for purposes of this paragraph," the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from "the other guidelines referenced in section 2713(a) of the PHS Act, which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients." *Id.* Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4) of the PHS Act, the Departments have previously promulgated regulations defining the scope of permissible exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92)

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. Congress did not intend to require entirely uniform coverage of

preventive services (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 of the PHS Act for grandfathered plans. In contrast, this exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include: Section 2704 of the PHS Act, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708 of the PHS Act, which prohibits excessive waiting periods (as of January 1, 2014); section 2711 of the PHS Act, which relates to lifetime limits; section 2712 of the PHS Act, which prohibits rescission of health insurance coverage; section 2714 of the PHS Act, which extends dependent coverage until age 26; and section 2718 of the PHS Act, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.⁵ As the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that "longstanding Federal laws to protect conscience * * * remain intact," including laws that protect religious beliefs (and moral convictions) from certain requirements in the health care context. While the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect religious beliefs

⁵ Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in accordance with the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, "Clinical Preventive Services for Women, Closing the Gaps" (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.⁶

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of "contraceptives" certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,⁷ the IOM's recommendation included several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason

⁶ Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings "with respect to women," the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

⁷ FDA's guide "Birth Control: Medicines To Help You," specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and "may also work * * * by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization. Available at <https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm>.

distinct from whether they also oppose contraception or sterilization.

One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He argued that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by the United States Preventive Services Task Force (USPSTF), HRSA's Bright Futures Project, and the Advisory Committee on Immunization Practices (ACIP) leads to lower rates of disability or disease and increased rates of well-being. He further argued that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and that "the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy." Dr. LoSasso also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.⁸ (IOM 2011 at 231–32). In its response to Dr. LoSasso, the other 15 committee members stated, in part, that "At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions."

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM <https://www.hrsa.gov/womensguidelines/>. The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

⁸ The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specify that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.⁹ The 2011 interim final rules defined an exempt "religious employer" narrowly as one that: (1) Had the inculcation of religious values as its purpose; (2) primarily employed persons who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a nonprofit organization, as described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Those relevant sections of the Code include only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of a religious order. The practical effect of the rules' definition of "religious employer" was to create potential uncertainty about whether employers, including many of those houses of worship or their integrated auxiliaries, would fail to qualify for the exemption if they engaged in outreach activities toward persons who did not share their religious tenets.¹⁰ As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some "States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services." (76 FR 46623). That same day, HRSA exercised the discretion described in the 2011 interim final rules to provide the exemption.

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of "religious employer" in the 2011 interim final rules without modification (2012 final regulations).¹¹ (77 FR 8725). The exemption did not require religious

⁹ The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011 (76 FR 46621).

¹⁰ See, for example, Comments of the United States Conference of Catholic Bishops on Interim Final Rules on Preventive Services, File Code CMS–9992–IFC2 (Aug. 31, 2011).

¹¹ The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

employers to file any certification form or comply with any other information collection process.

Contemporaneous with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).¹² The guidance provided that the temporary safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. The temporary safe harbor did not apply to for-profit entities. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve "two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services." (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer

¹² Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: <http://www.lfb7.uscourts.gov/documents/12cv3932.pdf>. The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer (1) have the inculcation of religious values as its purpose, (2) primarily employ persons who share its religious tenets, and (3) primarily serve persons who share its religious tenets.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible religious nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations “may be less likely than” employees of exempt houses of worship and integrated auxiliaries to share their employer’s faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization’s plan—and without any cost to the eligible organization.¹³ In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries.

On August 15, 2012, the Departments also extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

¹³ The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations “does not undermine the governmental interests furthered by the contraceptive coverage requirement.” (78 FR 39874). But, like the 2013 NPRM, the July 2013 regulations assumed that “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection” to contraceptives (*Id.*).

The July 2013 regulations also finalized an accommodation for eligible organizations. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization’s plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect.¹⁴ With respect to fully insured group health plans, the issuer was expected to

¹⁴ See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was \$33 million.

bear the cost of such payments,¹⁵ and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations.

With respect to self-insured group health plans, the July 2013 final regulations specified that the self-certification was an instrument under which the plan was operated and that it obligated the third party administrator to provide or arrange for contraceptive coverage by operation of section 3(16) of ERISA. The regulations stated that, by submitting the self-certification form, the eligible organization “complies” with the contraceptive coverage requirement and does not have to contract, arrange, pay, or refer for contraceptive coverage. See, for example, *Id.* at 39874, 39896. Consistent with these statements, the Departments, through the Department of Labor, issued a self-certification form, EBSA Form 700. The form stated, in indented text labeled as a “Notice to Third Party Administrators of Self-Insured Health Plans,” that “[t]he obligations of the third party administrator are set forth in 26 CFR 54.9815–2713A, 29 CFR 2510.3–16, and 29 CFR 2590.715–2713A” and concluded, in unindented text, that “[t]his form is an instrument under which the plan is operated.”

The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. The guidance extending the safe harbor included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary safe harbor if no prior form had been submitted.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others. Religious plaintiffs principally argued that the Mandate violated the Religious Freedom Restoration Act of 1993 (RFRA) by forcing them to provide coverage or payments for sterilization and contraceptive services, including what they viewed as early abortifacient items, contrary to their religious beliefs. Based on this claim, in July 2012 a

¹⁵ “[P]roviding payments for contraceptive services is cost neutral for issuers.” (78 FR 39877).

Federal district court issued a preliminary injunction barring the Departments from enforcing the Mandate against a family-owned business. *Newland v. Sebelius*, 881 F. Supp. 2d 1287 (D. Colo. 2012). Multiple other courts proceeded to issue similar injunctions against the Mandate, although a minority of courts ruled in the Departments' favor. *Compare Tyndale House Publishers, Inc. v. Sebelius*, 904 F. Supp. 2d 106 (D.D.C. 2012), and *The Seneca Hardwood Lumber Company, Inc. v. Sebelius* (sub nom *Geneva Coll. v. Sebelius*), 941 F. Supp. 2d 672 (W.D. Pa. 2013), with *O'Brien v. U.S. Dep't of Health & Human Servs.*, 894 F. Supp. 2d 1149 (E.D. Mo. 2012).

A circuit split swiftly developed in cases filed by religiously motivated for-profit businesses, to which neither the religious employer exemption nor the eligible organization accommodation (as then promulgated) applied. Several for-profit businesses won rulings against the Mandate before the Unites States Court of Appeals for the Tenth Circuit, sitting en banc, while similar rulings against the Departments were issued by the Seventh and District of Columbia (DC) Circuits. *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013); *Korte v. Sebelius*, 735 F.3d 654 (7th Cir. 2013); *Gilardi v. U.S. Dep't of Health & Human Servs.*, 733 F.3d 1208 (D.C. Cir. 2013). The Third and Sixth Circuits disagreed with similar plaintiffs, and in November 2013 the U.S. Supreme Court granted certiorari in *Hobby Lobby* and *Conestoga Wood Specialties Corp. v. Secretary of U.S. Department of Health & Human Services*, 724 F.3d 377 (3d Cir. 2013), to resolve the circuit split.

On June 30, 2014, the Supreme Court ruled against the Departments and held that, under RFRA, the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.¹⁶ *Burwell v. Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Court held that the "contraceptive mandate 'substantially burdens' the exercise of religion" as applied to employers that object to providing contraceptive coverage on religious grounds, and that the plaintiffs were therefore entitled to an exemption unless the Mandate was the least restrictive means of furthering a compelling governmental interest. *Id.* at 2775. The Court observed that, under

the compelling interest test of RFRA, the Departments could not rely on interests "couched in very broad terms, such as promoting 'public health' and 'gender equality,' but rather, had to demonstrate that a compelling interest was served by refusing an exemption to the "particular claimant[s]" seeking an exemption. *Id.* at 2779. Assuming without deciding that a compelling interest existed, the Court held that the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner. The Court observed that "[t]he most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections." *Id.* at 2780. The Court also observed that the Departments had "not provided any estimate of the average cost per employee of providing access to these contraceptives," nor "any statistics regarding the number of employees who might be affected because they work for corporations like Hobby Lobby, Conestoga, and Mardel". *Id.* at 2780–81. But the Court ultimately concluded that it "need not rely on the option of a new, government-funded program in order to conclude that the HHS regulations fail the least-restrictive means test" because "HHS itself ha[d] demonstrated that it ha[d] at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs." *Id.* at 2781–82. The Court explained that the "already established" accommodation process available to nonprofit organizations was a less-restrictive alternative that "serve[d] HHS's stated interests equally well," although the Court emphasized that its ruling did not decide whether the accommodation process "comple[d] with RFRA for purposes of all religious claims". *Id.* at 2788–82.

Meanwhile, another plaintiff obtained temporary relief from the Supreme Court in a case challenging the accommodation under RFRA. Wheaton College, a Christian liberal arts college in Illinois, objected that the accommodation was a compliance process that rendered it complicit in delivering payments for abortifacient contraceptive services to its employees. Wheaton College refused to execute the EBSA Form 700 required under the July 2013 final regulations. It was denied a preliminary injunction in the Federal district and appellate courts, and sought an emergency injunction pending

appeal from the Unites States Supreme Court on June 30, 2014. On July 3, 2014, the Supreme Court issued an interim order in favor of the College, stating that, "[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing [the Mandate] against the [plaintiff] . . . pending final disposition of appellate review." *Wheaton College v. Burwell*, 134 S. Ct. 2806, 2807 (2014). The order stated that Wheaton College did not need to use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for injunctive relief. *Id.*

In response to this litigation, on August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of the Department of Health and Human Services that an eligible organization had religious objections to coverage of all or a subset of contraceptive services. (79 FR 51092). In response to *Hobby Lobby*, the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations. (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption, and neither added a certification requirement for exempt entities.

In October 2014, based on an interpretation of the Supreme Court's interim order, HHS deemed Wheaton College as having submitted a sufficient notice to HHS. HHS conveyed that interpretation to the DOL, so as to trigger the accommodation process.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The preamble to the July 2015 final regulations stated that, through the accommodation, payments

¹⁶ The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

for contraceptives and sterilization would be provided in a way that is “seamless” with the coverage that eligible employers provide to their plan participants and beneficiaries. *Id.* at 41328. The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization’s name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan’s third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

When an eligible organization maintains an insured group health plan or student health plan and provides the alternative notice, the July 2015 final regulations provide that HHS will inform the health insurance issuer of its obligations to cover contraceptive services to which the eligible organization objects. Where an eligible organization maintains a self-insured plan under ERISA and provides the alternative notice, the regulations provide that DOL will work with HHS to send a separate notification to the self-insured plan’s third party administrator(s). The regulations further provide that such notification is an instrument under which the plan is operated for the purposes of section 3(16) of ERISA, and the instrument would designate the third party administrator as the entity obligated to provide or arrange for payments for contraceptives to which the eligible organization objects. The July 2015 final regulations continue to apply the amended notice requirement to eligible organizations that sponsor church plans exempt from ERISA pursuant to section 4(b)(2) of ERISA, but acknowledge that, with respect to the operation of the accommodation process, section 3(16) of ERISA does not provide a mechanism to impose an obligation to provide contraceptive coverage as a plan administrator on those eligible organizations’ third party administrators. (80 FR 41323).

Meanwhile, a second split among Federal appeals courts had developed involving challenges to the Mandate’s accommodation. Many religious nonprofit organizations argued that the accommodation impermissibly burdened their religious beliefs because it utilized the plans the organizations themselves sponsored to provide services to which they objected on

religious grounds. They objected to the self-certification requirement on the same basis. Federal district courts split in the cases, granting preliminary injunction motions to religious groups in the majority of cases, but denying them to others. In most appellate cases, religious nonprofit organizations lost their challenges, where the courts often concluded that the accommodation imposed no substantial burden on their religious exercise under RFRA. For example, *Priests for Life v. U.S. Dep’t of Health and Human Servs.*, 772 F.3d 229 (D.C. Cir. 2014); *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151 (10th Cir. 2015); *Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422 (3d Cir. 2015). But the Eighth Circuit disagreed and ruled in favor of religious nonprofit employers. *Dordt College v. Burwell*, 801 F.3d 946, 949–50 (8th Cir. 2015) (relying on *Sharpe Holdings, Inc. v. U.S. Dep’t of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015)).

On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik v. Burwell*. The Court held oral argument on March 23, 2016, and, after the argument, asked the parties to submit supplemental briefs addressing “whether and how contraceptive coverage may be obtained by petitioners’ employees through petitioners’ insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees”. In a brief filed with the Supreme Court on April 12, 2016, the Government stated on behalf of the Departments that the accommodation process for eligible organizations with insured plans could operate without any self-certification or written notice being submitted by eligible organizations.

On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik*, vacating the judgments of the Courts of Appeals and remanding the cases “in light of the substantial clarification and refinement in the positions of the parties” in their supplemental briefs. (136 S. Ct. 1557, 1560 (2016).) The Court stated that it anticipated that, on remand, the Courts of Appeals would “allow the parties sufficient time to resolve any outstanding issues between them.” *Id.* The Court also specified that “the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice” while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, some meetings were held between attorneys for the Government and for the plaintiffs in those cases. Separately, at various times after the Supreme Court’s remand order, HHS and DOL sent letters to the issuers and third party administrators of certain plaintiffs in *Zubik* and other pending cases, directing the issuers and third party administrators to provide contraceptive coverage for participants in those plaintiffs’ group health plans under the accommodation. The Departments also issued a Request for Information (RFI) on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court’s remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016.

On December 20, 2016, HRSA updated the Guidelines via its Web site, <https://www.hrsa.gov/womensguidelines2016/index.html>. HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the contraceptive method). They also specified that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women’s Preventive Services’ Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process.

On January 9, 2017, the Departments issued a document entitled, “FAQs About Affordable Care Act Implementation Part 36” (FAQ).¹⁷ The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments’ policy goals. Thus, the

¹⁷ Available at: <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.

litigation on remand from the Supreme Court remains unresolved.

A separate category of unresolved litigation involved religious employees as plaintiffs. For example, in two cases, the plaintiff-employees work for a nonprofit organization that agrees with the employees (on moral grounds) in opposing coverage of certain contraceptives they believe to be abortifacient, and that is willing to offer them insurance coverage that omits such services. See *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015); *Real Alternatives*, 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). In another case, the plaintiff-employees work for a State government entity that the employees claim is willing, under State law, to provide a plan omitting contraception consistent with the employees' religious beliefs. See *Wieland v. HHS*, 196 F. Supp. 3d 1010 (E.D. Mo. 2016). Those and similar employee-plaintiffs generally contend that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from their willing employer or in the individual market, because the Departments offer no exemptions encompassing either circumstance. Such challenges have seen mixed success. Compare, for example, *Wieland*, 196 F. Supp. 3d at 1020 (concluding that the Mandate violates the employee plaintiffs' rights under RFRA and permanently enjoining the Departments) and *March for Life*, 128 F. Supp. 3d at 133–34 (same), with *Real Alternatives*, 2017 WL 3324690 at *18 (affirming dismissal of employee plaintiffs' RFRA claim).

On May 4, 2017, the President issued an "Executive Order Promoting Free Speech and Religious Liberty." Regarding "Conscience Protections with Respect to Preventive-Care Mandate," that order instructs "[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services [to] consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code."

II. RFRA and Government Interests Underlying the Mandate

RFRA provides that the Government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" unless the Government "demonstrates that application of the burden to the person—(1) is in

furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. 2000bb–1(a) and (b). In *Hobby Lobby*, the Supreme Court had "little trouble concluding" that, in the absence of an accommodation or exemption, "the HHS contraceptive mandate 'substantially burden[s]' the exercise of religion." 42 U.S.C. 2000bb–1(a)." 134 S. Ct. at 2775. And although the Supreme Court did not resolve the RFRA claims presented in *Zubik* on their merits, it instructed the parties to consider alternative accommodations for the objecting plaintiffs, after the Government suggested that such alternatives might be possible.

Despite multiple rounds of rulemaking, however, the Departments have not assuaged the sincere religious objections to contraceptive coverage of numerous organizations, nor have we resolved the pending litigation. To the contrary, the Departments have been litigating RFRA challenges to the Mandate and related regulations for more than 5 years, and dozens of those challenges remain pending today. That litigation, and the related modifications to the accommodation, have consumed substantial governmental resources while creating uncertainty for objecting organizations, issuers, third party administrators, employees, and beneficiaries. Consistent with the President's Executive Order and the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.

These interim final rules (and the companion interim final rules published elsewhere in this **Federal Register**) are the result of that reexamination. The Departments acknowledge that coverage of contraception is an important and highly sensitive issue, implicating many different views, as reflected in the comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. After reconsidering the interests served by the Mandate in this particular context, the objections raised, and the applicable Federal law, the Departments have determined that an expanded exemption, rather than the existing accommodation, is the most appropriate administrative response to the religious objections raised by certain entities and organizations concerning the Mandate. The Departments have accordingly decided to revise the regulations channeling HRSA authority

under section 2713(a)(4) of the PHS to provide an exemption from the Mandate to a broader range of entities and individuals that object to contraceptive coverage on religious grounds, while continuing to offer the existing accommodation as an optional alternative. The Departments have also decided to create a process by which a willing employer and issuer may allow an objecting individual employee to obtain health coverage without contraceptive coverage. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

In addition to relying on the text of section 2713(a)(4) of the PHS Act and the Departments' discretion to promulgate rules to carry out the provisions of the PHS Act, the Departments also draw on Congress' decision in the Affordable Care Act neither to specify that contraception must be covered nor to require inflexible across-the-board application of section 2713 of the PHS Act. The Departments further consider Congress' extensive history of protecting religious objections when certain matters in health care are specifically regulated—often specifically with respect to contraception, sterilization, abortion, and activities connected to abortion.

Notable among the many statutes (listed in footnote 1 in Section I-Background) that include protections for religious beliefs are, not only the Church Amendments, but also protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. (42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1396u–2(b)(3)). In addition, Congress has protected individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31 (May 5, 2017). Congress likewise provided that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for

religious beliefs and moral convictions”. *Id.* at Division C, Title VIII, Sec. 808. In light of the fact that Congress did not require HRSA to include contraception in Guidelines issued under section 2713 of the PHS Act, we consider it significant, in support of the implementation of those Guidelines by the expanded exemption in these interim final rules, that Congress’ most recent statement on the prospect of Government mandated contraceptive coverage was to express the specific intent that a conscience clause be provided and that it should protect religious beliefs.

The Departments’ authority to guide HRSA’s discretion in determining the scope of any contraceptive coverage requirement under section 2713(a)(4) of the PHS Act includes the authority to provide exemptions and independently justifies this rulemaking. The Departments have also determined that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance violates their rights under RFRA.

A. Elements of RFRA

1. Substantial Burden

The Departments believe that agencies charged with administering a statute or associated regulations or guidance that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining how to avoid the imposition of such burden. The Departments have previously contended that the Mandate does not impose a substantial burden on entities and individuals. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with religious objections, our argument was rejected in *Hobby Lobby*, which held that the Mandate imposes a substantial burden. (134 S. Ct. at 2775–79.) With respect to whether the Mandate imposes a substantial burden on entities that may choose the accommodation, but must choose between the accommodation, the Mandate, or penalties for noncompliance, a majority of Federal appeals courts have held that the accommodation does not impose a substantial burden on such entities (mostly religious nonprofit entities).

The Departments have reevaluated our position on this question, however, in light of all the arguments made in various cases, public comments that have been submitted, and the concerns discussed throughout these rules. We have concluded that requiring certain objecting entities or individuals to

choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA. We believe that the Court’s analysis in *Hobby Lobby* extends, for the purposes of analyzing a substantial burden, to the burdens that an entity faces when it religiously opposes participating in the accommodation process or the straightforward Mandate, and is subject to penalties or disadvantages that apply in this context if it chooses neither. As the Eighth Circuit stated in *Sharpe Holdings*, “[i]n light of [nonprofit religious organizations’] sincerely held religious beliefs, we conclude that compelling their participation in the accommodation process by threat of severe monetary penalty is a substantial burden on their exercise of religion. . . . That they themselves do not have to arrange or pay for objectionable contraceptive coverage is not determinative of whether the required or forbidden act is or is not religiously offensive”. (801 F.3d at 942.)

Our reconsideration of these issues has also led us to conclude, consistent with the rulings in favor of religious employee plaintiffs in *Wieland* and *March for Life* cited above, that the Mandate imposes a substantial burden on the religious beliefs of individual employees who oppose contraceptive coverage and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because of the Mandate’s prohibition on that employer and/or issuer providing them with such a plan.

Consistent with our conclusion earlier this year after the remand of cases in *Zubik* and our reviewing of comments submitted in response to the 2016 RFI, the Departments believe there is not a way to satisfy all religious objections by amending the accommodation. Accordingly, the Departments have decided it is necessary and appropriate to provide the expanded exemptions set forth herein.

2. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Under such circumstances, the Departments are required by law to alleviate the substantial burden created by the Mandate. Here, informed by the Departments’ reassessment of the

relevant interests, as well as by our desire to bring to a close the more than 5 years of litigation over RFRA challenges to the Mandate, the Departments have determined that the appropriate administrative response is to create a broader exemption, rather than simply adjusting the accommodation process.

RFRA requires the Government to respect religious beliefs under “the most demanding test known to constitutional law”: Where the Government imposes a substantial burden on religious exercise, it must demonstrate a compelling governmental interest and show that the law or requirement is the least restrictive means of furthering that interest. *City of Boerne v. Flores*, 521 U.S. 507, 534 (1997). For an interest to be compelling, its rank must be of the “highest order”. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993); see also *Sherbert v. Verner*, 374 U.S. 398, 406–09 (1963); *Wisconsin v. Yoder*, 406 U.S. 205, 221–29 (1972). In applying RFRA, the Supreme Court has “looked beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants.” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 431 (2006). To justify a substantial burden on religious exercise under RFRA, the Government must show it has a compelling interest in applying the requirement to the “particular claimant[s] whose sincere exercise of religion is being substantially burdened.” *Id.* at 430–31. Moreover, the Government must meet the “exceptionally demanding” least-restrictive-means standard. *Hobby Lobby*, 134 S. Ct. at 2780. Under that standard, the Government must establish that “it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting parties.” *Id.*

Upon further examination of the relevant provisions of the Affordable Care Act and the administrative record on which the Mandate was based, the Departments have concluded that the application of the Mandate to entities with sincerely held religious objections to it does not serve a compelling governmental interest. The Departments have reached that conclusion for multiple reasons, no one of which is dispositive.

First, Congress did not mandate that contraception be covered at all under the Affordable Care Act. Instead, Congress merely provided for coverage

of “such additional preventive care and screenings” for women “provided for in comprehensive guidelines supported by [HRSA].” Congress, thus, left the identification of any additional required preventive services for women to administrative discretion. The fact that Congress granted the Departments the authority to promulgate all rules appropriate and necessary for the administration of the relevant provisions of the Code, ERISA, and the PHS Act, including by channeling the discretion Congress afforded to HRSA to decide whether to require contraceptive coverage, indicates that the Departments’ judgment should carry particular weight in considering the relative importance of the Government’s interest in applying the Mandate to the narrow population of entities exempted in these rules.

Second, while Congress specified that many health insurance requirements added by the Affordable Care Act—including provisions adjacent to section 2713 of the PHS Act—were so important that they needed to be applied to all health plans immediately, the preventive services requirement in section 2713 of the PHS Act was not made applicable to “grandfathered plans.” That feature of the Affordable Care Act is significant: As cited above, seven years after the Affordable Care Act’s enactment, approximately 25.5 million people are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act. We do not suggest that a requirement that is inapplicable to grandfathered plans or otherwise subject to exceptions could never qualify as a serving a compelling interest under RFRA. For example, “[e]ven a compelling interest may be outweighed in some circumstances by another even weightier consideration.” *Hobby Lobby*, 134 S. Ct. at 2780. But Congress’ decision not to apply section 2713 of the PHS Act to grandfathered plans, while deeming other requirements closely associated in the same statute as sufficiently important to impose immediately, is relevant to our assessment of the importance of the Government interests served by the Mandate. As the Departments observed in 2010, those immediately applicable requirements were “particularly significant.” (75 FR 34540). Congress’ decision to leave section 2713 out of that category informs the Departments’ assessment of the weight of the Government’s interest in applying the Guidelines issued pursuant to section 2713 of the PHS Act to religious objectors.

Third, various entities that brought legal challenges to the Mandate (including some of the largest employers) have been willing to provide coverage of some, though not all, contraceptives. For example, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of 14 of 18 FDA-approved women’s contraceptive and sterilization methods. (134 S. Ct. at 2766.) With respect to organizations and entities holding those beliefs, the fact that they are willing to provide coverage for various contraceptive methods significantly detracts from the government interest in requiring that they provide coverage for other contraceptive methods to which they object.

Fourth, the case for a compelling interest is undermined by the existing accommodation process, and how it applies to certain similarly situated entities based on whether or not they participate in certain self-insured group health plans, known as church plans, under applicable law. The Departments previously exempted eligible organizations from the contraceptive coverage requirement, and created an accommodation under which those organizations bore no obligation to provide for such coverage after submitting a self-certification or notice. Where a non-exempt religious organization uses an insured group health plan instead of a self-insured church plan, the health insurance issuer would be obliged to provide contraceptive coverage or payments to the plan’s participants under the accommodation. Even in a self-insured church plan context, the preventive services requirement in section 2713(a)(4) of the PHS Act applies to the plan, and through the Code, to the religious organization that sponsors the plan. But under the accommodation, once a self-insured church plan files a self-certification or notice, the accommodation relieves it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would normally transfer the obligation to provide or arrange for contraceptive coverage to a self-insured plan’s third party administrator (TPA). But the Departments lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers,

but not as they pertain to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713’s authority to remove contraceptive coverage obligations from self-insured church plans, and HHS’s and DOL’s lack of authority under the PHS Act or ERISA to require TPAs to become administrators of those plans to provide such coverage, has led to significant incongruity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

More specifically, issuers and third party administrators for some, but not all, religious nonprofit organizations are subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they participate in a self-insured church plan. Notably, many of those nonprofit organizations are not houses of worship or integrated auxiliaries. Under section 3(33)(C)(iv) of ERISA, many organizations in self-insured church plans need not be churches, but can merely “share[] common religious bonds and convictions with [a] church or convention or association of churches”. The effect is that many similar religious organizations are being treated very differently with respect to their employees receiving contraceptive coverage—depending on whether the organization is part of a church plan—even though the Departments claimed a compelling interest to deny exemptions to all such organizations. In this context, the fact that the Mandate and the Departments’ application thereof “leaves appreciable damage to [their] supposedly vital interest unprohibited” is strong evidence that the Mandate “cannot be regarded as protecting an interest ‘of the highest order.’” *Lukumi*, 508 U.S. at 520 (citation and quotation marks omitted).

Fifth, the Departments’ previous assertion that the exemption for houses of worship was offered to respect a certain sphere of church autonomy (80 FR 41325) does not adequately explain some of the disparate results of the existing rules. And the desire to respect church autonomy is not grounds to prevent the Departments from expanding the exemption to other religious entities. The Departments previously treated religious organizations that operate in a similar fashion very differently for the purposes of the Mandate. For example, the Departments exempted houses of worship and integrated auxiliaries that may conduct activities, such as the

operating of schools, that are also conducted by non-exempt religious nonprofit organizations. Likewise, among religious nonprofit groups that were not exempt as houses of worship or integrated auxiliaries, many operate their religious activities similarly even if they differ in whether they participate in self-insured church plans. As another example, two religious colleges might have the same level of religiosity and commitment to defined ideals, but one might identify with a specific large denomination and choose to be in a self-insured church plan offered by that denomination, while another might not be so associated or might not have as ready access to a church plan and so might offer its employees a fully insured health plan. Under the accommodation, employees of the college using a fully insured plan (or a self-insured plan that is not a church plan) would receive coverage of contraceptive services without cost sharing, while employees of the college participating in the self-insured church plan would not receive the coverage where that plan required its third party administrator to not offer the coverage.

As the Supreme Court recently confirmed, a self-insured church plan exempt from ERISA through ERISA 3(33) can include a plan that is not actually established or maintained by a church or by a convention or association of churches, but is maintained by “an organization . . . the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches” (a so-called “principal-purpose organization”). See *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1656–57 (U.S. June 5, 2017); ERISA 3(33)(C). While the Departments take no view on the status of these particular plans, the Departments acknowledge that the church plan exemption not only includes some non-houses-of-worship as organizations whose employees can be covered by the plan, but also, in certain circumstances, may include plans that are not themselves established and maintained by houses of worship. Yet, such entities and plans—if they file a self-certification or notice through the existing accommodation—are relieved of obligations under the contraceptive Mandate and their third party administrators are not subject to a

requirement that they provide contraceptive coverage to their plan participants and beneficiaries.

After considering the differential treatment of various religious nonprofit organizations under the previous accommodation, the Departments conclude that it is appropriate to expand the exemption to other religious nonprofit organizations with sincerely held religious beliefs opposed to contraceptive coverage. We also conclude that it is not appropriate to limit the scope of a religious exemption by relying upon a small minority of State laws that contain narrow exemptions that focus on houses of worship and integrated auxiliaries. (76 FR 46623.)

Sixth, the Government’s interest in ensuring contraceptive coverage for employees of particular objecting employers is undermined by the characteristics of many of those employers, especially nonprofit employers. The plaintiffs challenging the existing accommodation include, among other organizations, religious colleges and universities, and religious orders that provide health care or other charitable services. Based in part on our experience litigating against such organizations, the Departments now disagree with our previous assertion that “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.”¹⁸ (78 FR 39874.) Although empirical data was not required to reach our previous conclusion, we note that the conclusion was not supported by any specific data or other source, but instead was intended to be a reasonable assumption. Nevertheless, in the litigation and in numerous public comments submitted throughout the regulatory processes described above, many religious nonprofit organizations have indicated that they possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Some of the religious nonprofit groups challenging the accommodation claim that their employees are required to adhere to a statement of faith which includes the entities’ views on certain contraceptive

items.¹⁹ The Departments recognize, of course, that not all of the plaintiffs challenging the accommodation require all of their employees (or covered students) to share their religious objections to contraceptives. At the same time, it has become apparent from public comments and from court filings in dozens of cases—encompassing hundreds of organizations—that many religious nonprofit organizations express their beliefs publicly and hold themselves out as organizations for whom their religious beliefs are vitally important. Employees of such organizations, even if not required to sign a statement of faith, often have access to, and knowledge of, the views of their employers on contraceptive coverage, whether through the organization’s published mission statement or statement of beliefs, through employee benefits disclosures and other communications with employees and prospective employees, or through publicly filed lawsuits objecting to providing such coverage and attendant media coverage. In many cases, the employees of religious organizations will have chosen to work for those organizations with an understanding—explicit or implicit—that they were being employed to advance the organization’s goals and to be respectful of the organization’s beliefs even if they do not share all of those beliefs. Religious nonprofit organizations that engage in expressive activity generally have a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.²⁰

Given the sincerely held religious beliefs of many religious organizations, imposing the contraceptive-coverage requirement on those that object based on such beliefs might undermine the Government’s broader interests in ensuring health coverage by causing the entities to stop providing health coverage. For example, because the Affordable Care Act does not require

¹⁹ See, for example, *Geneva College v. Sebelius*, 929 F. Supp. 2d 402, 411 (W.D. Pa. 2013); *Grace Schools v. Sebelius*, 988 F. Supp. 2d 935, 943 (N.D. Ind. 2013); Comments of the Council for Christian Colleges & Universities, re: CMS–9968–P (filed Apr. 8, 2013) (“On behalf of [] 172 higher education institutions . . . a requirement for membership in the CCCU is that full-time administrators and faculty at our institutions share the Christian faith of the institution.”).

²⁰ Notably, “the First Amendment simply does not require that every member of a group agree on every issue in order for the group’s policy to be ‘expressive association.’” *Boy Scouts of America v. Dale*, 530 U.S. 640, 655 (2000).

¹⁸ In changing its position, an agency “need not demonstrate to a court’s satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or be subject to the accommodation with respect to such populations.²¹

Seventh, we now believe the administrative record on which the Mandate rests is insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. To begin, in support of the IOM's recommendations, which HRSA adopted, the IOM identified several studies showing a preventive services gap because women require more preventive care than men. (IOM 2011 at 19–21). Those studies did not identify contraceptives or sterilization as composing a specific portion of that gap, and the IOM did not consider or establish in the report whether any cost associated with that gap remains after all other women's preventive services are covered without cost-sharing. *Id.* Even without knowing what the empirical data would show about that gap, the coverage of the other women's preventive services required under both the HRSA Guidelines and throughout section 2713(a) of the PHS Act—including annual well-woman visits and a variety of tests, screenings, and counseling services—serves at a minimum to diminish the cost gap identified by IOM for women whose employers decline to cover some or all contraceptives on religious grounds.²²

Moreover, there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families. According to the Guttmacher Institute, government-subsidized family planning services are provided at 8,409 health centers overall.²³ The Title X program, for example, administered by the HHS Office of Population Affairs

(OPA), provides a wide variety of voluntary family planning information and services for clients based on their ability to pay, through a network that includes nearly 4,000 family planning centers. <http://www.hhs.gov/opa/title-x-family-planning/> Individuals with family incomes at or below the HHS poverty guideline (for 2017, \$24,600 for a family of four in the 48 contiguous States and the District of Columbia) receive services at no charge unless a third party (governmental or private) is authorized or obligated to pay for these services. Individuals with incomes in excess of 100 percent up to 250 percent of the poverty guideline are charged for services using a sliding fee scale based on family size and income.

Unemancipated minors seeking confidential services are assessed fees based on their own income level rather than their family's income. The availability of such programs to serve the most at-risk women (as defined in the IOM report) diminishes the Government's interest in applying the Mandate to objecting employers. Many forms of contraception are available for around \$50 per month, including long-acting methods such as the birth control shot and intrauterine devices (IUDs).²⁴ Other, more permanent forms of contraception like implantables bear a higher one-time cost, but when calculated over the duration of use, cost a similar amount.²⁵ Various State programs supplement the Federal programs referenced above, and 28 States have their own mandates of contraceptive coverage as a matter of State law. This existing inter-governmental structure for obtaining contraceptives significantly diminishes the Government's interest in applying the Mandate to employers over their sincerely held religious objections.

The record also does not reflect that the Mandate is tailored to the women most likely to experience unintended pregnancy, identified by the 2011 IOM report as “women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority”. (IOM 2011 at 102). For example, with respect to religiously objecting organizations, the Mandate applies in employer-based group health plans and student

insurance at private colleges and universities. It is not clear that applying the Mandate among those objecting entities is a narrowly tailored way to benefit the most at-risk population. The entities appear to encompass some such women, but also appear to omit many of them and to include a significantly larger cross-section of women as employees or plan participants. At the same time, the Mandate as applied to objecting employers appears to encompass a relatively small percentage of the number of women impacted by the Mandate overall, since most employers do not appear to have conscientious objections to the Mandate.²⁶ The Guttmacher Institute, on which the IOM relied, further reported that 89 percent of women who are at risk of unintended pregnancy and are living at 0 through 149 percent of the poverty line are already using contraceptives, as are 92 percent of those with incomes of 300 percent or more of the Federal poverty level.²⁷

The rates of—and reasons for—unintended pregnancy are notoriously difficult to measure.²⁸ In particular, association and causality can be hard to disentangle, and the studies referred to by the 2011 IOM Report speak more to association than causality. For example, IOM 2011 references Boonstra, et al.

²⁶ Prior to the implementation of the Affordable Care Act approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2010 Annual Survey” at 196, available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf>. It is not clear whether the minority of employers who did not cover contraception refrained from doing so for conscientious reasons or for other reasons. Estimates of the number of women who might be impacted by the exemptions offered in these rules, as compared to the total number of women who will likely continue to receive contraceptive coverage, is discussed in more detail below.

²⁷ “Contraceptive Use in the United States,” September 2016.

²⁸ The IOM 2011 Report reflected this when it cited the IOM's own 1995 report on unintended pregnancy, “The Best Intentions” (IOM 1995). IOM 1995 identifies various methodological difficulties in demonstrating the interest in reducing unintended pregnancies by means of a coverage mandate in employer plans. These include: The ambiguity of intent as an evidence-based measure (does it refer to mistimed pregnancy or unwanted pregnancy, and do studies make that distinction?); “the problem of determining parental attitudes at conception” and inaccurate methods often used for that assessment, such as “to use the request for an abortion as a marker”; and the overarching problem of “association versus causality,” that is, whether intent causes certain negative outcomes or is merely correlated with them. IOM 1995 at 64–66. See also IOM 1995 at 222 (“the largest public sector funding efforts, Title X and Medicaid, have not been well evaluated in terms of their net effectiveness, including their precise impact on unintended pregnancy”).

²¹ See, for example, Manya Brachear Pashman, “Wheaton College ends coverage amid fight against birth control mandate,” *Chicago Tribune* (July 29, 2015); Laura Bassett, “Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,” *HuffPost* (May 15, 2012).

²² The Departments are not aware of any objectors to the contraceptive Mandate that are unwilling to cover any of the other preventive services without cost sharing as required by PHS Act section 2713.

²³ “Facts on Publicly Funded Contraceptive Services in the United States,” March 2016.

²⁴ See, for example, Caroline Cunningham, “How Much Will Your Birth Control Cost Once the Affordable Care Act Is Repealed?” *Washingtonian* (Jan. 17, 2017), available at <https://www.washingtonian.com/2017/01/17/how-much-will-your-birth-control-cost-once-the-affordable-care-act-is-repealed/>; also, see <https://www.plannedparenthood.org/learn/birth-control>.

²⁵ *Id.*

(2006), as finding that, “as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined,”²⁹ and Santelli and Melnikas as finding that “increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use”. IOM 2011 at 105.³⁰ In this respect, the report does not show that access to contraception causes decreased incidents of unintended pregnancy, because both of the assertions rely on association rather than causation, and they associate reduction in unintended pregnancy with increased use of contraception, not merely with increased access to such contraceptives.

Similarly, in a study involving over 8,000 women between 2012 and 2015, conducted to determine whether contraceptive coverage under the Mandate changed contraceptive use patterns, the Guttmacher Institute concluded that “[w]e observed no changes in contraceptive use patterns among sexually active women.”³¹ With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship).³² Another study, which proposed an economic model for the decision to engage in sexual activity, stated that “[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.”³³ Regarding emergency contraception in particular, “[i]ncreased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates.”³⁴

²⁹ H. Boonstra, et al., “Abortion in Women’s Lives” at 18, *Guttmacher Inst.* (2006).

³⁰ Citing John S. Santelli & Andrea J. Melnikas, “Teen Fertility in Transition: Recent and Historic Trends in the United States,” 31 *Ann. Rev. Pub. Health* 371 (2010).

³¹ Bearak, J.M. and Jones, R.K., “Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis,” 27 *Women’s Health Issues* 316 (Guttmacher Inst. May–June 2017), available at [http://www.whijournal.com/article/S1049-3867\(17\)30029-4/fulltext](http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext).

³² 31 *Ann. Rev. Pub. Health* at 375–76.

³³ Peter Arcidiacono, et al., “Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?” (2005), available at <http://public.econ.duke.edu/~psarcidi/teensex.pdf>.

³⁴ G. Raymond et al., “Population effect of increased access to emergency contraceptive pills:

In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent,³⁵ unintended pregnancy rates in the United States rose from 35.4 percent³⁶ to 49 percent.”³⁷ The Departments note these and other studies³⁸ to observe the complexity and uncertainty in the relationship between contraceptive access, contraceptive use, and unintended pregnancy.

Contraception’s association with positive health effects might also be partially offset by an association with negative health effects. In 2013 the National Institutes of Health indicated, in funding opportunity announcement for the development of new clinically useful female contraceptive products, that “hormonal contraceptives have the disadvantage of having many undesirable side effects[,] are associated with adverse events, and obese women are at higher risk for serious complications such as deep venous

a systematic review,” 109 *Obstet. Gynecol.* 181 (2007).

³⁵ William D. Mosher & Jo Jones, U.S. Dep’t of HHS, CDC, National Center for Health Statistics, “Use of Contraception in the United States: 1982–2008” at 5 fig. 1, 23 *Vital and Health Statistics* 29 (Aug. 2010), available at https://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.

³⁶ Helen M. Alvaré, “No Compelling Interest: The ‘Birth Control’ Mandate and Religious Freedom,” 58 *Vill. L. Rev.* 379, 404–05 & n.128 (2013), available at <http://digitalcommons.law.villanova.edu/vlr/vol58/iss3/2> (quoting Christopher Tietze, “Unintended Pregnancies in the United States, 1970–1972,” 11 *Fam. Plan. Persp.* 186, 186 n.* (1979) (“in 1972, 35.4 percent percent of all U.S. pregnancies were ‘unwanted’ or ‘wanted later’”).

³⁷ *Id.* (citing Lawrence B. Finer & Stanley K. Henshaw, “Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001” 38 *Persp. on Sexual Reprod. Health* 90 (2006) (“In 2001, 49 percent of pregnancies in the United States were unintended”).

³⁸ See, for example, J.L. Dueñas, et al., “Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997–2007,” 83 *Contraception* 82 (2011) (as use of contraceptives increased from 49 percent to 80 percent, the elective abortion rate more than doubled); D. Paton, “The economics of family planning and underage conceptions,” 21 *J. Health Econ.* 207 (2002) (data from the UK confirms an economic model which suggests improved family planning access for females under 16 increases underage sexual activity and has an ambiguous impact on underage conception rates); T. Raine et al., “Emergency contraception: advance provision in a young, high-risk clinic population,” 96 *Obstet. Gynecol.* 1 (2000) (providing advance provision of emergency contraception at family planning clinics to women aged 16–24 was associated with the usage of less effective and less consistently used contraception by other methods); M. Belzer et al., “Advance supply of emergency contraception: a randomized trial in adolescent mothers,” 18 *J. Pediatr. Adolesc. Gynecol.* 347 (2005) (advance provision of emergency contraception to mothers aged 13–20 was associated with increased unprotected sex at the 12-month follow up).

thrombosis.”³⁹ In addition, IOM 2011 stated that “[l]ong-term use of oral contraceptives has been shown to reduce a woman’s risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).” (IOM 2011 at 107). However, after IOM 2011 made this statement, AHRQ (a component of HHS) completed its systematic evidence review.⁴⁰ Based on its review, AHRQ stated that: “[o]varian cancer incidence was significantly reduced in OC [oral contraceptive] users”; “[b]reast cancer incidence was slightly but significantly increased in OC users”; “[t]he risk of cervical cancer was significantly increased in women with persistent human papillomavirus infection who used OCs, but heterogeneity prevented a formal meta-analysis”; “[i]ncidences of both colorectal cancer [] and endometrial cancer [] were significantly reduced by OC use”; “[t]he risk of vascular events was increased in current OC users compared with nonusers, although the increase in myocardial infarction was not statistically significant”; “[t]he overall strength of evidence for ovarian cancer prevention was moderate to low”; and “[t]he simulation model predicted that the combined increase in risk of breast and cervical cancers and vascular events was likely to be equivalent to or greater than the decreased risk in ovarian cancer.”⁴¹ Based on these findings, AHRQ concluded that “[t]here is insufficient evidence to recommend for or against the use of OCs solely for the primary prevention of ovarian cancer . . . the harm/benefit ratio for ovarian cancer prevention alone is uncertain, particularly when the

³⁹ NIH, “Female Contraceptive Development Program (U01)” (Nov. 5, 2013), available at <https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-14-024.html>. Thirty six percent of women in the United States are obese. <https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity>. Also see “Does birth control raise my risk for health problems?” and “What are the health risks for smokers who use birth control?” HHS Office on Women’s Health, available at <https://www.womenshealth.gov/a-z-topics/birth-control-methods>; Skovlund, CW, “Association of Hormonal Contraception with Depression,” 73 *JAMA Psychiatry* 1154 (Nov. 1, 2016), available at <https://www.ncbi.nlm.nih.gov/pubmed/27680324>.

⁴⁰ Havrilesky, L.J. et al., “Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,” Agency for Healthcare Research and Quality, Report No.: 13–E002–EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html>.

⁴¹ *Id.*

potential quality-of-life impact of breast cancer and vascular events are considered.”⁴²

In addition, in relation to several studies cited above, imposing a coverage Mandate on objecting entities whose plans cover many enrollee families who may share objections to contraception could, among some populations, affect risky sexual behavior in a negative way. For example, it may not be a narrowly tailored way to advance the Government interests identified here to mandate contraceptive access to teenagers and young adults who are not already sexually active and at significant risk of unintended pregnancy.⁴³

Finally, evidence from studies that post-date the Mandate is not inconsistent with the observations the Departments make here. In 2016, HRSA awarded a 5-year cooperative agreement to the American College of Obstetricians and Gynecologists to develop recommendations for updated Women’s Preventive Services Guidelines. The awardee formed an expert panel called the Women’s Preventive Services Initiative that issued a report (the WPSI report).⁴⁴ After observing that “[p]rivate companies are increasingly challenging the contraception provisions in the Affordable Care Act,” the WPSI report cited studies through 2013 stating that application of HRSA Guidelines had applied preventive services coverage to 55.6 million women and had led to a 70 percent decrease in out-of-pocket expenses for contraceptive services among commercially insured women. *Id.* at 57–58. The WPSI report relied on a 2015 report of the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), “The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans,” which estimated that persons who have private insurance coverage of preventive services without cost sharing includes 55.6 million women.⁴⁵

⁴² *Id.* Also, see Kelli Miller, “Birth Control & Cancer: Which Methods Raise, Lower Risk,” *The Am. Cancer Society*, (Jan. 21, 2016), available at <http://www.cancer.org/cancer/news/features/birth-control-cancer-which-methods-raise-lower-risk>.

⁴³ For further discussion, see Alvaré, 58 *Vill. L. Rev.* at 400–02 (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

⁴⁴ “WPSI 2016 Recommendations: Evidence Summaries and Appendices,” at 54–64, available at <https://www.womenspreventivehealth.org/wp-content/uploads/2016/12/Evidence-Summaries-and-Appendices.pdf>.

⁴⁵ Available at <https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans>; also, see Abridged Report, available at <https://www.womenspreventive>

As discussed above and based on the Departments’ knowledge of litigation challenging the Mandate, during the time ASPE estimated the scope of preventive services coverage (2011–2013), houses of worship and integrated auxiliaries were exempt from the Mandate, other objecting religious nonprofit organizations were protected by the temporary safe harbor, and hundreds of accommodated self-insured church plan entities were not subject to enforcement of the Mandate through their third party administrators. In addition, dozens of for-profit entities that had filed lawsuits challenging the Mandate were protected by court orders pending the Supreme Court’s resolution of *Hobby Lobby* in June 2014. It would therefore appear that the benefits recorded by the report occurred even though most objecting entities were not in compliance.⁴⁶ Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.⁴⁷

The Departments need not take a position on these empirical questions.

health.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.

⁴⁶ In addition, as in IOM 2011, the WPSI report bases its evidentiary conclusions relating to contraceptive coverage, use, unintended pregnancy, and health benefits, on conclusions that the phenomena are “associated” with the intended outcomes, without showing there is a causal relationship. For example, the WPSI report states that “[c]ontraceptive counseling in primary care may increase the uptake of hormonal methods and [long-acting reversible contraceptives], although data on structured counseling in specialized reproductive health settings demonstrated no such effect.” *Id.* at 63. The WPSI report also acknowledges that a large-scale study evaluating the effects of providing no-cost contraception had “no randomization or control group.” *Id.* at 63.

The WPSI report also identifies the at-risk population as young, low-income, and/or minority women: “[u]nintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities.” *Id.* at 58. The WPSI report acknowledges that many in this population are already served by Title X programs, which provide family planning services to “approximately 1 million teens each year.” *Id.* at 58. The WPSI report observes that between 2008 and 2011—before the contraceptive coverage requirement was implemented—unintended pregnancy decreased to the lowest rate in 30 years. *Id.* at 58. The WPSI report does not address how to balance contraceptive coverage interests with religious objections, nor does it specify the extent to which applying the Mandate among commercially insured at objecting entities serves to deliver contraceptive coverage to women most at risk of unintended pregnancy.

⁴⁷ See Michael J. New, “Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,” 13 *Ave Maria L. Rev.* 345 (2015), available at <http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf>.

Our review is sufficient to lead us to conclude that significantly more uncertainty and ambiguity exists in the record than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals as set forth herein, and that no compelling interest exists to counsel against us extending the exemption.

During public comment periods, some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions. The IOM similarly stated that “the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain.” IOM 2011 at 107. Consequently, some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes. Section 2713(a)(4) of the PHS Act does not, however, apply to non-preventive care provided solely for treatment of an existing condition. It applies only to “such additional preventive care and screenings . . . as provided for” by HRSA (Section 2713(a)(4) of the PHS Act). HRSA’s Guidelines implementing this section state repeatedly that they apply to “preventive” services or care, and with respect to the coverage of contraception specifically, they declare that the methods covered are “contraceptive” methods as a “Type of Preventive Service,” and that they are to be covered only “[a]s prescribed” by a physician or other health care provider. <https://www.hrsa.gov/womensguidelines/> The contraceptive coverage requirement in the Guidelines also only applies for “women with reproductive capacity.” <https://www.hrsa.gov/womensguidelines/>; (80 FR 40318). Therefore, the Guidelines’ inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that the FDA has approved for contraceptive use is prescribed in whole or in part for such use. The Guidelines and section 2713(a)(4) of the PHS Act do not require coverage of such drugs where they are prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.⁴⁸ As discussed above, the last

⁴⁸ The Departments previously cited the IOM’s listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that “there are demonstrated preventive health benefits

Continued

Administration decided to exempt houses of worship and their integrated auxiliaries from the Mandate, and to relieve hundreds of religious nonprofit organizations of their obligations under the Mandate and not further require contraceptive coverage to their employees. In several of the lawsuits challenging the Mandate, some religious plaintiffs stated that they do not object and are willing to cover drugs prescribed for the treatment of an existing condition and not for contraceptive purposes—even if those drugs are also approved by the FDA for contraceptive uses. Therefore, the Departments conclude that the fact that some drugs that are approved for preventive contraceptive purposes can also be used for exclusively non-preventive purposes to treat existing conditions is not a sufficient reason to refrain from expanding the exemption to the Mandate.

An additional consideration supporting the Departments' present view is that alternative approaches can further the interests the Departments previously identified behind the Mandate. As noted above, the Government already engages in dozens of programs that subsidize contraception for the low-income women identified by the IOM as the most at risk for unintended pregnancy. The Departments have also acknowledged in legal briefing that contraception access can be provided through means other than coverage offered by religious objectors, for example, through "a family member's employer," "an Exchange," or "another government program."⁴⁹

Many employer plan sponsors, institutions of education arranging

from contraceptives relating to conditions other than pregnancy." 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act section 2713(a)(4) or the Guidelines require coverage of "contraceptive" methods when prescribed for an exclusively non-contraceptive, non-preventive use. Instead it was an observation that such drugs—generally referred to as "contraceptives"—also have some alternate beneficial uses to treat existing conditions. For the purposes of these interim final rules, the Departments clarify here that our previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines.

⁴⁹ Brief for the Respondents at 65, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14–1418).

student health coverage, and individuals enrolled in plans where their employers or issuers (as applicable) are willing to offer them a religiously acceptable plan, hold sincerely held religious beliefs against (respectively) providing, arranging, or participating in plans that comply with the Mandate either by providing contraceptive coverage or by using the accommodation. Because we have concluded that requiring such compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many such entities or individuals, and because we conclude requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest, we now believe that requiring such compliance led to the violation of RFRA in many instances. We recognize that this is a change of position on this issue, and we make that change based on all the matters discussed in this preamble.

B. Discretion To Provide Religious Exemptions

Even if RFRA does not compel the religious exemptions provided in these interim final rules, the Departments believe they are the most appropriate administrative response to the religious objections that have been raised. RFRA identifies certain circumstance under which government must accommodate religious exercise—when a government action imposes a substantial burden on the religious exercise of an adherent and imposition of that burden is not the least restrictive means of achieving a compelling government interest. RFRA does not, however, prescribe the accommodation that the government must adopt. Rather, agencies have discretion to fashion an appropriate and administrable response to respect religious liberty interests implicated by their own regulations. We know from *Hobby Lobby* that, in the absence of any accommodation, the contraceptive-coverage requirement imposes a substantial burden on certain objecting employers. We know from other lawsuits and public comments that many religious entities have objections to complying with the accommodation based on their sincerely held religious beliefs. Previously, the Departments attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA's requirements for imposing that burden.

Now, however, the Departments have reassessed the relevant interests and determined that, even if exemptions are

not required by RFRA, they would exercise their discretion to address the substantial burden identified in *Hobby Lobby* by expanding the exemptions from the Mandate instead of revising accommodations previously offered. In the Departments' view, a broader exemption is a more direct, effective means of satisfying all bona fide religious objectors. This view is informed by the fact that the Departments' previous attempt to develop an appropriate accommodation did not satisfy all objectors. That previous accommodation consumed Departmental resources not only through the regulatory process, but in persistent litigation and negotiations. Offering exemptions as described in these interim final rules is a more workable way to respond to the substantial burden identified in *Hobby Lobby* and bring years of litigation concerning the Mandate to a close.

C. General Scope of Expanded Religious Exemptions

1. Exemption and Accommodation for Religious Employers, Plan Sponsors, and Institutions of Higher Education

For all of these reasons, and as further explained below, the Departments now believe it is appropriate to modify the scope of the discretion afforded to HRSA in the July 2015 final regulations to direct HRSA to provide the expanded exemptions and change the accommodation to an optional process if HRSA continues to otherwise provide for contraceptive coverage in the Guidelines. As set forth below, the expanded exemption encompasses non-governmental plan sponsors that object based on sincerely held religious beliefs, and institutions of higher education in their arrangement of student health plans. The accommodation is also maintained as an optional process for exempt employers, and will provide contraceptive availability for persons covered by the plans of entities that use it (a legitimate program purpose).

The Departments believe this approach is sufficiently respectful of religious objections while still allowing the Government to advance other interests. Even with the expanded exemption, HRSA maintains the discretion to require contraceptive coverage for nearly all entities to which the Mandate previously applied (since most plan sponsors do not appear to possess the requisite religious objections), and to reconsider those interests in the future where no covered objection exists. Other Government subsidies of contraception are likewise not affected by this rule.

2. Exemption for Objecting Individuals Covered by Willing Employers and Issuers

As noted above, some individuals have brought suit objecting to being covered under an insurance policy that includes coverage for contraceptives. See, for example, *Wieland v. HHS*, 196 F. Supp. 3d 1010 (E.D. Mo. 2016); *Soda v. McGettigan*, No. 15–cv–00898 (D. Md.). Just as the Departments have determined that the Government does not have a compelling interest in applying the Mandate to employers that object to contraceptive coverage on religious grounds, we have also concluded that the Government does not have a compelling interest in requiring individuals to be covered by policies that include contraceptive coverage when the individuals have sincerely held religious objections to that coverage. The Government does not have an interest in ensuring the provision of contraceptive coverage to individuals who do not wish to have such coverage. Especially relevant to this conclusion is the fact that the Departments have described their interests of health and gender equality as being advanced among women who “want” the coverage so as to prevent “unintended” pregnancy. (77 FR 8727).⁵⁰ No asserted interest is served by denying an exemption to individuals who object to it. No unintended pregnancies will be avoided or costs reduced by imposing the coverage on those individuals.

Although the Departments previously took the position that allowing individual religious exemptions would undermine the workability of the insurance system, the Departments now agree with those district courts that have concluded that an exemption that allows—but does not require—issuers and employers to omit contraceptives from coverage provided to objecting individuals does not undermine any compelling interest. See *Wieland*, 196 F. Supp. 3d at 1019–20; *March for Life*, 128 F. Supp. 3d at 132. The individual exemption will only apply where the employer and issuer (or, in the individual market, the issuer) are willing to offer a policy accommodating the objecting individual. As a result, the Departments consider it likely that where an individual exemption is invoked, it will impose no burdens on

the insurance market because such burdens may be factored into the willingness of an employer or issuer to offer such coverage. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments’ previous exemption for houses of worship and integrated auxiliaries, and our lack of authority to enforce the accommodation with respect to self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.⁵¹ Furthermore, granting exemptions to individuals who do not wish to receive contraceptive coverage where the plan and, as applicable, issuer and plan sponsor are willing, does not undermine the Government’s interest in ensuring the provision of such coverage to other individuals who wish to receive it. Nor do such exemptions undermine the operation of the many other programs subsidizing contraception. Rather, such exemptions serve the Government’s interest in accommodating religious exercise. Accordingly, as further explained below, the Departments have provided an exemption to address the concerns of objecting individuals.

D. Effects on Third Parties of Exemptions

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 of the PHS Act requirements on grandfathered plans that cover millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have

other avenues for obtaining contraception, including the various governmental programs discussed above. As the Government is under no constitutional obligation to fund contraception, *cf. Harris v. McRae*, 448 United States 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their religious beliefs. *Cf. Rust v. Sullivan*, 500 U.S. 173, 192–93 (1991) (“A refusal to fund protected activity, without more, cannot be equated with the imposition of a ‘penalty’ on that activity.”).⁵²

That conclusion is consistent with the Supreme Court’s observation that RFRA may require exemptions even from laws requiring claimants “to confer benefits on third parties.” *Hobby Lobby*, 134 S. Ct. at 2781 n.37. The burdens imposed on such third parties may be relevant to the RFRA analysis, but they cannot be dispositive. “Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).” *Id.* Where, as here, contraceptives are readily accessible and, for many low income persons, are available at reduced cost or for free through various governmental programs, and contraceptive coverage may be available through State sources or family plans obtained through non-objecting employers, the Departments have determined that the expanded exemptions rather than accommodations are the appropriate response to the substantial burden that the Mandate has placed upon the religious exercise of many religious employers.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including prior interim final rules), public comments, and litigation throughout the Federal court system. The interim final rules seek to resolve this matter and the long-running litigation with respect to religious

⁵⁰ In this respect, the Government’s interest in contraceptive coverage is different than its interest in persons receiving some other kinds of health coverage or coverage in general, which can lead to important benefits that are not necessarily conditional on the recipient’s desire to use the coverage and the specific benefits that may result from their choice to use it.

⁵¹ Also, see *Real Alternatives*, 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) (“Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government’s interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the Affordable Care Act) would be unworkable, it has not satisfied strict scrutiny.” (citation and internal quotation marks omitted)).

⁵² *Cf. also Planned Parenthood Ariz., Inc. v. Am. Ass’n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (“a woman’s right to an abortion or to contraception does not compel a private person or entity to facilitate either.”).

objections by extending the exemption under the HRSA Guidelines to encompass entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage, and by making the accommodation process optional for eligible organizations.

The Departments acknowledge that the foregoing analysis represents a change from the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlie the Mandate. These changes in policy are within the Departments' authority. As the Supreme Court has acknowledged, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). This "reasoned analysis" requirement does not demand that an agency "demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates". *United Student Aid Funds, Inc. v. King*, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)); also, see *New Edge Network, Inc. v. FCC*, 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").

Here, for all of the reasons discussed above, the Departments have determined that the Government's interest in the application of contraceptive coverage requirements in this specific context to the plans of certain entities and individuals does not outweigh the sincerely held religious objections of those entities and individuals based on the analyses set forth above. Thus, these interim final rules amend the Departments' July 2015 final regulations to expand the exemption to include additional entities and persons that object based on sincerely held religious beliefs. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no such objection exists, and to the extent that section 2713 of the PHS Act applies. These interim final rules also maintain the existence of an accommodation process, but consistent with our expansion of the exemption, we make

the process optional for eligible organizations. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.⁵³

A. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules modify the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) introductory text and (a)(1)(iv), so that they conform to the statutory text of section 2713 of the PHS Act.

B. Prefatory Language of the Exemption in 45 CFR 147.132

These interim final rules move the religious exemption from 45 CFR 147.131 to a new § 147.132 and expand it as follows. In the prefatory language of § 147.132, these interim final rules specify that not only are certain entities "exempt," but the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such entities. This is an acknowledgement that section 2713(a)(4) of the PHS Act requires women's preventive services coverage only "as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." To the extent the HRSA Guidelines do not provide for or support the application of such coverage to exempt entities, the Affordable Care Act does not require the coverage. Section 147.132 not only describes the exemption of certain entities and plans, but does so by specifying that the HRSA Guidelines do not provide for, or support the application of, such coverage to exempt entities and plans.

C. General Scope of Exemption for Objecting Entities

In the new 45 CFR 147.132 as created by these interim final rules, these rules expand the exemption that was previously located in § 147.131(a). With respect to employers that sponsor group health plans, the new language of § 147.132(a)(1) introductory text and (a)(1)(i) provides exemptions for employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs.

⁵³ See <https://www.hrsa.gov/womensguidelines/> and <https://www.hrsa.gov/womensguidelines2016/index.html>.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption created in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.132(a)(1) introductory text and (a)(1)(i), by specifying that "[a] group health plan and health insurance coverage provided in connection with a group health plan" is exempt "to the extent the plan sponsor objects as specified in paragraph (a)(2)," exempt the group health plans the sponsors of which object, and exempt their health insurance issuers from providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.⁵⁴ Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage,

⁵⁴ See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. Also, see 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group & individual issuers).

otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.132(a) apply “to the extent” of the objecting entities’ sincerely held religious beliefs. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.132(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsor has no qualifying objection. The objection of a health insurance issuer in § 147.132(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

D. Exemption of Employers and Institutions of Higher Education

The scope of the exemption is expanded for non-governmental plan sponsors and certain entities that arrange health coverage under these interim final rules. The Departments have consistently taken the position that section 2713(a)(4) of the PHS Act grants HRSA authority to issue Guidelines that provide for and support exemptions from a contraceptive coverage requirement. Since the beginning of rulemaking concerning the Mandate, HRSA and the Departments have repeatedly exercised their discretion to create and modify various exemptions within the Guidelines.⁵⁵

The Departments believe the approach of these interim final rules better aligns our implementation of section 2713(a)(4) of the PHS Act with

Congress’ intent in the Affordable Care Act and throughout other Federal health care laws. As discussed above, many Federal health care laws and regulations provide exemptions for objections based on religious beliefs, and RFRA applies to the Affordable Care Act. Expanding the exemption removes religious obstacles that entities and certain individuals may face when they otherwise wish to participate in the health care market. This advances the Affordable Care Act’s goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate. These rules also leave in place many Federal programs that subsidize contraceptives for women who are most at risk of unintended pregnancy and who may have more limited access to contraceptives.⁵⁶ These interim final rules achieve greater uniformity and simplicity in the regulation of health insurance by expanding the exemptions to include entities that object to the Mandate based on their sincerely held religious beliefs.

The Departments further conclude that it would be inadequate to merely attempt to amend the accommodation process instead of expand the exemption. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way “seamless” to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. The Departments have engaged in an effort to attempt to identify an accommodation that would eliminate the plaintiffs’ religious objections, including seeking public comment through an RFI, but we stated in January 2017 that we were unable to develop such an approach at that time.

1. Plan Sponsors Generally

The expanded exemptions in these interim final rules cover any kind of non-governmental employer plan

sponsor with the requisite objections but, for the sake of clarity, they include an illustrative, non-exhaustive list of employers whose objections qualify the plans they sponsor for an exemption.

Under these interim final rules, the Departments do not limit the Guidelines exemption with reference to nonprofit status or to sections 6033(a)(3)(A)(i) or (iii) of the Code, as previous rules have done. A significant majority of States either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.⁵⁷ Although the practice of States is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor a statement about what the Federal Government may do consistent with RFRA or other limitations in federal law, such State practice can be informative as to the viability of broad protections for religious liberty. In this case, such practice supports the Departments’ decision to expand the federal exemption, bringing the Federal Government’s practice into greater alignment with the practices of the majority of the States.

2. Section 147.132(a)(1)(i)(A)

Despite not limiting the exemption to certain organizations referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, the exemption in these rules includes such organizations. Section 147.132(a)(1)(i)(A) specifies, as under the prior exemption, that the exemption covers “a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.” In the preamble to rules setting forth the prior exemption at § 147.132(a), the Departments interpreted this same language used in those rules by declaring that “[t]he final regulations continue to provide that the availability of the exemption or accommodation be determined on an employer by employer basis, which the Departments continue to believe best balances the interests of religious employers and eligible organizations and those of employees and their dependents.” (78 FR 39886). Therefore, under the prior exemption, if an employer participated in a house of worship’s plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not considered to be covered by the

⁵⁵ “The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.” *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863–64 (1984).

⁵⁶ See, for example, Family Planning grants in 42 U.S.C. 300, *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

⁵⁷ See Guttmacher Institute, “Insurance Coverage of Contraceptives” available at <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a “plan established or maintained by a [house of worship].”

Under these interim final rules, however, the Departments intend that, when this regulation text exempts a plan “established or maintained by” a house of worship or integrated auxiliary, such exemption will no longer “be determined on an employer by employer basis,” but will be determined on a plan basis—that is, by whether the plan is a “plan established or maintained by” a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these interim final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the threshold of being integrated auxiliaries. Moreover, under this interpretation, houses of worship would not be faced with the potential prospect of services to which they have a religious objection being covered for employees of an associated employer participating in a plan they have established and maintain.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted participation in its health plan, but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior rule, to the extent that, in practice and as discussed elsewhere herein, it does not force contraceptive coverage to be provided on behalf of the plan participants of many religious organizations in a self-insured church plan exempt from ERISA—which are exempt in part because the plans are established and maintained by a church. (Section 3(33)(A) of ERISA) In several lawsuits challenging the Mandate, the Departments took the position that some plans established and maintained by houses of worship, but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government “has no authority to require the plaintiffs’ TPAs to provide contraceptive coverage at this time.” *Roman Catholic Archdiocese of N.Y. v.*

Sebelius, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013). Therefore the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

3. Section 147.132(a)(1)(i)(B)

Section 147.132(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of plan sponsors that are nonprofit organizations.

4. Section 147.132(a)(1)(i)(C)

Under § 147.132(a)(1)(i)(C), the rules extend the exemption to the plans of closely held for-profit entities. This is consistent with the Supreme Court’s ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the Departments’ argument to the contrary. (134 S. Ct. 2768–75) Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.⁵⁸

5. Section 147.132(a)(1)(i)(D)

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. The Departments implicitly recognized the difficulty of providing an affirmative definition of closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely “substantially similar” to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. The exemptions in these interim final rules do not need to address this difficulty because they include both for-profit entities that are closely held and for-profit entities that are not closely held.⁵⁹

⁵⁸ See Jennifer Haberkorn, “Two years later, few Hobby Lobby copycats emerge,” *Politico* (Oct. 11, 2016), available at <http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627>.

⁵⁹ In the companion interim final rules published elsewhere in this *Federal Register*, the Departments

The mechanisms for determining whether a company has adopted and holds such principles or views is a matter of well-established State law with respect to corporate decision-making,⁶⁰ and the Departments expect that application of such laws would cabin the scope of this exemption.

In including entities in the exemption that are not closely held, these interim final rules provide for the possibility that some publicly traded entities may use the exemption. Even though the Supreme Court did not extend its holding in *Hobby Lobby* to publicly traded corporations (the matter could be resolved without deciding that question), the Court did instruct that RFRA applies to corporations because they are “persons” as that term is defined in 1 U.S.C. 1. Given that the definition under 1 U.S.C. 1 applies to any corporation, the Departments consider it appropriate to extend the exemption set forth in these interim final rules to for-profit corporations whether or not they are closely held. The Departments are generally aware that in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.⁶¹ The fact that such a company is religious does not mean that it will have an objection to contraceptive coverage, and there are many fewer publicly traded companies than there are closely held ones. But our experience with closely held companies is that some, albeit a small minority, do have religious objections to contraceptive coverage. Thus we consider it possible, though very unlikely, that a religious publicly

provide an exemption on an interim final basis to closely held entities by using a negative definition: entities that do not have publicly traded ownership interests as defined by certain securities required to be registered under section 12 of the Securities Exchange Act of 1934. Although this is a more workable definition than set forth in our previous rules, we have determined that it is appropriate to offer the expanded religious exemptions to certain entities whether or not they have publicly traded ownership interests.

⁶⁰ Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

⁶¹ See, e.g., *Nasdaq.com*, “4 Publicly Traded Religious Companies if You’re Looking to Invest in Faith” (Feb. 7, 2014), available at <http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665>.

traded company might have objections to contraceptive coverage. At the same time, we are not aware of any publicly traded entities that challenged the Mandate specifically either publicly or in court. The Departments agree with the Supreme Court that it is improbable that many publicly traded companies with numerous “unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs” and thereby qualify for the exemption. (134 S. Ct. at 2774)

6. Section 147.132(a)(1)(i)(E)

Under § 147.132(a)(1)(i)(E), the rules extend the exemption to the plans of any other non-governmental employer. The plans of governmental employers are not covered by the plan sponsor exemption of § 147.132(a)(1)(i). The Departments are not aware of reasons why it would be appropriate or necessary to offer religious exemptions to governmental employer plan sponsors in the United States with respect to the contraceptive Mandate. But, as discussed below, governmental employers are permitted to respect an individual’s objection under § 147.132(b) and thus to provide health insurance coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these interim final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization.

7. Section 147.132(a)(1)(ii)

As in the previous rules, the plans of institutions of higher education that arrange student health insurance coverage will continue to be treated similarly to the way in which the plans of employers are treated, but for the purposes of such plans being exempt or electing the optional accommodation, rather than merely being eligible for the accommodation as in the previous rule. These interim final rules specify, in § 147.132(a)(1)(ii), that the exemption is

extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor. As mentioned above, because the Affordable Care Act does not require institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or use the accommodation. Extending the exemption in these interim final rules may remove an obstacle to such entities deciding to offer student plans, thereby giving students another health insurance option.

E. Exemption for Issuers

These interim final rules extend the exemption, in § 147.132(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services.

The Departments are not currently aware of health insurance issuers that possess their own religious objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations are protected from being required to provide coverage or pay for abortions. See, for example, Consolidated Appropriations Act of 2017, Public Law 115–31, Div. H, Title V, Sec. 507(d). Congress also declared this year that “it is the intent of Congress” to include a “conscience clause” which provides exceptions for religious beliefs if the District of Columbia requires “the provision of contraceptive coverage by health insurance plans.” See *Id.* at Div. C, Title VIII, Sec. 808. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections

with respect to providing coverage in those plans. The issuer exemption in § 147.132(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. As set forth in these interim final rules, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection. Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under 42 CFR 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include coverage for some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt. Issuers that hold religious objections should identify to plan sponsors the lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer’s exemption, and communicate the group health plan’s independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers’ sincerely held religious beliefs, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to

continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4) of the PHS Act or related provisions for their failure to provide contraceptive coverage.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these interim final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these interim final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) of the PHS Act to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators under section 3(16) of ERISA and, therefore, would not normally act as plan administrators under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These interim final rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or continue, contracts as third party administrators of such plans. For these reasons, these interim final rules do not otherwise exempt third party administrators. The Departments solicit public comment, however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have religious beliefs implicated by the Mandate.

F. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.132(a)(2). That paragraph specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.132(a)(1) objects to its

establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

G. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the "individual exemption"). Section 147.132(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held religious beliefs. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. See *Wieland*, 196 F. Supp. 3d at 1015-16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit

contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This "individual exemption" cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other Federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.⁶² At the same time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement,"⁶³ because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

H. Optional Accommodation

Despite expanding the scope of the exemption, these rules also keep the accommodation process, but revise it so as to make it optional. In this way, objecting employers are no longer required to choose between direct compliance or compliance through the accommodation. These rules maintain the location of the accommodation process in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815-2713A, and 29 CFR 2590.715-2713A. These rules, by virtue of expanding the plan sponsor exemption beyond houses of worship and integrated auxiliaries that were

⁶² See, for example, *Wieland*, 196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to "forgo health insurance altogether."

⁶³ 78 FR 39874.

previously exempt, and beyond religious nonprofit groups that were previously accommodated, and by defining eligible organizations for the accommodation with reference to those covered by the exemption, likewise expand the kinds of entities that may use the optional accommodation. This includes plan sponsors with sincerely held religious beliefs for the reasons described above. Consequently, under these interim final rules, objecting employers may make use of the exemption, or may choose to pursue the optional accommodation process. If an eligible organization pursues the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

The fees adjustment process for qualifying health issuers or third party administrators pursuant to 45 CFR 156.50 is not modified, and (as specified therein) requires for its applicability that an exception under OMB Circular No. A–25R be in effect as the Secretary of the Department of Health and Human Services requests.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these interim final rules and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. This revocation process applies both prospectively to eligible organizations who decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that were included in the accommodation prior to the effective date of these interim final rules either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. If contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, the revocation

will be effective on the 1st day of the 1st plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act,⁶⁴ if applicable, to revoke its use of the accommodation process.

The Departments have eliminated the provision in the previous accommodation under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. Because any organization with a sincerely held religious objection to contraceptive coverage is now eligible for the optional accommodation under these interim final rules and is also exempt, the Departments believe there is minimal opportunity for mistake or misrepresentation by the organization, and the reliance provision is no longer necessary.

I. Definition of Contraceptive Services for the Purpose of These Rules

The interim final rules specify that when the rules refer to “contraceptive” services, benefits, or coverage, such terms include contraceptive or sterilization items, services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv). This was the case under the previous rules, as expressed in the preamble text of the various iterations of the regulations, but the Departments wish to make the scope clear by specifying it in the regulatory text.

J. Conclusion

The Departments believe that the Guidelines and the exemptions expanded herein will advance the limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress’ well-established record of allowing for religious exemptions with respect to especially sensitive health care and health insurance requirements. These interim final rules leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. These interim final rules also maintain HRSA’s

discretion to decide whether to continue to require contraceptive coverage under the Guidelines (in plans where Congress applied section 2713 of the PHS Act) if no objection exists. The Departments believe this array of programs and requirements better serves the interest of providing contraceptive coverage while protecting the conscience rights of entities that have sincerely held religious objections to some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

V. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; 79 FR 51092).

Section 553(b) of the Administrative Procedure Act (APA) requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated

⁶⁴ See also 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to continue to update the Guidelines.

Dozens of lawsuits over the Mandate have been pending for nearly 5 years. The Supreme Court remanded several of those cases more than a year ago, stating that on remand “[w]e anticipate that the Courts of Appeals will allow the parties sufficient time to resolve any outstanding issues between them”. *Zubik*, 136 S. Ct. at 1560. During that time, Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days. Those status reports have informed the courts that the parties were in discussions, and about the RFI issued in late 2016 and its subsequent comment process and the FAQ the Departments issued indicating that we could not find a way at that time to amend the accommodation process so as to satisfy objecting eligible organizations while pursuing the Departments’ policy goals. Since then, several courts have issued orders setting more pressing deadlines. For example, on March 10, 2017, the United States Court of Appeals for the Seventh Circuit ordered that, by May 1, 2017, “the court expects to see either a report of an agreement to resolve the case or detailed reports on the parties’ respective positions. In the event no agreement is reported on or before May 1, 2017, the court will plan to schedule oral argument on the merits of the case on short notice after that date”. The Departments submitted a status report but were unable to set forth their specific position because this interim final rule was not yet on public display. Instead, the Departments informed the Court that we “are now considering whether further administrative action would be appropriate”. In response, the court extended the deadline to June 1, 2017, again declaring the court expected “to see either a report of an agreement to resolve the case or detailed reports on the parties’ respective positions”. The Departments were again unable to set forth their position in that status report, but were able to state that the “Departments of Health and Human Services, Labor, and the Treasury are engaged in rulemaking to reconsider the regulations at issue here,” citing <https://www.reginfo.gov/public/do/eoDetails?rrid=127381>.

As discussed above, the Departments have concluded that, in many instances, requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance has

violated RFRA. Good cause exists to issue the expanded exemption in these interim final rules in order to cure such violations (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters.

The Departments have also been subject to temporary injunctions protecting many religious nonprofit organizations from being subject to the accommodation process against their wishes, while many other organizations are fully exempt, have permanent court orders blocking the contraceptive coverage requirement, or are not subject to section 2713 of the PHS Act and its enforcement due to Congress’ limited application of that requirement. Good cause exists to change the Departments’ previous rules to direct HRSA to bring its Guidelines in accord with the legal realities and remove the threat of a future violation of religious beliefs, including where such violations are contrary to Federal law.

Other objecting entities similarly have not had the protection of court injunctions. This includes some nonprofit entities that have sued the Departments, but it also includes some organizations that do not have lawsuits pending against us. For example, many of the closely held for-profit companies that brought the array of lawsuits challenging the Mandate leading up to the decision in *Hobby Lobby* are not protected by injunctions from the current rules, including the requirement that they either fully comply with the Mandate or subject themselves to the accommodation. Continuing to apply the Mandate’s regulatory burden on individuals and organizations with religious beliefs against it could serve as a deterrent for citizens who might consider forming new entities—nonprofit or for-profit—and to offering health insurance in employer-sponsored plans or plans arranged by institutions of higher education. Delaying the protection afforded by these interim final rules would be contrary to the public interest because it would serve to extend for many months the harm caused to all entities and individuals with religious objections to the Mandate. Good cause exists to provide immediate resolution to this myriad of situations rather than leaving them to continued uncertainty, inconsistency, and cost during litigation challenging the previous rules.

These interim final rules provide a specific policy resolution that courts

have been waiting to receive from the Departments for more than a year. If the Departments were to publish a notice of proposed rulemaking instead of these interim final rules, many more months could pass before the current Mandate is lifted from the entities receiving the expanded exemption, during which time those entities would be deprived of the relief clearly set forth in these interim final rules. In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and by what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed.

As the United States Court of Appeals for the D.C. Circuit stated with respect to an earlier interim final rule promulgated with respect to this issue in *Priests for Life v. U.S. Department of Health and Human Services*, 772 F.3d 229, 276 (D.C. Cir. 2014), vacated on other grounds, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), “[S]everal reasons support HHS’s decision not to engage in notice and comment here”. Among other things, the Court noted that “the agency made a good cause finding in the rule it issued”; that “the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues”; that “HHS will expose its interim rule to notice and comment before its permanent implementation”; and that “delay in implementation of the rule would interfere with the prompt availability of contraceptive coverage and delay the implementation of the alternative opt-out for religious objectors”. *Id.* at 277.

Delaying the availability of the expanded exemption would delay the ability of those organizations and individuals to avail themselves of the relief afforded by these interim final rules. Good cause is supported by

providing relief for entities and individuals for whom the Mandate operates in violation of their sincerely held religious beliefs, but who would have to experience that burden for many more months under the prior regulations if these rules are not issued on an interim final basis. Good cause is also supported by the effect of these interim final rules in bringing to a close the uncertainty caused by years of litigation and regulatory changes made under section 2713(a)(4) of the PHS Act. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

Delaying the availability of the expanded exemption would also increase the costs of health insurance. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover contraception. They wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. They are refraining from making those changes—and therefore are continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. Issuing these rules on an interim final basis is necessary in order to help reduce the costs of health insurance for such entities and their plan participants.

These interim final rules also set forth an optional accommodation process, and expand eligibility for that process to a broader category of entities. Delaying the availability of the optional accommodation process would delay the ability of organizations that do not now qualify for the accommodation, but wish to opt into it, to be able to do so and therefore to provide a mechanism for contraceptive coverage to be provided to their employees while the organization's religious objections are accommodated.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these

interim final rules effective immediately upon filing at the Office of the Federal Register.

VI. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with

economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of \$100 million or more in any 1 year, and therefore do not meet the definition of “economically significant” under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations to expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, and to revise the accommodation process to make it optional for eligible organizations. The expanded exemption would apply to individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action is taken, among other reasons, to provide for participation in the health insurance market by certain entities or individuals free from penalties for violating sincerely held religious beliefs opposed to providing or receiving coverage of contraceptive services, and to resolve many of the lawsuits that have been filed against the Departments.

2. Anticipated Effects

The Departments assess this interim final rule together with a companion interim final rule concerning moral but non-religious conscientious objections to contraception, published elsewhere in this **Federal Register**. Regarding entities that are extended an exemption, absent expansion of the exemption the Guidelines would require many of these entities and individuals to either: Pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which some entities also believe entangles them in the provision of such objectionable coverage; or, pay tax penalties or be

subject to other adverse consequences for non-compliance with these requirements. These interim final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections and exempting them—on the basis of such objections— from the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption immediately, a notice will need to be sent to enrollees (either by the entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during a plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these interim final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be \$51,990.

The Departments estimate that these interim final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their newly exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation that were not provided access to it previously. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations on issuers and third party administrators serving the fewer number of entities that will newly opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party

administrators, who will no longer have continuing obligations imposed on them by the accommodation.

These interim final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. The Departments do not have sufficient data to determine the actual effect of these rules on plan participants and beneficiaries, including for costs they may incur for contraceptive coverage, nor of unintended pregnancies that may occur. As discussed above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- how many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby*, several objecting entities still provide coverage for 14 of the 18 women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- how many women will be covered by plans of entities using their newly exempt status.
- which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- the degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- the degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- the degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- the extent to which such women will qualify for alternative sources of

contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

The Departments have access to sources of information discussed in the following paragraphs that are relevant to this issue, but those sources do not provide a full picture of the impact of these interim final rules.

First, the prior rules already exempted certain houses of worship and their integrated auxiliaries. Further, as discussed above, the prior accommodation process allows hundreds of additional religious nonprofit organizations in self-insured church plans that are exempt from ERISA to file a self-certification or notice that relieves not only themselves but, in effect, their third party administrators of any obligation to provide contraceptive coverage or payments. Although in the latter case, third party administrators are legally permitted to provide the coverage, several self-insured church plans themselves have expressed an objection in litigation to allowing such contraceptive coverage to be provided, and according to information received during litigation, it appears that such contraceptive coverage has not been provided. In addition, a significant portion of the lawsuits challenging the Mandate were brought by a single firm representing Catholic dioceses and related entities covered by their diocese-sponsored plans. In that litigation, the Departments took the position that, where those diocese-sponsored plans are self-insured, those plans are likely church plans exempt from ERISA.⁶⁵ For the purposes of considering whether the expanded exemption in these rules affects the persons covered by such diocese-sponsored plans, the Departments continue to assume that such plans are similar to other objecting entities using self-insured church plans with respect to their third party administrators being unlikely to provide contraceptive coverage to plan participants and beneficiaries under the previous rule. Therefore the

⁶⁵ See, for example, Brief in Opp. To Pls.' Mot. for Prelim. Inj., *Brandt v. Burwell*, No. 2:14-cv-681-AJS, doc. #23 (W.D. Pa. filed June 10, 2014) (arguing that "plaintiffs have not established an injury in fact to the degree plaintiffs have a self-insured church plan," based on the fact that "the same law firm representing the plaintiffs here has suggested in another similar case that all 'Catholic entities like the Archdiocese participate in 'church plans.'"); *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013) ("because plaintiffs' self-insured plans are church plans, their third party administrators would not be required to provide contraceptive coverage").

Departments estimate that these interim final rules have no significant effect on the contraceptive coverage of women covered by plans of houses of worship and their integrated auxiliaries, entities using a self-insured church plan, or church dioceses sponsoring self-insured plans.

It is possible that an even greater number of litigating or accommodated plans might have made use of self-insured church plan status under the previous accommodation. Notably, one of the largest nonprofit employers that had filed suit challenging the Mandate had, under these prior rules, shifted most of their employees into self-insured church plans, and the Departments have taken the position that various other employers that filed suit were eligible to assume self-insured church plan status.⁶⁶ The Supreme Court's recent decision in *Advocate Health Care Network*, while not involving this Mandate, also clarifies certain circumstances under which religious hospitals may be eligible for self-insured church plan status. See 137 S. Ct. at 1656–57, 1663 (holding that a church plan under ERISA can be a plan not established and maintained by a church, if it is maintained by a principal-purpose organization).

Second, when the Departments previously created the exemption, expanded its application, and provided an accommodation (which, as mentioned, can lift obligations on self-insured church plans for hundreds of nonprofit organizations), we concluded that no significant burden or costs would result at all. (76 FR 46625; 78 FR 39889.) We reached this conclusion despite the impact, just described, whereby the previous rule apparently lead to women not receiving contraceptive coverage through hundreds of nonprofit entities using self-insured church plans. We also reached this conclusion without counting any significant burden or cost to some women covered in the plans of houses of worship or integrated auxiliaries that might want contraceptive coverage. This conclusion was based in part on the assertion, set forth in previous regulations, that employees of houses of worship and integrated auxiliaries likely share their employers' opposition to contraception. Many other religious nonprofit entities, however, both adopt and implement religious principles with similar

fervency. For the reasons discussed above, the Departments no longer believe we can distinguish many of the women covered in the plans of religious nonprofit entities from the women covered in the plans of houses of worship and integrated auxiliaries regarding which the Departments assumed share their employers' objection to contraception, nor from women covered in the plans of religious entities using self-insured church plans regarding which we chose not to calculate any anticipated effect even though we conceded we were not requiring their third party administrators to provide contraceptive coverage. In the estimates and assumptions below, we include the potential effect of these interim rules on women covered by such entities, in order to capture all of the anticipated effects of these rules.

Third, these interim final rules extend the exemption to for-profit entities. Among the for-profit employers that filed suit challenging the Mandate, the one with the most employees was *Hobby Lobby*.⁶⁷ As noted above, and like some similar entities, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of various contraceptive services: 14 of 18 FDA-approved women's contraceptive and sterilization methods.⁶⁸ (134 S. Ct. at 2766.) The effect of expanding the exemption to for-profit entities is therefore mitigated to the extent many of the persons covered by such entities' plans may receive coverage for at least some contraceptive services. No publicly traded for-profit entities have

filed lawsuits challenging the Mandate. The Departments agree with the Supreme Court's expectation in this regard: "it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable". *Hobby Lobby*, 134 S. Ct. at 2774. Therefore, although publicly traded entities could make use of exempt status under these interim final rules, the Departments do not expect that very many will do so, as compared to the 87 religious closely held for-profit entities that brought litigation challenging the Mandate (some of which might be content with the accommodation).

Fourth, the Departments have a limited amount of information about entities that have made use of the accommodation process as set forth in the previous rules. HHS previously estimated that 209 entities would make use of the accommodation process. That estimate was based on HHS's observation in its August 2014 interim final rules and July 2015 final regulations that there were 122 eligible entities that had filed litigation challenging the accommodation process, and 87 closely held for-profit entities that had filed suit challenging the Mandate in general. (79 FR 51096; 80 FR 41336). The Departments acknowledged that entities that had not litigated might make use of the accommodation, but we stated we did not have better data to estimate how many might use the accommodation overall.

After issuing those rules, the Departments have not received complete data on the number of entities actually using the accommodation, because the accommodation does not require many accommodated entities to submit information to us. Our limited records indicate that approximately 63 entities have affirmatively submitted notices to HHS to use the accommodation. This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. We have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being

⁶⁶ See <https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf>; see, for example, *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

⁶⁷ Verified Complaint ¶ 34, *Hobby Lobby Stores, Inc., et al. v. Sebelius*, No. 5:12-cv-01000-HE (Sept. 12, 2012 W.D. Okla.) (13,240 employees).

⁶⁸ By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, <https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf>, *Hobby Lobby* and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). See 134 S. Ct. at 2765–66. *Hobby Lobby* was willing to cover: Sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives ("the Pill"—combined pill); oral contraceptives ("the Pill"—extended/continuous use/combined pill); oral contraceptives ("the Mini Pill"—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that *Hobby Lobby* and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and "[t]he pill and female sterilization have been the two most commonly used methods since 1982." See Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or we were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage. Our records also indicate that 60 plans used the contraceptive user fees adjustments in the 2015 plan year, the last year for which we have data. This includes only self-insured plans, and it includes some plans that self-certified through submitting notices and other plans that, presumably, self-certified through the EBSA form 700.

These sets of data are not inconsistent with our previous estimate that 209 entities would use the accommodation, but they indicate that some non-litigating entities used the accommodation, and some litigating entities did not, possibly amounting to a similar number. For this reason, and because we do not have more complete data available, we believe the previous estimate of 209 accommodated entities is still the best estimate available for how many entities have used the accommodation under the previous rule. This assumes that the number of litigating entities that did not use the accommodation is approximately the same as the number of non-litigating entities that did use it.

In considering how many entities will use the voluntary accommodation moving forward—and how many will use the expanded exemption—we also do not have specific data. We expect the 122 nonprofit entities that specifically challenged the accommodation in court to use the expanded exemption. But, as noted above, we believe a significant number of them are not presently participating in the accommodation, and that some nonprofit entities in self-insured church plans are not providing contraceptive coverage through their third party administrators even if they are using the accommodation. Among the 87 for-profit entities that filed suit challenging the Mandate in general, few if any filed suit challenging the accommodation. We do not know how many of those entities are using the accommodation, how many may be complying with the Mandate fully, how many may be relying on court injunctions to do neither, or how many will use the expanded exemption moving forward. Among entities that never litigated but used the accommodation, we expect many but not all of them to continue using the accommodation, and we do not have data to estimate how many such entities

there are or how many will choose either option.

Overall, therefore, without sufficient data to estimate what the estimated 209 previously accommodated entities will do under these interim final rules, we assume that just over half of them will use the expanded exemption, and just under half will continue their accommodated status under the voluntary process set forth in these rules. Specifically, we assume that 109 previously accommodated entities will make use of their exempt status, and 100 will continue using the accommodation. This estimate is based in part on our view that most litigating nonprofit entities would prefer the exemption to the accommodation, but that many of either have not been using the accommodation or, if they have been using it, it is not providing contraceptive coverage for women in their plans where they participate in self-insured church plans. This estimate is also consistent with our lack of knowledge of how many for-profit entities were using the accommodation and will choose the exemption or the accommodation, given that many of them did not bring legal challenges against the accommodation after *Hobby Lobby*. This estimate is further consistent with our view, explained in more detail below, that some entities that are using the accommodation and did not bring litigation will use the exemption, but many accommodated, non-litigating entities—including the ones with the largest relative workforces among accommodated entities—will continue using the accommodation. The Departments recognize that we do not have better data to estimate the effects of these interim final rules on such entities.

In addition to these factors, we recognize that the expanded exemption and accommodation are newly available to religious for-profit entities that are not closely held and some other plan sponsors. As explained above, the Departments believe religious for-profit entities that are not closely held may exist, or may wish to come into being. HHS does not anticipate that there will be significant number of such entities, and among those, we believe that very few if any will use the accommodation. All of the for-profit entities that have challenged the Mandate have been religious closely held entities.

It is also possible that religious nonprofit or closely held for-profit entities that were already eligible for the accommodation but did not previously use it will opt into it moving forward, but because they could have done so under the previous rules, their opting

into the accommodation is not caused by these rules.

Without any data to estimate how many of any entities newly eligible for and interested in using the accommodation might exist, HHS assumes for the purposes of estimating the anticipated effect of these rules that less than 10 entities (9) will do so. Therefore, we estimate that 109 entities will use the voluntary accommodation moving forward, 100 of which were already using the previous accommodation, and that 109 entities that have been using the previous accommodation will use the expanded exemption instead.

Fifth, in attempting to estimate the anticipated effect of these interim final rules on women receiving contraceptive coverage, the Departments have limited information about the entities that have filed suit challenging the Mandate. Approximately 209 entities have brought suit challenging the Mandate over more than 5 years. They have included a broad range of nonprofit entities and closely held for-profit entities. We discuss a number of potentially relevant points:

First, the Departments do not believe that out-of-pocket litigation costs have been a significant barrier to entities choosing to file suit. Based on the Departments' knowledge of these cases through public sources and litigation, nearly all the entities were represented pro bono and were subject to little or no discovery during the cases, and multiple public interest law firms publicly provided legal services for entities willing to challenge the Mandate.⁶⁹ (It is noteworthy, however, that such pro bono arrangements and minimization of discovery do not eliminate 100 percent of the time costs of participating in litigation or, as discussed in more detail below, the potential for negative

⁶⁹ See, for example, Catholic Diocese of Pittsburgh, "Award-winning attorney 'humbled' by recognition," *Pittsburgh Catholic* ("Jones Day is doing the cases 'pro bono,' or voluntarily and without payment.") (quoting Paul M. Pohl, Partner, Jones Day), available at <http://diopitt.org/pittsburgh-catholic/award-winning-attorney-humbled-recognition>; "Little Sisters Fight for Religious Freedom," *National Review* (Oct. 2, 2013) ("the Becket Fund for Religious Liberty is representing us pro bono, as they do all their clients.") (quoting Sister Constance Veit, L.S.P., communications director for the Little Sisters of the Poor), available at <http://www.nationalreview.com/article/360103/little-sisters-fight-religious-freedom-interview>; Suzanne Cassidy, "Meet the major legal players in the Conestoga Wood Specialties Supreme Court case," *LancasterOnline* (Mar. 25, 2014) ("Cortman and the other lawyers arguing on behalf of Conestoga Wood Specialties and Hobby Lobby are offering their services pro bono."), available at http://lancasteronline.com/news/local/meet-the-major-legal-players-in-the-conestoga-wood-specialties/article_302bc8e2-b379-11e3-b669-001a4bcf6878.html.

publicity. Both concerns could have dissuaded participation in lawsuits, and the potential for negative publicity may also dissuade participation in the expanded exemptions.)

Second, prior to the Affordable Care Act, the vast majority of entities already covered contraception, albeit not always without cost-sharing. The Departments do not have data to indicate why entities that did not cover contraception prior to the Affordable Care Act chose not to cover it. As noted above, however, the Departments have maintained that compliance with the contraceptive Mandate is cost-neutral to issuers, which indicates that no significant financial incentive exists to omit contraceptive coverage. As indicated by the report by HHS ASPE discussed above, we have assumed that millions of women received preventive services after the Mandate went into effect because nearly all entities complied with the Guidelines. We are not aware of expressions from most of those entities indicating that they would have sincerely held religious objections to complying with the Mandate, and therefore that they would make use of the expanded exemption provided here.

Third, omitting contraceptive coverage has subjected some entities to serious public criticism and in some cases organized boycotts or opposition campaigns that have been reported in various media and online outlets regarding entities that have filed suit. The Departments expect that even if some entities might not receive such criticism, many entities will be reluctant to use the expanded exemption unless they are committed to their views to a significant degree.

Overall, the Departments do not know how many entities will use the expanded exemption. We expect that some non-litigating entities will use it, but given the aforementioned considerations, we believe it might not be very many more. Moreover, many litigating entities are already exempt or are not providing contraceptive coverage to women in their plans due to their participating in self-insured church plans, so the effect of the expanded exemption among litigating entities is significantly lower than it would be if all the women in their plans were already receiving the coverage.

To calculate the anticipated effects of this rule on contraceptive coverage among women covered by plans provided by litigating entities, we start by examining court documents and other public sources.⁷⁰ These sources

provide some information, albeit incomplete, about how many people are employed by these entities. As noted above, however, contraceptive coverage among the employees of many litigating entities will not be affected by these rules because some litigating entities were exempt under the prior rule, while others were or appeared to be in self-insured church plans so that women covered in their plans were already not receiving contraceptive coverage.

Among litigating entities that were neither exempt nor likely using self-insured church plans, our best estimate based on court documents and public sources is that such entities employed approximately 65,000 persons, male and female.⁷¹ The average number of workers at firms offering health benefits that are actually covered by those benefits is 62 percent.⁷² This amounts to approximately 34,000 employees covered under those plans. DOL estimates that for each employee policyholder, there is approximately one dependent.⁷³ This amounts to approximately 68,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—compose 20.2 percent of the general population.⁷⁴ In addition,

number of employees that work for an entity, and that entity was not apparently exempt as a house of worship or integrated auxiliary, and it was not using the kind of plan that we have stated in litigation qualifies for self-insured church plan status (see, for example, *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013)), we examined employment data contained in some IRS form W-3's that are publicly available online for certain nonprofit groups, and looked at other Web sites discussing the number of people employed at certain entities.

⁷¹ In a small number of lawsuits, named plaintiffs include organizations claiming to have members that seek an exemption. We have very little information about the number, size, and types of entities those members. Based on limited information from those cases, however, their membership appears to consist mainly, although not entirely, of houses of worship, integrated auxiliaries, and participants in self-insured plans of churches. As explained above, the contraceptive coverage of women covered by such plans is not likely to be affected by the expanded exemption in these rules. However, to account for plans subject to contraceptive coverage obligations among those members we have added 10,000 to our estimate of the number of persons among litigants that may be impacted by these rules.

⁷² See Kaiser Family Foundation and Health Research and Educational Trust, "Employer Health Benefits: 2017 Annual Survey" at 57, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

⁷³ "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

⁷⁴ United States Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at <https://www.census.gov/prod/cen2010/briefs/>

approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.⁷⁵ Therefore, we estimate that approximately 7,221 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that have filed lawsuits challenging the Mandate, where those plans are neither exempt under the prior rule nor are self-insured church plans.

We also estimate that for the educational institutions objecting to the Mandate as applied to student coverage that they arranged, where the entities were neither exempt under the prior rule nor were their student plans self-insured, such student plans likely covered approximately 3,300 students. On average, we expect that approximately half of those students (1,650) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. We expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, we assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 3,300. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, we assume they are. Therefore, for the purposes of this estimate, we assume that the effect of these expanded exemptions on student plans of litigating entities includes 3,300 women. Assuming that 44.3 percent of such women use contraception covered by the Guidelines,⁷⁶ we estimate that

c2010br-03.pdf. The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." <https://www.hrsa.gov/womensguidelines/>; also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁷⁵ See <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states> (reporting that of 60,877,000 women aged 15–44, 26,945,000 use women's contraceptive methods covered by the Guidelines).

⁷⁶ It would appear that a smaller percentage of college-aged women use contraception—and use more expensive methods such as long acting methods or sterilization—than among other women of childbearing age. See NCHS Data Brief, "Current Contraceptive Status Among Women Aged 15–44: United States, 2011–2013" (Dec. 2014), available at

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⁷⁰ Where complaints, affidavits, or other documents filed in court did not indicate the

1,462 of those women would be affected by these rules.

Together, this leads the Departments to estimate that approximately 8,700 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted above, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do we know how many would have alternative contraceptive access from a parent's or spouse's plan, or from Federal, State, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

Sixth, in a brief filed in the *Zubik* litigation, the Departments stated that "in 2014, [HHS] provided user-fee reductions to compensate TPAs for making contraceptive coverage available to more than 600,000 employees and beneficiaries," and that "[t]hat figure includes both men and women covered under the relevant plans."⁷⁷ HHS has reviewed the information giving rise to that estimate, and has received updated information for 2015. In 2014, 612,000 persons were covered by plans claiming contraceptive user fees adjustments, and in 2015, 576,000 persons were covered by such plans. These numbers include all persons in such plans, not just women of childbearing age.

HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly 100,000 persons each, and several others cover approximately 40,000 persons each. In other words, these plans were proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

There are two reasons to believe that a significant fraction of the persons covered by previously accommodated

plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.⁷⁸ Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these interim final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.⁷⁹ As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.⁸⁰ (The Departments take no view on the status of these particular plans under ERISA, but simply make this observation for the purpose of seeking to estimate the impact of these interim final rules.) Nevertheless, overall it seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these interim final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations these interim final rules would not have an

anticipated effect on the contraceptive coverage of women in those plans.

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these interim final rules. The Departments begin with the 8,700 women of childbearing age that use contraception who we estimate will be affected by use of the expanded exemption among litigating entities. In addition to that number, we calculate the following number of women affected by accommodated entities using the expanded exemption. As noted above, approximately 576,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2014. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, we do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, we assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer sponsored insurance, 56.1 percent are covered by self-insured plans and 43.9 percent are covered by fully insured plans.⁸¹ Therefore, corresponding to the 576,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 451,000 persons were covered by fully insured plans using the accommodation. This yields an estimate of 1,027,000 covered persons of all ages and sexes in plans using the previous accommodation.

As discussed below, and recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the prior rule

⁷⁸ See, for example, <https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule> ("HHS has now established an accommodation that will allow our ministries to continue offering health insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.") In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it "is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia." Comments on CMS-9968-ANPRM (dated June 15, 2012).

⁷⁹ See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, *Advocate Health Care Network*, Nos. 16-74, 16-86, 16-258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) ("CHA members have relied for decades that the 'church plan' exemption contained in" ERISA.).

⁸⁰ See supra note 66.

⁸¹ "Health Insurance Coverage Bulletin" Table 3A, page 15. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

<https://www.cdc.gov/nchs/data/databriefs/db173.pdf>.

⁷⁷ Brief of Respondents at 18-19 & n.7, *Zubik v. Burwell*, No. 14-1418, et al. (U.S. filed Feb. 10, 2016). The actual number is 612,487.

will continue to opt into it under these interim final rules. Notably, however, the data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As also cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these interim final rules would not impact the contraceptive coverage their employees receive. We do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. We assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data. Based on these assumptions and without better data available, we assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, we assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.

Applying these percentages to the total number of 1,027,000 persons we estimate are covered in accommodated plans, we estimate that approximately 257,000 persons previously covered in accommodated plans will be covered in the 109 plans that use the expanded exemption, and 770,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, 20.2 percent of these persons are women of childbearing age, which amounts to approximately 51,900 women of childbearing age in previously accommodated plans that we estimate will use the expanded exemption. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that we expect approximately 23,000 women that use contraception covered by the Guidelines

to be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 8,700 women in plans of litigating entities that may be affected by these rules. Based on our limited information from the litigation and accommodation notices, we expect that the overlap is significant. Nevertheless, in order to estimate the possible effects of these rules, we assume there is no overlap between these two numbers, and therefore that these interim final rules would affect the contraceptive costs of approximately 31,700 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these interim final rules is less than 0.1 percent of the 55.6 million women in private plans that HHS ASPE estimated⁸² receive preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the prior accommodation process, the total user fee adjustment amount for self-insured plans for the 2015 benefit year was \$33 million. These adjustments covered the cost of contraceptive coverage provided to women participants and beneficiaries in self-insured plans where the employer objected and made use of the accommodation, and where an authorizing exception under OMB Circular No. A-25R was in effect as the Secretary of the Department of Health and Human Services requests. Nine percent of that amount was attributable to administrative costs and margin, according to the provisions of 45 CFR 156.50(d)(3)(ii). Thus the amount of the adjustments attributable to the cost of contraceptive services was about \$30 million. As discussed above, in 2015 that amount corresponded to 576,000 persons covered by such plans. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age—that is, approximately 116,000 women. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, which includes 51,400 women in those plans. Therefore, entities using contraceptive user fees adjustments received

⁸² Available at <https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans>; also, see Abridged Report, available at https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.

approximately \$584 per year per woman of childbearing age that use contraception covered by the Guidelines and are covered in their plans.

As discussed above, the Departments estimate that the expanded exemptions will impact the contraceptive costs of approximately 31,700 women of childbearing age that use contraception covered by the Guidelines. At an average of \$584 per year, the financial transfer effects attributable to the interim final rules on those women would be approximately \$18.5 million.^{83 84}

To account for uncertainty in the estimate, we conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these interim final rules.

As noted above, the HHS ASPE report estimated that 55.6 million women aged 15 to 64 and covered by private insurance had preventive services coverage under the Affordable Care Act. Approximately 16.2 percent of those women were enrolled in plans on exchanges or were otherwise not covered by employer sponsored insurance, so only 46.6 million women aged 15 to 64 received the coverage through employer sponsored private insurance plans.⁸⁵ In addition, some of those private insurance plans were offered by government employers, encompassing approximately 10.5 million of those women aged 15 to 64.⁸⁶

⁸³ As noted above, the Departments have taken the position that providing contraceptive coverage is cost neutral to issuers. (78 FR 39877). At the same time, because of the up-front costs of some contraceptive or sterilization methods, and because some entities did not cover contraception prior to the Affordable Care Act, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent.

⁸⁴ Describing this impact as a transfer reflects an implicit assumption that the same products and services would be used with or without the rule. Such an assumption is somewhat oversimplified because the interim final rules shift cost burden to consumption decision-makers (that is, the women who choose whether or not to use the relevant contraceptives) and thus can be expected to lead to some decrease in use of the affected drugs and devices and a potential increase in pregnancy—thus leading to a decrease and an increase, respectively, in medical expenditures.

⁸⁵ Available at <https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf>.

⁸⁶ The ASPE study relied on Census data of private health insurance plans, which included plans sponsored by either private or public sector

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The expanded exemption in these interim final rules does not apply to government plan sponsors. Thus we estimate that the number of women aged 15 to 64 covered by private sector employer sponsored insurance who receive preventive services coverage under the Affordable Care Act is approximately 36 million.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.⁸⁷ The 6 percent may have included approximately 2.16 million of the women aged 15–64 covered by employer sponsored insurance plans in the private sector. According to Census data, 59.9 percent of women aged 15 to 64 are of childbearing age (aged 15 to 44), in this case, 1.3 million. And as noted above, approximately 44.3 percent of women of childbearing age

employers. See Table 2, notes 2 & 3 (explaining the scope of private plans and government plans for purposes of Table 2), available at <https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-250.pdf>.

According to data tables from the Medical Expenditure Panel Survey (MEPS) of the Agency for Healthcare Research and Quality of HHS (<https://meps.ahrq.gov/mepsweb/>), State and local governments employ 19,297,960 persons; 99.2 percent of those employers offer health insurance; and 67.4 percent of employees that work at such entities where insurance is offered are enrolled in those plans, amounting to 12.9 million persons enrolled. DOL estimates that in the public sector, for each policyholder there is an average of slightly less than one dependent. “Health Insurance Coverage Bulletin” Table 4, page 21. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>. Therefore, State and local government employer plans cover approximately 24.8 million persons of all ages. Census data indicates that on average, 12 percent of persons covered by private insurance plans are aged 65 and older. Using these numbers, we estimate that State and local government employer plans cover approximately 21.9 million persons under age 65.

The Federal Government has approximately 8.2 million persons covered in its employee health plans. According to information we received from the Office of Personnel Management, this includes 2.1 million employees having 3.2 million dependents, and 1.9 million retirees (annuitants) having 1 million dependents. We do not have information about the ages of these policyholders and dependents, but for the purposes of this estimate we assume the annuitants and their dependents are aged 65 or older and the employees and their dependents are under age 65, so that the Federal Government’s employee health plans cover 5.3 million persons under age 65.

Thus, overall we estimate there are 27.2 million persons under age 65 enrolled in private health insurance sponsored by government employers. Of those, 38.3 percent are women aged 15–64, that is, 10.5 million.

⁸⁷ Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2010 Annual Survey” at 196, available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf>.

use women’s contraceptive methods covered by the Guidelines. Therefore we estimate that 574,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.⁸⁸

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for conscientious reasons, or for other reasons. Despite our lack of information about their motives, we attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, we estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court’s decision in *Hobby Lobby*, where the Court observed that “HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run

⁸⁸ Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers’ lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity’s mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these interim final rules.

a corporation under the same religious beliefs seems improbable”. 134 S. Ct. at 2774. The Departments are aware of several Federal health care conscience laws⁸⁹ that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but we are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while we consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions we agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.⁹⁰ That means that only approximately 394,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, these interim final rules build on existing rules that already exempt houses of worship and integrated auxiliaries and, as explained above, effectively remove obligations to provide contraceptive coverage within objecting self-insured church plans. These rules will therefore not effect transfers to women in the plans of such employers. In attempting to estimate the number of such employers, we consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the

⁸⁹ For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

⁹⁰ John Asker, et al., “Corporate Investment and Stock Market Listing: A Puzzle?” 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at <https://doi.org/10.1093/rfs/hhu077>. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, “The number of publicly-traded US companies is down 46% in the past two decades,” *Yahoo! Finance* (Aug. 8, 2016), available at <https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html>.

United States,⁹¹ 197 Catholic dioceses,⁹² 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.⁹³ Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so we use the number of schools to estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention. It covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.⁹⁴ Christian Brothers is a plan that covers Catholic organizations. It covers Catholic churches and integrated auxiliaries, which are estimated above, but also it has said in litigation that it also covers about 500 additional entities that are not exempt as churches. In total, therefore, we estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous rules. We do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include “churches, mission-sending agencies, hospitals, educational institutions and other related ministries.” Using that ratio, we estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 would be of childbearing age, and 32,100 would use contraceptives covered by the Guidelines. Therefore, we estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous rules nor were participants in self-insured church plans that oppose

contraceptive coverage, covered 362,100 women aged 15 to 44 that use contraceptives covered by the Guidelines. As noted above, we estimate an average annual expenditure on contraceptive products and services of \$584 per user. That would amount to \$211.5 million in potential transfer impact among entities that did not cover contraception pre-Affordable Care Act for any reason.

We do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these interim final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous rules on this matter, we are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, we believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 120,000 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these interim final rules. Consequently, as explained below, we believe that the potential impact of these interim final rules falls substantially below the \$100 million threshold for economically significant and major rules.

First, as mentioned, we are not aware of information that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or religious beliefs specifically, as opposed to having done so for other reasons. Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees. Also, avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts, all provide reasons for some employers not to return to pre-Affordable Care Act lack of contraceptive coverage. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover

as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.⁹⁵ Furthermore, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

In addition, not all sincerely held conscientious objections to contraceptive coverage are likely to be held by persons with religious beliefs as distinct from persons with sincerely held non-religious moral convictions, whose objections would not be encompassed by these interim final rules.⁹⁶ We do not have data to indicate, among entities that did not cover contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, which ones did so based on religious beliefs and which ones did so instead based on non-religious moral convictions. Among the general public, polls vary about religious beliefs but one prominent poll shows that 89 percent of Americans say they believe in God, while 11 percent say they do not or are agnostic.⁹⁷ Therefore, we estimate that for every ten entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, one did so based on sincerely held non-religious moral convictions, and therefore are not affected by the expanded exemption provided by these interim final rules for religious beliefs.

Based on our estimate of an average annual expenditure on contraceptive products and services of \$584 per user,

⁹⁵ On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered “yes” or “don’t know” to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule’s effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

⁹⁶ Such objections may be encompassed by companion interim final rules published elsewhere in this **Federal Register**. Those rules, however, as an interim final matter, are more narrow in scope than these rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

⁹⁷ Gallup, “Most Americans Still Believe in God” (June 14–23, 2016), available at <http://www.gallup.com/poll/193271/americans-believe-god.aspx>.

⁹¹ Roman Catholic Diocese of Reno, “Diocese of Reno Directory: 2016–2017,” available at <http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf>.

⁹² Wikipedia, “List of Catholic dioceses in the United States,” available at https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.

⁹³ National Catholic Educational Association, “Catholic School Data,” available at http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.

⁹⁴ Guidestone Financial Resources, “Who We Serve,” available at <https://www.guidestone.org/AboutUs/WhoWeServe>.

the effect of the expanded exemptions on 120,000 women would give rise to approximately \$70.1 million in potential transfer impact. This falls substantially below the \$100 million threshold for economically significant and major rules. In addition, as noted above, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent $\times$ 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent, yielding a potential transfer of \$63.8 million.

We request comment on all aspects of the preceding regulatory impact analysis, as well as on how to attribute impacts to this interim final rule and the companion interim final rule concerning exemptions provided based on sincerely held (non-religious) moral convictions published elsewhere in this **Federal Register**.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments anticipate that there will be more entities reluctantly using the existing accommodation that will choose to operate under the newly expanded exemption, than entities that are not currently eligible to use the accommodation that will opt into it. The effect of this rule will therefore be that fewer overall adjustments are made to the Federally facilitated Exchange user fees for entities using the accommodation process, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect, than would have occurred under the previous rule if this rule were not finalized. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a

general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities, and in many cases will relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization, the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to

minimize the information collection burden.

However, we are requesting an emergency review of the information collection referenced later in this section. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we have submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting an emergency review and approval under both 5 CFR 1320.13(a)(2)(i) and (iii) of the implementing regulations of the PRA in order to implement provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). In accordance with 5 CFR 1320.13(a)(2)(i), we believe public harm is reasonably likely to ensue if the normal clearance procedures are followed. The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information. Similarly, in accordance with 5 CFR 1320.13(a)(2)(iii), we believe the use of normal clearance procedures is reasonably likely to cause a statutory or court ordered deadline to be missed. Many cases have been on remand for over a year from the Supreme Court, asking the Departments and the parties to resolve this matter. These interim final rules extend exemptions to entities, which involves no collection of information and which the Departments have statutory authority to do by the use of interim final rules. If the information collection involved in the amended accommodation process is not approved on an emergency basis, newly exempt entities that wish to opt into the amended accommodation process might not be able to do so until normal clearance procedures are completed.

A description of the information collection provisions implicated in these interim final rules is given in the following section with an estimate of the annual burden. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.⁹⁸

a. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under

⁹⁸ May 2016 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm.

these interim final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these interim final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations. The burden related to the notice to HHS is currently approved under OMB Control Number 0938–1248 and the burden related to the self-certification (EBSA Form 700) is currently approved under OMB control number 0938–1292.

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these interim final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party administrator). As explained above, HHS assumes that, among the 209 entities we estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes, as it did in its August 2014 interim final rules, that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.⁹⁹ HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$55.68 per hour,¹⁰⁰ 10 minutes for a

compensation and benefits manager at a cost of \$122.02 per hour,¹⁰¹ 5 minutes for legal counsel at a cost of \$134.50 per hour,¹⁰² and 5 minutes by a senior executive at a cost of \$186.88 per hour¹⁰³) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$74.96 for a total hour burden of approximately 7.5 hours with an equivalent cost of approximately \$675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for approximately 3.75 burden hours with an equivalent cost of approximately \$337.

HHS estimates that each self-certification or notice to HHS will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be \$0.54. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately \$2.70 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so each will account for \$1.35 of the cost burden.

b. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but

contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language set forth previously by HHS or substantially similar language. The burden for this ICR is currently approved under OMB control number 0938–1292.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$55.68 per hour)¹⁰⁴ and 15 minutes of management review (at \$117.40 per hour)¹⁰⁵ to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$85.03. The total burden for all issuers or third party administrators will be 136 hours, with an equivalent cost of \$9,268. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 68 burden hours with an equivalent cost of \$4,634, with approximately 55 respondents.

As discussed above, the Departments estimate that 770,000 persons will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. It is not known how many persons will be covered in the plans of the 9 entities newly using the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity, we estimate that all 109 accommodated entities will encompass 839,300 covered persons. We assume that sending one notice to each participant will satisfy the need to send the notices to all participants and dependents. Among persons covered by plans, approximately 50.1 percent are participants and 49.9 percent are

⁹⁹ For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

¹⁰⁰ Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage \$27.84, <https://www.bls.gov/oes/current/oes436011.htm>.

¹⁰¹ Occupation code 11–3111 for Compensation and Benefits Managers with mean hourly wage \$61.01, <https://www.bls.gov/oes/current/oes113111.htm>.

¹⁰² Occupation code 23–1011 for Lawyers with mean hourly wage \$67.25, <https://www.bls.gov/oes/current/oes231011.htm>.

¹⁰³ Occupation code 11–1011 for Chief Executives with mean hourly wage \$93.44, <https://www.bls.gov/oes/current/oes111011.htm>.

¹⁰⁴ Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage \$27.84.

¹⁰⁵ Occupation code 11–1021 General and Operations Managers with mean hourly wage \$58.70.

dependents.¹⁰⁶ For 109 entities, the total number of notices will be 420,490. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.¹⁰⁷ Therefore, approximately 194,687 notices will be mailed. HHS estimates that each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54. The total cost for sending approximately 194,687 notices by mail is approximately \$105,131. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for \$52,565 of the cost burden.

c. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke

their use of the accommodation, and will therefore be required to cause the notification to be sent (the issuer or third party administrator can send the notice on behalf of the entity). For the purpose of calculating ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke it fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of \$117.40 per hour,¹⁰⁸ 30 minutes for legal counsel at a cost of \$134.50 per hour¹⁰⁹, 1 hour for clerical labor at a cost of \$55.68 per hour¹¹⁰). The burden per respondent will be 2 hours with an equivalent cost of \$181.63; for 109 entities, the total burden will be 218 hours with an equivalent cost of

approximately \$19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an equivalent cost of approximately \$9,899.

As discussed above, HHS estimates that there are 257,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.¹¹¹ As before, we use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 128,757 notices will be sent, of which 59,615 notices will be mailed. HHS estimates that each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54. The total cost for sending approximately 59,615 notices by mail is approximately \$32,192. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 64,379 notices, with an equivalent cost of approximately \$16,096.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total cost (\$)
Self-Certification or Notices to HHS	0938—NEW ...	*5	5	0.83	3.75	\$89.95	\$337.31	\$338.66
Notice of Availability of Separate Payments for Contraceptive Services.	0938—NEW ...	*55	210,245	1.25	68.13	68.02	4,634.14	57,199.59
Notice of Revocation of Accommodation	0938—NEW ...	*55	64,379	2.00	109	90.82	9,898.84	25,994.75
Total		*115	274,629	4.08	180.88		14,870.29	83,533.00

* The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

We are soliciting comments on all of the information collection requirements contained in these interim final rules. In addition, we are also soliciting

comments on all of the related information collection requirements currently approved under 0938—1292 and 0938—1248. HHS is requesting a

new OMB control number that will ultimately contain the approval for the new information collection requirements contained in these interim

¹⁰⁶ “Health Insurance Coverage Bulletin” Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

¹⁰⁷ According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the Internet outside of work. According to a Pew Research Center survey, 61

percent of Internet users use online banking, which is used as the proxy for the number of Internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

¹⁰⁸ Occupation code 11—1021 for General and Operations Managers with mean hourly wage \$58.70, <https://www.bls.gov/oes/current/oes111021.htm>.

¹⁰⁹ Occupation code 23—1011 for Lawyers with mean hourly wage \$67.25, <https://www.bls.gov/oes/current/oes231011.htm>.

¹¹⁰ Occupation code 43—6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage \$27.84, <https://www.bls.gov/oes/current/oes436011.htm>.

¹¹¹ In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, we indicated that we do not know the extent to which the number of women in accommodated plans affected by these rules overlap with the number of women in plans offered by litigating entities that will be affected by these rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

final rules as well as the related requirements currently approved under 0938–1292 and 0938–1248. In an effort to consolidate the number of information collection requests, we will formally discontinue the control numbers 0938–1292 and 0938–1248 once the new information collection request associated with these interim final rules is approved.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

These interim final rules amend the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer who revokes their accommodation. DOL submitted the ICRs in order to obtain OMB approval under the PRA for the regulatory

revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. In an effort to consolidate the number of information collection requests, DOL will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once the ICR is approved DOL will discontinue 1210–0152. A copy of the information collection request may be obtained free of charge on the [RegInfo.gov](http://www.reginfo.gov) Web site at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001. This approval will allow respondents to temporarily utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden.

Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur \$0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur \$0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 420,489 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke its use and will therefore be required to cause the Notice of Revocation of Accommodation to be sent (the issuer or third party administrator can send the notice on behalf of the entity). These entities will spend approximately two hours in preparation time and incur \$0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 128,757 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114¹¹² (combined with HHS total is 227).

Total Responses: 274,628 (combined with HHS total is 549,255).

Frequency of Response: On occasion.

Estimated Total Annual Burden

Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: \$68,662 (combined with HHS total is \$137,325).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, “[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” In addition, agencies are directed to “take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.” These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting

¹¹² Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

costs.¹¹³ Therefore, this interim final rule is considered an Executive Order 13771 deregulatory action.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.

G. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials,

¹¹³ Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB’s guidance on E.O. 13771 implementation (<https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation>) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule’s medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VII. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* [Reserved]. For further guidance, see § 54.9815–2713T(a)(1) introductory text.

* * * * *

(iv) [Reserved]. For further guidance, see § 54.9815–2713T(a)(1)(iv).

* * * * *

■ 3. Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of § 54.9815–2713 and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i)–(iii) [Reserved]. For further guidance, see § 54.9815–2713(a)(1)(i) through (iii).

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of § 54.9815–2713 as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

(2)–(c) [Reserved]. For further guidance, see § 54.9815–2713(a)(2) through (c).

(d) *Effective/Applicability date.* (1) Paragraphs (a) through (c) of this section are applicable beginning on April 16, 2012, except—

(2) Paragraphs (a)(1) introductory text and (a)(1)(iv) of this section are effective on October 6, 2017.

(e) *Expiration date.* This section expires on October 6, 2020.

■ 4. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) through (f) [Reserved]. For further guidance, see § 54.9815–2713AT.

(b)

■ 5. Section 54.9815–2713AT is added to read as follows:

§ 54.9815–2713AT Accommodations in connection with coverage of preventive health services (temporary).

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to

make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give sixty-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an

identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans—*(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group

health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(g) *Expiration date.* This section expires on October 6, 2020.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 2590.715–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 8. Section 2590.715–2713A is revised to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its exempt status under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under § 2510.3–16 of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible

organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing

coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715–2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) for plan participants and beneficiaries

for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges

separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 2590.715–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42

U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131 and 147.132, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132.

* * * * *

■ 11. Section 147.131 is revised to read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process.

(d) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church

plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments

only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) “Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer].”

(f) *Definition*. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(g) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 12. Add § 147.132 to read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities*. (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines’ requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors

include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) *Objecting individuals*. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(c) *Definition*. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD-9828]

RIN 1545-BN91

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS-9925-IFC]

RIN 0938-AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs or moral convictions. These interim final rules expand exemptions to protect moral convictions for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the United States Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also provide certain morally objecting entities access to the voluntary “accommodation” process regarding such coverage. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES:

Effective date: These interim final rules are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by “Preventive Services,” may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9925-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9925-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave

their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492-4305 or marketreform@cms.hhs.gov for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317-5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor’s Web site (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS’s Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the context of legal requirements touching on certain sensitive health care issues—including health coverage of contraceptives—Congress has a consistent history of supporting conscience protections for moral convictions alongside protections for religious beliefs, including as part of its efforts to promote access to health services.¹ Against that backdrop,

¹ See, for example, 42 U.S.C. 300a-7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their “religious beliefs or moral convictions”); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS,

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, “with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by” HRSA (the “Guidelines”). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,² while the

and Education, and Related Agencies Appropriations Act), Public Law 115–31 (protecting any “health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan” in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of “the provision of contraceptive coverage by health insurance plans” in the District of Columbia, “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions”); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their “religious or conscientious commitment to offer only natural family planning”); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on “religious beliefs or moral objections”); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on “conscience” as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on “religious beliefs or moral convictions”); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by “aliens” due to “religious beliefs or moral convictions”); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on “moral or religious convictions”); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their “religious or moral objection”).

² This document’s references to “contraception,” “contraceptive,” “contraceptive coverage,” or

administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, “the Departments”),³ exercised both the discretion granted to HHS through HRSA, its component, in PHS Act section 2713(a)(4), and the authority granted to the Departments as administering agencies (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92) to issue regulations to guide HRSA in carrying out that provision. Through rulemaking, including three interim final rules, the Departments exempted and accommodated certain religious objectors, but did not offer an exemption or accommodation to any group possessing non-religious moral objections to providing coverage for some or all contraceptives. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the “contraceptive Mandate,” or the “Mandate”) as being inconsistent with various legal protections. These challenges included lawsuits brought by some non-religious organizations with sincerely held moral convictions inconsistent with providing coverage for some or all contraceptive services, and those cases continue to this day. Various public comments were also submitted asking the Departments to protect objections based on moral convictions.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as: The interests served by the existing Guidelines, regulations, and accommodation process;⁴ the extensive litigation; Executive Order 13798, “Promoting Free Speech and Religious Liberty” (May 4, 2017); Congress’ history of providing protections for moral convictions alongside religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under PHS Act section 2713(a)(4); the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; and the history of the regulatory process and comments submitted in various requests for public comments (including in the

“contraceptive services” generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

³ Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

⁴ In this IFR, we generally use “accommodation” and “accommodation process” interchangeably.

Departments’ 2016 Request for Information). Elsewhere in this issue of the **Federal Register**, the Departments published, contemporaneously with these interim final rules, companion interim final rules expanding exemptions to protect sincerely held religious beliefs in the context of the contraceptive Mandate.

In light of these considerations, the Departments issue these interim final rules to better balance the Government’s interest in promoting coverage for contraceptive and sterilization services with the Government’s interests in providing conscience protections for individuals and entities with sincerely held moral convictions in certain health care contexts, and in minimizing burdens imposed by our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, “[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact” and that “[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the Department of Health and Human Services (HHS).” Those laws protect objections based on moral convictions in addition to religious beliefs.

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS

Act requires coverage without cost sharing for “such additional” women’s preventive care and screenings “as provided for” and “supported by” guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

The Departments have consistently interpreted section 2713(a)(4)’s of the PHS Act grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women’s preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA’s Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women’s preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act reference to “comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph” to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines “supported by the Health Resources and Services Administration for purposes of this paragraph,” the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from “the other guidelines referenced in section 2713(a), which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients.” *Id.* Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4), the Departments have previously promulgated regulations defining the scope of permissible religious exemptions and accommodations for

such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority delegated to the Departments as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act’s statutory structure. The Congress did not intend to require entirely uniform coverage of preventive services. (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 for grandfathered plans. This exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing “particularly significant protections.” (75 FR 34540). Those provisions include: Section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime limits; section 2712, which prohibits rescissions of health insurance coverage; section 2714, which extends dependent coverage until age 26; and section 2718, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.⁵ As the Supreme Court observed, “there is no legal requirement that grandfathered plans ever be phased out.” *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments’ interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments’ own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that “longstanding Federal laws to protect conscience . . . remain intact,” including laws that protect religious beliefs and moral convictions from

certain requirements in the health care context. Although the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect conscience regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in consideration of the protections set forth in those laws.

B. The Regulations Concerning Women’s Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS Act.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women’s preventive services, issued on July 19, 2011, “Clinical Preventive Services for Women, Closing the Gaps” (IOM 2011). The IOM’s report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation, pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women’s health and well-being.⁶

The IOM made a number of recommendations with respect to women’s preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of “contraceptives” certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,⁷ the IOM’s recommendation included

⁶ Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings “with respect to women,” the Guidelines exclude services relating to a man’s reproductive capacity, such as vasectomies and condoms.

⁷ FDA’s guide “Birth Control: Medicines To Help You,” specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and “may also work . . . by preventing attachment (implantation) to the womb (uterus)” of a human embryo after fertilization. Available at <https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm>.

⁵ Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2017 Annual Survey,” available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason distinct from whether they also oppose contraception or sterilization. One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He stated that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by section 2713(a)(1) through (3) of the PHS Act leads to lower rates of disability or disease and increased rates of well-being, such that the IOM should recommend additional services to be included under Guidelines issued under section 2713(a)(4) of the PHS Act. He further stated that “the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered,” and that “the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee’s composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy.” He also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.⁸ IOM 2011 at 231–32. In its response to Dr. LoSasso, the other 15 committee members stated in part that “At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions.”

2. HRSA’s 2011 Guidelines and the Departments’ Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women’s preventive services, adopting the recommendations of the IOM. <https://www.hrsa.gov/womensguidelines/> The Guidelines

included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (hereinafter “the Mandate”).

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules. (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specified that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.⁹ The 2011 interim final rules only offered the exemption to a narrow scope of employers, and only if they were religious. As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some “States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services.” (76 FR 46623). Several comments were submitted asking that the exemption include those who object to contraceptive coverage based on non-religious moral convictions, including pro-life, non-profit advocacy organizations.¹⁰

3. The Departments’ Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of “religious employer” in the 2011 interim final rules without modification (2012 final regulations).¹¹ (77 FR 8725). The exemption did not require exempt employers to file any certification form or comply with any other information collection process.

Contemporaneously with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group

health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).¹² The temporary safe harbor did not include nonprofit organizations that had an objection to contraceptives based on moral convictions but not religious beliefs, nor did it include for-profit entities of any kind. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve “two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations’ religious objections to covering contraceptive services.” (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of “religious employer” for purposes of the religious employer exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer—(1) have the inculcation of religious values as its purpose; (2) primarily employ persons who share its religious tenets; and (3) primarily serve persons who share its religious tenets. The proposed expanded

¹² Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: <http://www.lb7.uscourts.gov/documents/12cv3932.pdf>. The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled “Student Health Insurance Coverage” published March 21, 2012 (77 FR 16457).

⁸ The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

⁹ The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011. (76 FR 46621).

¹⁰ See, for example, Americans United for Life (“AUL”) Comment on CMA–9992–IFC2 at 10 (Nov. 1, 2011), available at <http://www.regulations.gov/#/documentDetail;D=HHS-OS-2011-0023-59496>.

¹¹ The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

definition still encompassed only religious entities.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations “may be less likely than” employees of exempt houses of worship and integrated auxiliaries to share their employer’s faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization’s plan—and without any cost to the eligible organization.¹³ In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries. The proposed accommodation process was not to be offered to non-religious nonprofit organizations, nor to any for-profit entities. Public comments again included the request that exemptions encompass objections to contraceptive coverage based on moral convictions and not just based on religious beliefs.¹⁴ On August 15, 2012, the Departments extended our temporary safe harbor

until the first plan year beginning on or after August 1, 2013.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations “does not undermine the governmental interests furthered by the contraceptive coverage requirement.” (78 FR 39874). However, like the 2013 NPRM, the July 2013 regulations assumed that “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection” to contraceptives. *Id.*

The July 2013 regulation also finalized an accommodation for eligible organizations, which were then defined to include solely organizations that are religious. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization’s plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the HHS Secretary requests and an authorizing exception under OMB Circular No. A–25R is in effect.¹⁵ With respect to fully insured group health

plans, the issuer was expected to bear the cost of such payments,¹⁶ and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations. The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. Religious for-profit entities won various court decisions leading to the Supreme Court’s ruling in *Burwell v. Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.¹⁷

On August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of HHS that an eligible organization had religious objections to coverage of all or a subset of contraceptive services (79 FR 51092). In response to *Hobby Lobby*, the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption; neither added a certification requirement for

¹³ The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

¹⁴ See, for example, AUL Comment on CMS–9968–P at 5 (Apr. 8, 2013), available at <http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115>.

¹⁵ See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally-facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was \$33 million.

¹⁶ “[P]roviding payments for contraceptive services is cost neutral for issuers.” (78 FR 39877).

¹⁷ The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

exempt entities; and neither encompassed objections based on non-religious moral convictions.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

Meanwhile, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik v. Burwell*. On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik*, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases “in light of the substantial clarification and refinement in the positions of the parties” that had been filed in supplemental briefs. 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would “allow the parties sufficient time to resolve any outstanding issues between them.” *Id.* The Court also specified that “the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice” while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, meetings were held between attorneys for the Government and for the plaintiffs in those cases. The Departments also issued a Request for Information (“RFI”) on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the

Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016. Those comments included the request that the exemption be expanded to include those who oppose the Mandate for either religious “or moral” reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.¹⁸

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations asserted that they believe some methods classified by FDA as contraceptives may have an abortifacient effect and therefore, in their view, are morally equivalent to abortion. These organizations have neither received an exemption from the Mandate nor do they qualify for the accommodation. For example, the organization that since 1974 has sponsored the annual March for Life in Washington, DC (March for Life), filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, (77 FR 8727), March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who “want” the coverage so as to prevent “unintended” pregnancy. March for Life contended that because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and therefore doing so was arbitrary and capricious in violation of the APA. March for Life further contended that because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on our assumption that such entities are relatively more likely than other religious nonprofits to have employees that share their views against

contraception), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and therefore violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real Alternatives, Inc. v. Burwell*, 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the Federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims (not specifically ruling on the APA claim), and issued a permanent injunction against the Departments that is still in place. *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, Federal district and appellate courts in Pennsylvania disagreed with the reasoning from *March for Life* and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives*, 150 F. Supp. 3d 419, affirmed by 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. *Id.* at *18.

On December 20, 2016, HRSA updated the Guidelines via its Web site, <https://www.hrsa.gov/womensguidelines2016/index.html>. HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the

¹⁸ See, for example, <https://www.regulations.gov/document?D=CMS-2016-0123-54142>; see also <https://www.regulations.gov/document?D=CMS-2016-0123-54218> and <https://www.regulations.gov/document?D=CMS-2016-0123-46220>.

contraceptive method). They also specified, for the first time, that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process, nor did they extend the exemption or accommodation process to organizations or individuals that oppose certain forms of contraception (and coverage thereof) on moral grounds.

On January 9, 2017, the Departments issued a document entitled, "FAQs About Affordable Care Act Implementation Part 36."¹⁹ The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. The Departments did not adopt the approach requested by certain commenters, cited above, to expand the exemption to include those who oppose the Mandate for moral reasons.

On May 4, 2017, the President issued Executive Order 13798, "Promoting Free Speech and Religious Liberty." Section 3 of that order declares, "Conscience Protections with Respect to Preventive-Care Mandate. The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code."

II. Expanded Exemptions and Accommodations for Moral Convictions

These interim final rules incorporate conscience protections into the contraceptive Mandate. They do so in part to bring the Mandate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues, cognizant that Congress neither required the Departments to impose the Mandate nor prohibited them from providing

conscience protections if they did so. Specifically, these interim final rules expand exemptions to the contraceptive Mandate to protect certain entities and individuals that object to coverage of some or all contraceptives based on sincerely held moral convictions but not religious beliefs, and these rules make those exempt entities eligible for accommodations concerning the same Mandate.

A. Discretion To Provide Exemptions Under Section 2713(a)(4) of the PHS Act and the Affordable Care Act

The Departments have consistently interpreted HRSA's authority under section 2713(a)(4) of the PHS Act to allow for exemptions and accommodations to the contraceptive Mandate for certain objecting organizations. Section 2713(a)(4) of the PHS Act gives HRSA discretion to decide whether and in what circumstances it will support Guidelines providing for additional women's preventive services coverage. That authority includes HRSA's discretion to include contraceptive coverage in those Guidelines, but the Congress did not specify whether or to what extent HRSA should do so. Therefore, section 2713(a)(4) of the PHS Act allows HRSA to not apply the Guidelines to certain plans of entities or individuals with religious or moral objections to contraceptive coverage, and by not applying the Guidelines to them, to exempt those entities from the Mandate. These rules are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92).

Our protection of conscience in these interim final rules is consistent with the structure and intent of the Affordable Care Act. The Affordable Care Act refrains from applying section 2713(a)(4) of the PHS Act to millions of women in grandfathered plans. In contrast, we anticipate that conscientious exemptions to the Mandate will impact a much smaller number of women. President Obama emphasized in signing the Affordable Care Act that "longstanding Federal law to protect conscience"—laws with conscience protections encompassing moral (as well as religious) objections—specifically including (but not limited to) the Church Amendments (42 U.S.C. 300a-7), "remain intact." Executive Order 13535. Nothing in the Affordable Care Act suggests Congress' intent to deviate from its long history, discussed

below, of protecting moral convictions in particular health care contexts. The Departments' implementation of section 2713(a)(4) of the PHS Act with respect to contraceptive coverage is a context similar to those encompassed by many other health care conscience protections provided or supported by Congress. This Mandate concerns contraception and sterilization services, including items believed by some citizens to have an abortifacient effect—that is, to cause the destruction of a human life at an early stage of embryonic development. These are highly sensitive issues in the history of health care regulation and have long been shielded by conscience protections in the laws of the United States.

B. Congress' History of Providing Exemptions for Moral Convictions

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on nearly 50 years of statutory law and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health insurance coverage. Congress very recently expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808, Public Law 115-31 (May 5, 2017). In support of these interim final rules, we consider it significant that Congress' most recent statement on the prospect of Government mandated contraceptive coverage specifically intends that a conscience clause be included to protect moral convictions.

The many statutes listed in Section I-Background under footnote 1, which show Congress' consistent protection of moral convictions alongside religious beliefs in the Federal regulation of health care, includes laws such as the 1973 Church Amendments, which we discuss at length below, all the way to the 2017 Consolidated Appropriations Act discussed above. Notably among those laws, the Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w-

¹⁹ Available at: <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.

22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”). The Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions.” Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.

C. The Church Amendments’ Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations. These sections of the United States Code are known as the Church Amendments, named after their primary sponsor Senator Frank Church (D–Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions. Among other things, the amendments protect the recipients of certain Federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object “on the basis of religious beliefs or moral convictions,” and they prohibit recipients of certain Federal health funds from discriminating against any personnel “because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions” (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to “any lawful health service,” or to “any part of a health service program.” (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute “any lawful health service” or a “part of a health service program.” As such, the

protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court’s decision in *Roe v. Wade*, 410 U.S. 113 (1973). Even though the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens must facilitate its exercise. Thus, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared “Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.” 410 U.S. at 144 & n.38 (1973). Likewise in *Roe*’s companion case, *Doe v. Bolton*, the Court observed that, under State law, “a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.” 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions “obviously . . . afford appropriate protection.” *Id.* at 198. As an Arizona court later put it, “a woman’s right to an abortion or to contraception does not compel a private person or entity to facilitate either.” *Planned Parenthood Ariz., Inc. v. Am. Ass’n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains relevant discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe v. Wade* but also an instance where a Federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D–IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record is particularly relevant to this discussion:

MR. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.

One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or

participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.

As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?

Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words “or moral”?

MR. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words “or moral conviction” were added after “religious belief.” I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.

MR. STEVENSON. The Senator’s suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18.

As the debate proceeded, Senator Church went on to quote *Doe v. Bolton*’s reliance on a Georgia statute that stated “a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.” 119 Congr. Rec. at S5722 (quoting 410 U.S. at 197–98). Senator Church added, “I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations.” *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D–WI) asked whether, “if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, ‘We are not going to bother with this kind of procedure in this hospital,’ would the pending amendment permit that?” 119 Congr. Rec. at S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C–NY), speaking in support of the amendment, added the following perspective:

MR. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the

recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic]²⁰ to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words “moral conviction,” because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. at S5723.

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R-MA)²¹ likewise observed that “the right of conscience has long been recognized in the parallel situation in which the individual’s right to conscientious objector status in our selective service system has been protected” and “expanded by the Supreme Court to include moral conviction as well as formal religious belief.” 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, “We are concerned here only with the right of moral conscience, which has always been a part of our national tradition.” *Id.* at 4149.

These first of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions. And, as noted above, subsequent statutes add protections for

moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion: See 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31;
- Protections for entities and individuals that object to providing or covering contraceptives: See *id.* at Div. C, Title VIII, Sec. 808; *id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act); and *id.* at Div. I, Title III; and
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives: See 42 U.S.C. 290bb–36; 42 U.S.C. 14406; 42 U.S.C. 18113; and 42 U.S.C. 1396a(w)(3).

The Departments believe that the intent behind Congress’ protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports our decision in these interim final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

D. Court Precedents Relevant to These Expanded Exemptions

The legislative history of the protection of moral convictions in the first Church Amendments shows that Members of Congress saw the protection as being consistent with Supreme Court decisions. Not only did Senator Church cite the abortion case *Doe v. Bolton* as a parallel instance of conscience protection, but he also spoke of the Supreme Court generally giving “comparable treatment to deeply held moral convictions.” Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court’s protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh v. United States*, 398 U.S. 333 (1970), which the Supreme Court decided just 3 years earlier.

Welsh involved what is perhaps the Government’s paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on “religious training and belief,” that protection would also extend to avowedly non-religious objections to war held with the same moral strength. *Id.* at 343. The Court declared, “[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that

nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual ‘a place parallel to that filled by . . . God’ in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a ‘religious’ conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions.”

The Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in these interim final rules. Neither these interim final rules, nor the Church Amendments or other Federal health care conscience statutes, define “moral convictions” (nor do they define “religious beliefs”). But in issuing these interim final rules, we seek to use the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the “individual deeply and sincerely holds”; (2) “that are purely ethical or moral in source and content; (3) “but that nevertheless impose upon him a duty”; (4) and that “certainly occupy in the life of that individual a place parallel to that filled by . . . God’ in traditionally religious persons,” such that one could say “his beliefs function as a religion in his life.” (398 U.S. at 339–40). As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises “capriciously.” Instead, along with the requirement that protected moral convictions must be “sincerely held,” this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby*, Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan’s opinion in *Welsh*, 398 U.S. at 357–58, in support of her statement that “[s]eparating moral convictions from religious beliefs would be of questionable legitimacy.” 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious

²⁰ The Senator might have meant “[forced] . . . against his will.”

²¹ Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

beliefs constitute an illegitimate “separat[ion]” of moral convictions, nor do we assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress’ intent in the Church Amendments and in later Federal conscience statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

E. Conscience Protections in Regulations and Among the States

The tradition of protecting moral convictions in certain health contexts is not limited to Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.²² Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs when they have determined that it is appropriate to do so in particular circumstances. The Equal Employment Opportunity Commission has consistently protected “moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views” alongside religious views under the “standard [] developed in *United States v. Seeger*, 380 U.S. 163 (1965) and [*Welsh*].” (29 CFR 1605.1). The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so “is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such

participation or attendance contrary to medical ethics.” (28 CFR 26.5).²³

Forty-five States have health care conscience protections covering objections to abortion, and several of those also cover sterilization or contraception.²⁴ Most of those State laws protect objections based on “moral,” “ethical,” or “conscientious” grounds in addition to “religious” grounds. Particularly in the case of abortion, some Federal and State conscience laws do not require any specified motive for the objection. (42 U.S.C. 238n). These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts.

The contraceptive Mandate implicates that governmental interest. Many persons and entities object to this Mandate in part because they consider some forms of FDA-approved contraceptives to be abortifacients and morally equivalent to abortion due to the possibility that some of the items may have the effect of preventing the implantation of a human embryo after fertilization. Based on our knowledge from the litigation, all of the current litigants asserting purely non-religious objections share this view, and most of the religious litigants do as well. The Supreme Court, in describing family business owners with religious objections, explained that “[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions.” *Hobby Lobby*, 134 S. Ct. at 2751. Outside of the context of abortion, as cited above, Congress has also provided health care conscience protections pertaining to sterilization, contraception, and other health care services and practices.

F. Founding Principles

The Departments also look to guidance from the broader history of

respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. As quoted above, in supporting protecting conscience based on non-religious moral convictions, Senator Buckley declared “[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.” Rep. Heckler similarly stated that “the right of moral conscience . . . has always been a part of our national tradition.” This tradition is reflected, for example, in a letter President George Washington wrote saying that “[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of citizenship.”²⁵ Thomas Jefferson similarly declared that “[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority.”²⁶ Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience “the most sacred of all property,” and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that “the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed.”²⁷

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context. We do not suggest that the specific protections offered in this rule would also be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These interim final rules do not address in any way how the Government would balance its interests with respect to

²² See, for example, 42 CFR 422.206 (declaring that the general Medicare Advantage rule “does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds.”); 42 CFR 438.102 (declaring that information requirements do not apply “if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds”); 48 CFR 1609.7001 (“health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs.”); 48 CFR 352.270–9 (“Non-Discrimination for Conscience” clause for organizations receiving HIV or Malaria relief funds).

²³ See also 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA’s request will depend in part on “[c]ultural, religious, or moral objections to the request”).

²⁴ According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). “Refusing to Provide Health Services” (June 1, 2017), available at <https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services>.

²⁵ From George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790), available at <https://founders.archives.gov/documents/Washington/05-06-02-0135>.

²⁶ Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809), available at <https://founders.archives.gov/documents/Jefferson/99-01-02-9714>.

²⁷ James Madison, “Essay on Property” (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

other health services not encompassed by the contraceptive Mandate.²⁸ Instead we highlight this tradition of respect for conscience from our Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4) of the PHS Act, while protecting conscience in the exercise of moral convictions. We believe that these interim final rules are consistent both with the American tradition of respect for conscience and with Congress' history of providing conscience protections in the kinds of health care matters involved in this Mandate.

G. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in the expanded exemptions and accommodations of these rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for "religious" beliefs, but for "conscience." We interpret that term to include moral convictions and not just religious beliefs. Likewise, President Trump's first Executive Order, EO 13765, declared that "the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." This Mandate imposes both a cost, fee, tax, or penalty, and a regulatory burden, on individuals and purchasers of health insurance that have moral convictions opposed to providing contraceptive coverage. These interim final rules exercise the Departments' discretion to grant exemptions from the Mandate to reduce and relieve regulatory burdens and promote freedom in the health care market.

H. Litigation Concerning the Mandate

The sensitivity of certain health care matters makes it particularly important for the Government to tread carefully when engaging in regulation concerning those areas, and to respect individuals and organizations whose moral convictions are burdened by Government regulations. Providing conscience protections advances the Affordable Care Act's goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to cover procedures that the owners "could not in good conscience" cover, such as abortion, "HHS would effectively exclude these people from full participation in the economic life of the Nation." 134 S. Ct. at 2783. That would be a serious outcome. As demonstrated by litigation and public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that some of those items may cause early abortions. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) of the PHS Act in a way that respects the moral convictions of our citizens so that they are more free to engage in "full participation in the economic life of the Nation." These expanded exemptions do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. See *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court recently affirmed a district court ruling that allows the previous regulations to be imposed in a way that violates the moral convictions of a small nonprofit pro-life organization and its employees. See *Real Alternatives*, 2017 WL 3324690. Our litigation of these cases has led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The

organizations that have sued seeking a moral exemption have all adopted moral tenets opposed to contraception and hire only employees who share this view. It is reasonable to conclude that employees of these organizations would therefore not benefit from the Mandate. As a result, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, and our requirement to comply with permanent injunctive relief currently imposed in *March for Life*, provide substantial reasons for the Departments to protect moral convictions through these interim final rules. Even though, as discussed below, we assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, we know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, we consider it appropriate to issue the protections set forth in these interim final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so we, too, believe that "our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government" in this situation.

I. The Departments' Rebalancing of Government Interests

For additional discussion of the Government's balance of interests concerning religious beliefs issued contemporaneously with these interim final rules, see the related document published by the Department elsewhere in this issue of the **Federal Register**. There, we acknowledge that the Departments have changed the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlying it, and we assert that we now believe the Government's legitimate interests in providing for contraceptive coverage do not require us to violate sincerely held religious beliefs while implementing the Guidelines. For parallel reasons, the Departments believe Congress did not set forth—and we do not possess—interests that require us to violate sincerely held moral convictions in the course of generally requiring contraceptive coverage. These changes in policy are

²⁸ As the Supreme Court stated in *Hobby Lobby*, the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

within the Departments' authority. As the Supreme Court has acknowledged, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). This "reasoned analysis" requirement does not demand that an agency "demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." *United Student Aid Funds, Inc. v. King*, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)); see also *New Edge Network, Inc. v. FCC*, 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").²⁹

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. In addition to the apparent fact that many entities with non-religious moral objections to the Mandate appear to only hire persons that share those objections, Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 requirements on grandfathered plans benefitting millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including through various other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, and which these interim final rules leave unchanged.³⁰ As the

Government is under no constitutional obligation to fund contraception, *cf. Harris v. McRae*, 448 U.S. 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their moral convictions. *Cf. Rust v. Sullivan*, 500 U.S. 173, 192–93 (1991) ("A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.").

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. Our expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant Federal law, the Departments have determined that expanding the exemptions to include protections for moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to take advantage of these exemptions and accommodations may be small, we believe that it is important formally to codify such protections for objections based on moral conviction, given the long-standing recognition of such protections in health care and health insurance context in law and regulation and the particularly sensitive nature of these issues in the health care context. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including 3 previous interim final rules), public comments, and the long-running litigation from non-religious moral objectors to the Mandate, as well as the information contained in the companion interim final rules issued elsewhere in this issue of the **Federal Register**. These interim final rules seek to resolve these matters by directing HRSA, to the extent it requires coverage for certain contraceptive services in its Guidelines, to afford an exemption to certain entities and individuals with sincerely held moral convictions by which they object to contraceptive or sterilization coverage, and by making the accommodation process available for certain organizations with such convictions.

For all of the reasons discussed and referenced above, the Departments have determined that the Government's interest in applying contraceptive coverage requirements to the plans of certain entities and individuals does not outweigh the sincerely held moral objections of those entities and individuals. Thus, these interim final rules amend the regulations amended in both the Departments' July 2015 final regulations and in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

These interim final rules expand those exemptions to include additional entities and persons that object based on sincerely held moral convictions. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no objection specified in the regulations exists, and if section 2713 of the PHS Act otherwise applies. These interim final rules also maintain the existence of an accommodation process as a voluntary option for organizations with moral objections to contraceptive coverage, but consistent with our expansion of the exemption, we expand eligibility for the accommodation to include organizations with sincerely held moral convictions concerning contraceptive coverage. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.³¹

³¹ See <https://www.hrsa.gov/womensguidelines/> and <https://www.hrsa.gov/womensguidelines2016/index.html>.

²⁹ See also *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863–64 (1984) ("The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.")

³⁰ See, for example, Family Planning grants in 42 U.S.C. 300, *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal

1. Exemption for Objecting Entities Based on Moral Convictions

In the new 45 CFR 147.133 as created by these interim final rules, we expand the exemption that was previously located in § 147.131(a), and that was expanded in § 147.132 by the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

With respect to employers that sponsor group health plans, § 147.133(a)(1) and (a)(1)(i) provide exemptions for certain employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held moral convictions.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption in § 147.133(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with prior rules have worked by means of similar language. Section 147.133(a)(1) and (a)(1)(i), by specifying that "[a] group health plan and health insurance coverage provided in connection with a group health plan" is exempt "to the extent the plan sponsor objects as specified in paragraph (a)(2)," exempt the group health plans the sponsors of which object, and exempt their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan

document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.³² Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures should reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.133(a) apply "to the extent" of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.133(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsors have no qualifying objection. The objection of a health insurance issuer in § 147.133(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

2. Exemption of Certain Plan Sponsors

The rules cover certain kinds of non-governmental employer plan sponsors with the requisite objections, and the rules specify which kinds of entities qualify for the exemption.

Under these interim final rules, the Departments do not limit the exemption

with reference to nonprofit status as previous rules have done. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities without regard to whether they operate as nonprofits or for-profit entities. In addition, a significant majority of states either impose no contraceptive coverage requirement, or offer broader exemptions than the exemption contained in the July 2015 final regulations.³³ States also generally protect moral convictions in health care conscience laws, and they often offer those protections whether or not an entity operates as a nonprofit.³⁴ Although the practice of states is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor is it a statement about what the Federal Government may do consistent with other protections or limitations in federal law, such state practice can be informative as to the viability of offering protections for conscientious objections in particularly sensitive health care contexts. In this case, the existence of many instances where conscience protections are offered, or no underlying mandate of this kind exists that could violate moral convictions, supports the Departments' decision to expand the Federal exemption concerning this Mandate as set forth in these interim final rules.

Section 147.133(a)(1)(i)(A) of the rules specifies that the exemption includes the plans of a plan sponsor that is a nonprofit organization with sincerely held moral convictions.

Section 147.133(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of a plan sponsor that is a for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

Extending the exemption to certain for-profit entities is consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the

³² See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. See also 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group & individual issuers).

³³ See Guttmacher Institute, "Insurance Coverage of Contraceptives" (Aug. 1, 2017), available at <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

³⁴ See, for example, Guttmacher Institute, "Refusing to Provide Health Services" (Aug. 1, 2017), available at <https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services>.

Departments' argument to the contrary. 134 S. Ct. 2768–75. Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.³⁵ The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held moral convictions, is a matter of well-established State law with respect to corporate decision-making,³⁶ and the Departments expect that application of such laws would cabin the scope of this exemption.

The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. Any such positive definition runs up against the myriad state differences in defining such entities, and potentially intrudes into a traditional area of state regulation of business organizations. The Departments implicitly recognized the difficulty of defining closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely “substantially similar” to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. Instead of attempting to positively define closely held businesses for the purpose of this rule, the Departments consider it much more clear, effective, and preferable to define the category negatively by reference to one element of our previous definition, namely, that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

In this way, these interim final rules differ from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in § 147.132(a)(1)—those extend to for-profit entities whether or not they are closely held or publicly traded. The Departments seek public comment on

whether the exemption in § 147.133(a)(1)(i) for plan sponsors with moral objections to the Mandate should be finalized to encompass all of the types of plan sponsors covered by § 147.132(a)(1)(i), including publicly traded corporations with objections based on sincerely held moral convictions, and also non-federal governmental plan sponsors that may have objections based on sincerely held moral convictions.

In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without precluding publicly traded and governmental entities from using those protections. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. The Coats-Snowe Amendment likewise provides certain protections for health care entities and postgraduate physician training programs that choose not to perform, refer for, or provide training for abortions, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 238n).

The Weldon Amendment³⁷ provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions, and the statute does not limit those protections based on whether the entity is publicly traded or governmental. The Affordable Care Act provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service

furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing, and the statute similarly does not limit those protections based on whether the entity is publicly traded or governmental. (42 U.S.C. 18113).³⁸

Sections 1395w–22(j)(3)(B) and 1396u–2(b)(3) of 42 U.S.C. protect organizations that offer Medicaid and Medicare Advantage managed care plans from being required to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds, and those paragraphs do not further specify that publicly traded entities do not qualify for the protections. Congress' most recent statement on Government requirements of contraceptive coverage specified that, if the District of Columbia requires “the provision of contraceptive coverage by health insurance plans,” “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.” Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808. Congress expressed no intent that such a conscience should be limited based on whether the entity is publicly traded.

At the same time, the Departments lack significant information about the need to extend the expanded exemption further. We have been subjected to litigation by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, and we have been sued by closely held for-profit entities expressing religious objections. This combination of different types of plaintiffs leads us to believe that there may be a small number of closely held for-profit entities that would seek to use an exemption to the contraceptive Mandate based on moral convictions. The fact that many closely held for-profit entities brought challenges to the Mandate has led us to offer protections that would include publicly traded entities with religious objections to the Mandate if such entities exist. But the combined lack of any lawsuits challenging the Mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity, leads us to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so in

³⁵ See Jennifer Haberkorn, “Two years later, few Hobby Lobby copycats emerge,” *Politico* (Oct. 11, 2016), available at <http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627>.

³⁶ Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

³⁷ Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. 115–31.

³⁸ The lack of the limitation in this provision may be particularly relevant since it is contained in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—are promulgated.

a way parallel to the protections set forth in § 147.132(a)(1)(i). We agree with the Supreme Court that it is improbable that many publicly traded companies with numerous “unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs” (or moral convictions) and thereby qualify for the exemption. *Hobby Lobby*, 134 S. Ct. at 2774. We are also not aware of other types of plan sponsors (such as non-Federal governmental entities) that might possess moral objections to compliance with the Mandate, including whether some might consider certain contraceptive methods as having a possible abortifacient effect. Nevertheless, we would welcome any comments on whether such corporations or other plan sponsors exist and would benefit from such an exemption.

Despite our a lack of complete information, the Departments know that nonprofit entities have challenged the Mandate, and we assume that a closely held business might wish to assert non-religious moral convictions in objecting to the Mandate (although we anticipate very few if any will do so). Thus we have chosen in these interim final rules to include them in the expanded exemption and thereby remove an obstacle preventing such entities from claiming an exemption based on non-religious moral convictions. But we are less certain that we need to use these interim final rules to extend the expanded exemption for moral convictions to encompass other kinds of plan sponsors not included in the protections of these interim final rules. Therefore, with respect to plan sponsors not included in the expanded exemptions of § 147.133(a)(1)(i), and non-federal governmental plan sponsors that might have moral objections to the Mandate, we invite public comment on whether to include such entities when we finalize these rules at a later date.

The Departments further conclude that it would be inadequate to merely provide entities access to the accommodation process instead of to the exemption where those entities object to the Mandate based on sincerely held moral convictions. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way “seamless” to those plans. As a result, in significant respects, the

accommodation process does not actually accommodate the objections of many entities. This has led many religious groups to challenge the accommodation in court, and we expect similar challenges would come from organizations objecting to the accommodation based on moral convictions if we offered them the accommodation but not an exemption. When we took that narrow approach with religious nonprofit entities it led to multiple cases in many courts that we needed to litigate to the Supreme Court various times. Although objections to the accommodation were not specifically litigated in the two cases brought by nonprofit non-religious organizations (because we have not even made them eligible for the accommodation), those organizations made it clear that they and their employees strongly oppose coverage of certain contraceptives in their plans and in connection with their plans.

3. Exemption for Institutions of Higher Education

The plans of institutions of higher education that arrange student health insurance coverage will be treated similarly to the way that plans of employers are treated for the purposes of such plans being exempt or accommodated based on moral convictions. These interim final rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

The Departments are not aware of institutions of higher education that arrange student coverage and object to the Mandate based on non-religious moral convictions. We have been sued by several institutions of higher education that arrange student coverage and object to the Mandate based on religious beliefs. We believe the existence of such entities with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible so that we should provide protections for them in these interim final rules. But based on a lack of information about such entities, we assume that none will use the exemption concerning student coverage at this time.

4. Exemption for Issuers

These interim final rules extend the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection (whether the objection is based on moral convictions, as set forth in these rules, or on religious beliefs, as set forth in exemptions created by the companion interim final rules published elsewhere in this issue of the **Federal Register**). Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt.

Under the rules as amended, issuers with objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions, and issuers with sincerely held religious beliefs could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Issuers that hold moral objections should identify to plan sponsors the

lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Protecting issuers that object to offering contraceptive coverage based on sincerely held moral convictions will help preserve space in the health insurance market for certain issuers so that exempt plan sponsors and individuals will be able to obtain coverage.

The Departments are not currently aware of health insurance issuers that possess their own religious or moral objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations from being required to provide coverage or pay for abortions. *See, for example*, Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31. The most recently enacted Consolidated Appropriations Act declares that Congress supports a “conscience clause” to protect moral convictions concerning “the provision of contraceptive coverage by health insurance plans.” *See id.* at Div. C, Title VIII, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published

elsewhere in this issue of the **Federal Register**. The Departments solicit public comment; however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have moral convictions implicated by the Mandate.³⁹

5. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.133(a)(2). That section specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.133(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) for coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held moral convictions.

6. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the “individual exemption”). Section 147.133(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan and/or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held moral convictions. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

³⁹ The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for business entities. Because the issuer exemption operates more narrowly than the exemption for business plan sponsors operates, in the ways described here, and exists in part to help preserve market options for objecting plan sponsors, the Departments consider it appropriate to not draw such a distinction among issuers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' moral convictions, or against the individual employees who accept such offers. *See Wieland*, 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the sincerely held moral objections of individual employees by offering them plans that omit contraception, even if those governmental entities do not object to offering contraceptive coverage in general.

This “individual exemption” cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held moral convictions.⁴⁰ At the same

⁴⁰ This prospect has been raised in cases of religious individuals—see, for example, *Wieland*, Continued

time, this individual exemption “does not undermine the governmental interests furthered by the contraceptive coverage requirement,”⁴¹ because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered. In addition, because the individual exemption only operates when the employer and/or issuer, as applicable, are willing, the exemption will not undermine any governmental interest in the workability of the insurance market, because we expect that any workability concerns will be taken into account in the decision of whether to be willing to offer the individual morally acceptable coverage.

For similar reasons, we have changed our position and now believe the individual exemption will not undermine any Government interest in uniformity in the health insurance market. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. The Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments’ previous exemption for houses of worship and integrated auxiliaries, and our accommodation of self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.⁴²

With respect to operationalizing this provision of these rules, as well as the similar provision protecting individuals with religious objections to purchasing insurance that covers some or all contraceptives, in the interim final rules published elsewhere in this issue of the **Federal Register**, the Departments note that a plan sponsor or health insurance issuer is not required to offer separate and different benefit package options, or separate and different forms of policy, certificate, or contract of insurance with respect to those individuals who object

on moral bases from those who object on religious bases. That is, a willing employer or issuer may offer the same benefit package option or policy, certificate, or contract of insurance—which excludes the same scope of some or all contraceptive coverage—to individuals who are exempt from the Mandate because of their moral convictions (under these rules) or their religious beliefs (under the regulations as amended by the interim final rules pertaining to religious beliefs).

7. Optional Accommodation

In addition to expanding the exemption to those with sincerely held moral convictions, these rules also expand eligibility for the optional accommodation process to include employers with objections based on sincerely held moral convictions. This is accomplished by inserting references to the newly added exemption for moral convictions, 45 CFR 147.133, into the regulatory sections where the accommodation process is codified, 45 CFR 147.131, 26 CFR 54.9815–2713AT, and 29 CFR 2590.715–2713A. In all other respects the accommodation process works the same as it does for entities with objections based on sincerely held religious beliefs, as described in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

The Departments are not aware of entities with objections to the Mandate based on sincerely held moral convictions that wish to make use of the optional accommodation, and our present assumption is that no such entities will seek to use the accommodation rather than the exemption. But if such entities do wish to use the accommodation, making it available to them will both provide contraceptive coverage to their plan participants and respect those entities’ objections. Because entities with objections to the Mandate based on sincerely held non-religious moral convictions have not previously had access to the accommodation, they would not be in a position to revoke their use of the accommodation at the time these interim final rules are issued, but could do so in the future under the same parameters set forth in the accommodation regulations.

8. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules insert references to 45 CFR 147.133 into the restatements of the requirements of

section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713T(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv).

9. Conclusion

The Departments believe that the Guidelines, and the expanded exemptions and accommodations set forth in these interim final rules, will advance the legitimate but limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress’ well-established record of allowing for moral exemptions with respect to various health care matters. These interim final rules maintain HRSA’s discretion to decide whether to continue to require contraceptive coverage under the Guidelines if no regulatorily recognized exemption exists (and in plans where Congress applied section 2713 of the PHS Act). As cited above, these interim final rules also leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. The Departments believe this array of programs and requirements better serves the interests of providing contraceptive coverage while protecting the moral convictions of entities and individuals concerning coverage of some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

IV. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; and 79 FR 51092).

Section 553(b) of the APA requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior

196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130—where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to “forgo health insurance altogether.”

⁴¹ 78 FR 39874.

⁴² See also *Real Alternatives*, 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) (“Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government’s interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.” (citation and internal quotation marks omitted)).

to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to so continue to update the Guidelines.

Two lawsuits have been pending for several years by entities raising non-religious moral objections to the Mandate.⁴³ In one of those cases, the Departments are subject to a permanent injunction and the appeal of that case has been stayed since February 2016. In the other case, Federal district and appeals courts ruled in favor of the Departments, denying injunctive relief to the plaintiffs, and that case is also still pending. Based on the public comments the Departments have received, we have reason to believe that some similar nonprofit entities might exist, even if it is likely a small number.⁴⁴

For entities and individuals facing a burden on their sincerely held moral convictions, providing them relief from Government regulations that impose such a burden is an important and urgent matter, and delay in doing so injures those entities in ways that cannot be repaired retroactively. The burdens of the existing rules undermine these entities' and individuals' participation in the health care market because they provide them with a

serious disincentive—indeed a crisis of conscience—between participating in or providing quality and affordable health insurance coverage and being forced to violate their sincerely held moral convictions. The existence of inconsistent court rulings in multiple proceedings has also caused confusion and uncertainty that has extended for several years, with different federal courts taking different positions on whether entities with moral objections are entitled to relief from the Mandate. Delaying the availability of the expanded exemption would require entities to bear these burdens for many more months. Continuing to apply the Mandate's regulatory burden on individuals and organizations with moral convictions objecting to compliance with the Mandate also serves as a deterrent for citizens who might consider forming new entities consistent with their moral convictions and offering health insurance through those entities.

Moreover, we separately expanded exemptions to protect religious beliefs in the companion interim final rules issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. Because Congress has provided many statutes that protect religious beliefs and moral convictions similarly in certain health care contexts, it is important not to delay the expansion of exemptions for moral convictions set forth in these rules, since the companion rules provide protections for religious beliefs on an interim final basis. Otherwise, our regulations would simultaneously provide and deny relief to entities and individuals that are, in the Departments' view, similarly deserving of exemptions and accommodations consistent with similar protections in other federal laws. This could cause similarly situated entities and individuals to be burdened unequally.

In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and to what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. As noted above, the public comments in response to both the RFI and various prior rulemaking proceedings included specific requests

that the exemptions be expanded to include those who oppose the Mandate for either religious or “moral” reasons.⁴⁵ In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

As the U.S. Court of Appeals for the D.C. Circuit stated with respect to an earlier IFR promulgated with respect to this issue in *Priests for Life v. U.S. Department of Health and Human Services*, 772 F.3d 229, 276 (D.C. Cir. 2014), *vacated on other grounds*, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), “[S]everal reasons support HHS’s decision not to engage in notice and comment here.” Among other things, the Court noted that “the agency made a good cause finding in the rule it issued”; that “the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues”; that “HHS will expose its interim rule to notice and comment before its permanent implementation”; and that not proceeding under interim final rules would “delay the implementation of the alternative opt-out for religious objectors.” *Id.* at 277. Similarly, not proceeding with exemptions and accommodations for moral objectors here would delay the implementation of those alternative opt-outs for moral objectors.

Delaying the availability of the expanded exemption could also increase the costs of health insurance for some entities. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover

⁴³ *March for Life*, 128 F. Supp. 3d 116; *Real Alternatives*, 867 F.3d 338.

⁴⁴ See, for example, *Americans United for Life (“AUL”) Comment on CMA-9992-IFC2* at 10 (Nov. 1, 2011), available at <http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496>, and *AUL Comment on CMS-9968-P* at 5 (Apr. 8, 2013), available at <http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115>.

⁴⁵ See, for example, <http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496>, <http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115>, <https://www.regulations.gov/document?D=CMS-2016-0123-54142>, <https://www.regulations.gov/document?D=CMS-2016-0123-54218>, and <https://www.regulations.gov/document?D=CMS-2016-0123-46220>.

contraception. As such, they may wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. To the extent that entities with objections to the Mandate based on moral convictions but not religious beliefs fall into this category, they may be refraining from making those changes—and therefore may be continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. We are not aware of the extent to which such entities exist, but 17 percent of all covered workers are in grandfathered health plans, encompassing tens of millions of people.⁴⁶ Issuing these rules on an interim final basis reduces the costs of health insurance and regulatory burdens for such entities and their plan participants.

These interim final rules also expand access to the optional accommodation process for certain entities with objections to the Mandate based on moral convictions. If entities exist that wish to use that process, the Departments believe they should be able to do so without the delay that would be involved by not offering them the optional accommodation process by use of interim final rules. Proceeding otherwise could delay the provision of contraceptive coverage to those entities' employees.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final rules effective immediately upon filing for public inspection at the Office of the Federal Register.

V. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the

Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under

Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations and do so in conjunction with the amendments made in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. These interim final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process to make entities with such convictions eligible to use it. The expanded exemption would apply to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to providing coverage for some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action is taken, among other reasons, to provide for conscientious participation in the health insurance market free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to resolve lawsuits that have been filed against the Departments by some such entities, and to avoid similar legal challenges.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these interim final rules, they believe it to be small.

With respect to the expanded exemption for nonprofit organizations, as noted above the Departments are aware of two small nonprofit

⁴⁶ Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2017 Annual Survey,” available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the coverage.⁴⁷ Based on comments submitted in response to prior rulemakings on this subject, we believe that at least one other similar entity exists. However, we do not know how many similar entities exist. Lacking other information we assume that the number is small. Without data to estimate the number of such entities, we believe it to be less than 10, and assume the exemption will be used by nine nonprofit entities.

We also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with our conclusion in previous rules that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (See 76 FR 46625 and 78 FR 39889). We reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception, and without even requiring that such entities actually oppose contraception in order to be exempt (in contrast, the expanded exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to the coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, we relied on our assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is supported with respect to the expanded exemption for nonprofit organizations. To our knowledge, the vast majority of organizations objecting to the Mandate assert religious beliefs. The only nonprofit organizations of which we are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It

is possible that the exemption for nonprofit organizations with moral convictions in these interim final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under our previous rules that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.⁴⁸ Although we are unable to find sufficient data on this issue, we believe that there are far fewer non-religious moral nonprofit organizations opposed to contraceptive coverage than there are churches with religious objections to such coverage. Based on our limited data, we believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose the coverage. Therefore, we expect that the expanded exemption for nonprofit entities will have no effect of reducing contraceptive coverage to employees who want that coverage.

These interim final rules expand the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and they make exempt entities with moral objections eligible to use the accommodation. The Departments are not aware of either kind of entity. We believe the number of entities that object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education, and appear to hold objections that we assume would likely lead them to reject the accommodation process. Therefore, for the purposes of estimating the anticipated effect of these interim final rules on contraceptive coverage of women who wish to receive such coverage, we assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might

come into existence, based on similar reasons to those given above for why the exemptions and accommodations are extended to other entities. We invite public comment on whether and how many such entities will make use of these interim final rules.

The expanded exemption for issuers will not result in a distinct effect on contraceptive coverage for women who wish to receive it because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein. The expanded exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The expanded moral exemption would also cover for-profit entities that do not have publicly traded ownership interests, and that have non-religious moral objections to the Mandate. The Departments are not aware of any for-profit entities that possess non-religious moral objections to the Mandate. However, scores of for-profit entities have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—both were nonprofit. Among the general public polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.⁴⁹ Among non-religious persons, only a very small percentage appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.⁵⁰ Combined, this suggests that 0.2 percent of Americans at most⁵¹ might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. We have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral

⁴⁹ Gallup, "Most Americans Still Believe in God" (June 14–23, 2016), available at <http://www.gallup.com/poll/193271/americans-believe-god.aspx>.

⁵⁰ Pew Research Center, "Where the Public Stands on Religious Liberty vs. Nondiscrimination" at page 26 (Sept. 28, 2016), available at <http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf>.

⁵¹ The study defined religiously "unaffiliated" as agnostic, atheist or "nothing in particular" (*id.* at 8), as distinct from several versions of Protestants, or Catholics. "Nothing in particular" might have included some theists.

⁴⁷ Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

⁴⁸ *Cf.*, for example, Gallup, "Americans, Including Catholics, Say Birth Control Is Morally OK," (May 22, 2012) ("Eighty-two percent of U.S. Catholics say birth control is morally acceptable"), available at <http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx>.

convictions set forth in these interim final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, we assume that some similar for-profit entities with non-religious moral objections exist. But we expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities that do not have publicly traded ownership interests and that have objections to the Mandate based on sincerely held moral convictions, we expect that fewer than 10 entities, if any, will do so—we assume nine for-profit entities will use the exemption in these interim final rules.

The expanded exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS-IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.⁵² The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known what size the for-profit employers will be that might claim this exemption, but as discussed above these interim final rules do not include publicly traded companies (and we invite public comments on whether to do so in the final rules), and both of the two nonprofit entities that challenged the Mandate included fewer than five policyholders in each entity. Therefore we assume the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For nine entities, the total number of policyholders would be 81. DOL estimates that for each policyholder, there is approximately one dependent.⁵³ This amounts to 162

covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—comprise 20.2 percent of the general population.⁵⁴ This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.⁵⁵ Thus we estimate that 15 women may incur contraceptive costs due to for-profit entities using the expanded exemption provided in these interim final rules.⁵⁶ In the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, within health plans that cover contraception, is \$584. Consequently, we estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded exemption in these interim final rules is approximately \$8,760.

The Departments estimate that these interim final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will use the accommodation, although we wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to

its plan participants and beneficiaries. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, we do not anticipate that these interim final rules will result in any burden from such entities revoking their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the rules expanded exemptions. The Departments acknowledge uncertainty in the estimate and therefore conducted a second analysis using an alternative framework, which is set forth in the companion interim final rule concerning religious beliefs issued contemporaneously with this interim final rule and published elsewhere in this issue of the **Federal Register**. Under either estimate, this interim final rule is not economically significant.

We reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

We request comment on all aspects of the preceding regulatory impact analysis.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments estimate that the likely effect of these interim final rules will be that entities will use the exemption and not the accommodation. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public

⁵⁴ U.S. Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at <https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf>. The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." <https://www.hrsa.gov/womensguidelines/>; see also 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁵⁵ See <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁵⁶ We note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion—and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

⁵² "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf> Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance

⁵³ "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to some or all contraceptives and/or sterilization, the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act— Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We estimate that these interim final rules will not result in additional burdens not accounted for as set forth in the companion interim final rules concerning religious beliefs issued

contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. As discussed there, regulations covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burdens related to those ICRs are currently approved under OMB Control Numbers 0938–1248 and 0938–1292. These interim final rules amend the accommodation regulations to make entities with moral objections to the Mandate eligible to use the same accommodation processes. The Departments will update the forms and model notices regarding these processes to reflect that entities with sincerely held moral convictions are eligible organizations.

As discussed above, however, we assume that no entities with non-religious moral objections to the Mandate will use the accommodation, and we know that no such entities were eligible for it until now, so that they do not possess accommodated status to revoke. Therefore we believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1248 and 0938–1292, as described in the interim final rules concerning religious beliefs issued contemporaneously with these interim final rules.

We are soliciting comments on all of the possible information collection requirements contained in these interim final rules, including those discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, for which these interim final rules provide eligibility to entities with objections based on moral convictions. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938–1292 and 0938–1248.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of these interim final rules with comment period.

E. Paperwork Reduction Act— Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these interim final rules make entities with certain moral convictions eligible for the accommodation, we assume that no entities will use it rather than the exemption, and such entities were not previously eligible for the accommodation so as to revoke it. Therefore we believe these interim final rules do not involve additional burden not accounted for under OMB control number 1210–0150.

Regarding the ICRs discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, the forms for which would be used if any entities with moral objections used the accommodation process in the future, DOL submitted those ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. OMB approved the ICRs under the emergency clearance process. In an effort to consolidate the number of information collection requests, DOL indicated it will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once

the ICR is approved, DOL indicated it will discontinue 1210–0152. OMB approved the ICR under control number 1210–0150 through [DATE]. A copy of the information collection request may be obtained free of charge on the *RegInfo.gov* Web site at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001. This approval allows respondents temporarily to utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden. Contemporaneously with the publication of these interim final rules, DOL will publish a notice in the **Federal Register** informing the public of its intention to extend the OMB approval.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, “[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” In addition, agencies are directed to “take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.” These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting costs.⁵⁷ Therefore, this interim final rule

is considered an EO 13771 deregulatory action.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the

including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB’s guidance on E.O. 13771 implementation (<https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation>) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule’s medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

concerns of state and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VI. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

⁵⁷ Other noteworthy potential impacts encompass potential changes in medical expenditures,

requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713T [Amended]

■ 2. Section 54.9815–2713T, as added elsewhere in this issue of the **Federal Register**, is amended in paragraph (a)(1)(iv) by removing the reference “147.131 and 147.132” and adding in its place the reference “147.131, 147.132, and 147.133”.

§ 54.9815–2713AT [Amended]

■ 3. Section 54.9815–2713AT, as added elsewhere in this issue of the **Federal Register**, is amended—

■ a. In paragraph (a)(1) by removing “or (ii)” and adding in its place “or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)”;

■ b. In paragraph (a)(2) by removing the reference “147.132(a)” and adding in its place the reference “147.132(a) or 147.133(a)”;

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ d. In paragraph (b)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ f. In paragraph (c)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”; and

■ g. In paragraph (c)(2) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

§ 2590.715–2713 [Amended]

■ 4. Section 2590.715–2713, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraph (a)(1)(iv) by removing the reference “147.131 and 147.132” and adding in its place the reference “147.131, 147.132, and 147.133”.

§ 2590.715–2713A [Amended]

■ 5. Section 2590.715–2713A, as revised elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (a)(1) by removing “(ii)” and adding in its place “(ii), or 45 CFR 147.133(a)(1)(i) or (ii)”;

■ b. In paragraph (a)(2) by removing the reference “147.132(a)” and adding in its place the reference “147.132(a) or 147.133(a)”;

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ d. In paragraph (b)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ f. In paragraph (c)(1)(ii)(B) by removing the reference “147.132” and

adding in its place the reference “147.132 or 147.133”; and

■ g. In paragraph (c)(2) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 6. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

§ 147.130 [Amended]

■ 7. Section 147.130, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraphs (a)(1) introductory text and (a)(1)(iv) by removing the reference “§§ 147.131 and 147.132” and adding in its place the reference “§§ 147.131, 147.132, and 147.133”.

§ 147.131 [Amended]

■ 8. Section 147.131, as revised elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (c)(1) by removing the reference “(ii)” and adding in its place the reference “(ii), or 45 CFR 147.133(a)(1)(i) or (ii)”.

■ b. In paragraph (c)(2) by removing the reference “§ 147.132(a)” and adding in its place the reference “§ 147.132(a) or 147.133”;

■ c. In paragraphs (d)(1)(ii) introductory text, (d)(1)(ii)(B) and (d)(2) by removing the reference “§ 147.132” and to adding in its place the reference “§ 147.132 or 147.133”.

■ 9. Add § 147.133 to read as follows:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus

the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage

to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be

construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21852 Filed 10–6–17; 11:15 am]

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STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

DIVISION OF SOCIAL JUSTICE
HEALTH CARE BUREAU

December 5, 2017

Via Federal eRulemaking Portal

Acting Secretary Eric Hargan
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW., Room 445-G
Washington, DC 20201

Re: Comments on Interim Final Rules: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act, and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act
45 C.F.R §§ 147.130-147.133

Dear Acting Secretary Hargan:

The undersigned State Attorneys General submit these comments in response to the Departments of Health and Human Services, Labor, and Treasury's (the "Departments") issuance of the proposed interim final rules ("IFRs"): the Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (filed Oct. 6, 2017), and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (filed Oct. 6, 2017). By creating broad new exemptions from the Affordable Care Act's contraceptive mandate, thereby allowing employers to deprive women of contraceptive health coverage, the IFRs will harm women and children, and the public health in general, and result in significant financial and administrative burdens to the States. As discussed more fully below, the IFRs violate the Administrative Procedure Act, the equal protection guarantee of the Fifth Amendment, and the Establishment Clause of the First Amendment, and as such, the undersigned Attorneys General urge that the IFRs be rescinded.¹

¹ State Attorneys General have also filed lawsuits challenging the IFRs. See States' Notice Mot. & Mot. Prelim. Inj., with Mem. P. & A., § I.A.–E., at 11–27, *California v. Eric D. Hargan*, No. 4:17-cv-05783-HSG (N.D. Cal. filed Nov. 9, 2017) ("CA Br.") (attached as Exhibit 1); Mem. Law Support Pls.' Mot. Prelim. Inj., § I.A., C.–D., at 18–

Eric Hargan, Acting Secretary
December 5, 2017
Page 2 of 9

I. Background

Before implementation of the Affordable Care Act (“ACA”), one in seven women with private health insurance, and nearly one-third of women covered by Medicaid, either postponed or went without needed health care because they could not afford it.² With respect to birth control in particular, women were forced to spend between 30 percent and 44 percent of their total out-of-pocket health costs.³ These out-of-pocket costs prevented many women, not solely those with lower incomes, from accessing preventive services, including contraception.⁴

During this period before the ACA’s passage, an estimated 49 percent of all pregnancies in the United States were unintended, and 42 percent of those unintended pregnancies ended in abortion.⁵ Unintended pregnancies are associated with increases in maternal and child morbidity, including increased odds of preterm birth, low birth weight, and the potentially life-long negative health effects of premature birth.⁶ Significantly, the risk of unintended pregnancy is greatest for the most vulnerable women: young, low-income, minority women, without high school or college education.⁷

Within this public health landscape, Congress passed the “Women’s Health Amendment” (“WHA”) to expand women’s access to preventive health services through health plan coverage and no cost-sharing responsibilities.⁸ The Department of Health and Human Services (“HHS”) commissioned the Institute of Medicine (“IOM”) to issue recommendations identifying the

22, 32–38, *Pennsylvania v. Donald J. Trump*, No. 2:17-cv-04540-WB (E.D. Pa. filed Oct. 11, 2017) (“PA Br.”) (attached as Exhibit 2); *Complt. Declaratory & Injunctive Relief, Massachusetts v. U.S. Dept. of Health & Human Servs.*, No. 17-cv-11930-NMG (D. Mass. filed Oct. 6, 2017); *Complt. Declaratory & Injunctive Relief, Washington v. Trump*, No. 2:17-cv-01510-RBL (W.D. Wa. filed Oct. 9, 2017). State Attorneys General have also submitted amicus briefs in support of plaintiffs in two lawsuits. *See, e.g.*, Br. for Mass. & Cal. et al. as Amici Curiae in Support of Pls.’ Mot. Prelim. Inj., § II, at 18–30, *Pennsylvania v. Donald J. Trump*, No. 2:17-cv-04540-WB (E.D. Pa. filed Oct. 11, 2017) (“Amici Br.”) (attached as Exhibit 3).

² Usha Ranji & Alina Salganicoff, *Women’s Health Care Chartbook: Key Findings from the Kaiser Women’s Health Survey*, HENRY J. KAISER FAMILY FOUND. 1, 4 (2011), <http://www.kaiserfamilyfoundation.files.wordpress.com/2013/01/8164.pdf>.

³ Laurie Sobel et al., *The Future of Contraceptive Coverage*, HENRY J. KAISER FAMILY FOUND. 1, 4 (2017), <http://www.files.kff.org/attachment/Issue-Brief-The-Future-of-Contraceptive-Coverage>.

⁴ Su-Ying Liang et al., *Women’s Out-of-Pocket Expenditures and Dispensing Patterns for Oral Contraceptive Pills between 1996 and 2006*, 83 *CONTRACEPTION* 491, 531 (2010); *see also* COMM. ON PREVENTIVE SERVS. FOR WOMEN & BD. ON POPULATION HEALTH & PUB. HEALTH PRACTICE, INST. OF MED. OF THE NAT’L ACADS., *CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS* 19 (Nat’l Acad. Press, 2011), *available at* <https://www.nap.edu/read/13181/chapter/1> (“IOM Report”). Another study of approximately 11,000 employees with employer-sponsored coverage found that cost-sharing reduced use of pap smears, preventive counseling, and mammography. Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 *HEALTH SERVS. RESEARCH* 1331, 1342–43 (2000), *available at* <http://www.pubmedcentralcanada.ca/pmc/articles/PMC1089084/pdf/hsresearch00023-0075.pdf>; *see also* David Machledt & Jane Perkins, *Medicaid Premiums & Cost-Sharing*, NAT’L HEALTH LAW PROGRAM 2-3 (2014), <http://www.healthlaw.org/component/jsfsubmit/showAttachment?tmpl=raw&id=00Pd000000ANrCpEAL>.

⁵ IOM Report at 102.

⁶ *Id.* at 103.

⁷ *Id.*

⁸ *See* S. Amdt. 2791, 111th Congress (2009–2010); Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010); Public Health Service Act (as amended by ACA) § 2713, 42 U.S.C. § 300gg-13(a)(4).

Eric Hargan, Acting Secretary
December 5, 2017
Page 3 of 9

specific preventive women's health services that should be covered under the ACA. In 2011, the IOM recommended, and the Health Resources and Services Administration ("HRSA") adopted, a list that includes all FDA-approved contraceptives, sterilization procedures, and reproductive education and counseling.⁹ In 2016, the Women's Preventive Services Initiative,¹⁰ led by the American Congress of Obstetricians and Gynecologists ("ACOG"), updated the preventive services guidelines and continued to include coverage of all FDA-approved contraceptive methods, reiterating their importance to women.

The IOM, ACOG, and other experts based their decisions to include coverage of contraception on the considerable evidence that the use of contraception has contributed to lower unintended pregnancy and abortion rates in the United States.¹¹ With the decrease in unintended pregnancies, there has been a corresponding decrease in the risk of maternal mortality, adverse child outcomes, behavior problems in children, and negative psychological outcomes associated with unintended pregnancies for both mothers and children.¹² Contraceptive use contributes to longer spacing between pregnancies, which decreases the risk of adverse health outcomes for pregnancies that are too closely spaced, and is especially critical for the health of women with certain medical conditions.¹³

Significantly, access to contraceptive coverage has given women the option to delay childbearing and pursue additional education, spend additional time in their careers, and increase earning power over the long-term. One-third of the wage gains women have made since the 1960s have been attributed to access to oral contraceptives.¹⁴ Access to birth control has helped narrow the wage gap between women and men. The decrease in the wage gap among 25 to 49-year-olds between men's and women's annual incomes would have been 10 percent smaller in the 1980s and 30 percent smaller in the 1990s in the absence of widespread legal birth control access for women.¹⁵

⁹ *Women's Preventive Services Guidelines: Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being*, HEALTH RESOURCES & SERVS. ADMIN., <http://www.hrsa.gov/womens-guidelines/index.html> (last reviewed Oct. 2017).

¹⁰ The Women's Preventive Services Initiative also included the American Academy of Family Physicians, the American College of Physicians, and the National Association of Nurse Practitioners in Women's Health.

¹¹ IOM Report at 104–05.

¹² See IOM Report 103–04.

¹³ IOM Report at 103–04. There are additional benefits of contraceptive use for treating medical conditions, including menstrual disorders and pelvic pain, and long-term use of oral contraceptives has been shown to reduce women's risk of endometrial cancer, pelvic inflammatory disease, and some benign breast diseases. *Id.* at 107.

¹⁴ *Birth Control Has Expanded Opportunity for Women—in Economic Advancement, Educational Attainment, and Health Outcomes*, PLANNED PARENTHOOD 1,1 (June 2015), http://www.plannedparenthood.org/files/1614/3275/8659/BC_factsheet_may2015_updated_1.pdf.

¹⁵ See Martha J. Bailey et al., *The Opt-In Revolution? Contraception and the Gender Gap in Wages* 27 (Nat'l Bureau of Econ. Research, Working Paper No. 17322, 2012), http://www-personal.umich.edu/~baileymj/Opt_In_Revolution.pdf.

Eric Hargan, Acting Secretary
December 5, 2017
Page 4 of 9

Since the ACA's requirement that health plans cover contraception benefits and services, women with employer-sponsored coverage have had increased access to contraception,¹⁶ and have saved \$1.4 billion in out-of-pocket costs on birth control pills in 2013 alone.¹⁷ The share of women of reproductive age who had out-of-pocket spending on oral contraceptive pills fell sharply after the ACA's implementation; spending on oral contraceptive pills plummeted from 20.9 percent in 2012 to 3.6 percent in 2014, corresponding to the timing of the contraception provision.¹⁸ Also during this time, the proportion of privately insured women who paid no out-of-pocket costs for oral contraception increased from 15 percent to 67 percent, with similar changes for injectable contraceptives, the vaginal ring and the intrauterine device.¹⁹ To date, over 62.4 million women have benefited from ACA-mandated contraceptive coverage.²⁰

Several of the undersigned States, in recognition that no-cost contraception is critical to women's health and autonomy, have enacted statutory schemes to require no-cost coverage for state-regulated plans.²¹ However, the federal Employee Retirement Income Security Act of 1974 ("ERISA") preempts States from imposing coverage requirements on self-funded plans offered by employers.²² Such plans cover about 58 percent of workers with employer-sponsored insurance.²³ The IFRs threaten this access by allowing virtually any employer with a self-insured plan to opt-out of the contraceptive-coverage requirement based on the employer's own religious or moral beliefs without offering any explanation or requiring any certification process

¹⁶ Adam Sonfield et al., *Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update*, 91 CONTRACEPTION 44, 45-47 (2014), available at [http://www.contraceptionjournal.org/article/S0010-7824\(14\)00687-8/pdf](http://www.contraceptionjournal.org/article/S0010-7824(14)00687-8/pdf).

¹⁷ *Reproductive Rights & Health: The Affordable Care Act's Birth Control Benefit Is Working for Women*, NAT'L WOMEN'S LAW CTR. (Dec. 2016), <http://www.nwlc.org/wp-content/uploads/2016/06/The-ACAs-Birth-Control-Benefit-1.pdf>.

¹⁸ Laurie Sobel et al., *Private Insurance Coverage of Contraception*, HENRY J. KAISER FAMILY FOUND. (2016), <http://www.files.kff.org/attachment/issue-brief-private-insurance-coverage-of-contraception>.

¹⁹ Adam Sonfield et al., *Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update*, 91 CONTRACEPTION 44, 45 (2015), available at [http://www.contraceptionjournal.org/article/S0010-7824\(14\)00687-8/pdf](http://www.contraceptionjournal.org/article/S0010-7824(14)00687-8/pdf).

²⁰ *Reproductive Rights & Health: New Data Estimates 62.4 Million Women Have Coverage of Birth Control Without Out-of-Pocket Costs*, NAT'L WOMEN'S LAW CTR. 1, 2 (2017), <http://www.nwlc.org/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf>.

²¹ An overview of State laws and regulations is provided by Guttmacher Institute. *Insurance Coverage of Contraceptives*, GUTTMACHER INST., <http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives> (last updated Dec. 1, 2017). See also Cal. Ins. Code § 10123.196; Conn. Gen. Stat. § 38A-503e; Haw. Rev. Stat. § 432:1-604.5; 215 Ill. Comp. Stat. 5/356Z.4; Iowa Code § 514C.19; Me. Rev. Stat. tit. 24, § 2332-J, amended by Public Law, Chapter 190 (June 13, 2017); Md. Code, Ins. §§ 15-826, 15-826.1; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017; N.M. Stat. Ann. §§ 59A-22-42; 59A-46-44; N.Y. Ins. Law §§ 3216, 3221, and 4303; N.C. Gen. Stat. § 58-3-178; Or. Rev. Stat. § 743A.066; R.I. Gen. Laws §§ 27-19-48, 27-18-57, 27-20-43; Vt. Stat. tit. 8, § 4099c; Wash. Admin. Code § 284-43-5150. State laws routinely include exemptions from mandatory coverage for prescription contraceptives for religious employers. See, e.g., Conn. Gen. Stat. § 38A-503e; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017; N.Y. Insur. L. § 4303(cc).

²² 29 U.S.C. § 1144(b).

²³ *Medical Expenditure Panel Survey: Percent of Private-Sector Enrollees That Are Enrolled in Self-Insured Plans at Establishments That Offer Health Insurance by Firm Size and State: United States, 2016*, U.S. DEPT. OF HEALTH & HUMAN SERVS., http://www.meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2016/tiib2b1.pdf (last visited Dec. 4, 2017) ("ARHQ Database").

Eric Hargan, Acting Secretary
December 5, 2017
Page 5 of 9

by regulators charged with enforcing the ACA's requirements. Moreover, some of the undersigned States do not have state laws requiring no-cost contraception coverage for state-regulated plans, and as such, the threatened harm of the IFRs extends to *all* employee insurance plans.

II. The IFRs violate the Administrative Procedure Act

(A) *The IFRs are contrary to law.*

The IFRs violate numerous requirements of the ACA. First, the IFRs stand in direct conflict with the WHA, which mandates that employers provide health plans that cover women's preventive care with no cost-sharing.²⁴ While the Religious Freedom Restoration Act (RFRA) requires protection of religious beliefs, the ACA already provides religious exemptions that satisfy RFRA's requirements.²⁵ The IFRs' vast exemptions go well beyond what is required to avoid a substantial religious burden by permitting a broad range of employers, including publicly-traded companies, to evade compliance with the contraceptive mandate, rather than the narrower class of churches, religious non-profits, and closely held for-profit corporations that the Supreme Court has held are protected by RFRA.²⁶ The IFRs also excuse these employers from undertaking any steps, however minimal, to ensure that their employees retain access to contraceptive coverage through other means, eviscerating any accommodation requirements.²⁷ As such, the IFRs allow for noncompliance with a mandatory statute so long as there is *any* religious burden, rather than a *substantial* one. Moreover, RFRA's protection of religious belief does not authorize the IFRs' exemptions for wholly expansive moral beliefs. (See further discussion in *CA Br.* § I.A.1.–2., at 11–14; *PA Br.* § I.A.2.i.–ii., at 23–27; *Amici Br.* § II.B.2., at 21–24.)

Second, the IFRs violate the ACA's nondiscrimination provision that prohibits an individual from being “excluded from participation in,” “denied the benefits of,” or “subjected to discrimination under, any health program or activity” receiving federal funds, to the extent that the grounds for such discrimination are otherwise unlawful under federal law.²⁸ The IFRs violate this nondiscrimination provision because they selectively authorize denial of coverage for women's preventive care benefits only. Indeed, the Equal Employment Opportunity Commission has previously held that an employer who offers coverage for preventive

²⁴ See *FAQs about Affordable Care Act Implementation Part 36*, EMPLOYEE BENEFITS SEC. ADMIN., U.S. DEPT. OF LABOR, 1, 1 (2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> (explaining the effects of the Women's Health Amendment on insurance coverage of women's preventive care).

²⁵ *Id.* at 4–5.

²⁶ See *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2768–69 (2014).

²⁷ The IFRs also eliminate the requirement for employers to notify the federal government if they choose to avail themselves of the exemption, thereby allowing for contraceptive coverage to be quietly eliminated without oversight or transparency.

²⁸ 42 U.S.C. § 18116.

Eric Hargan, Acting Secretary
December 5, 2017
Page 6 of 9

prescription drugs and services but does not offer coverage for contraception violates Title VII.²⁹ (See further discussion in *CA Br.* § I.A.3., at 14; *PA Br.* § II.B., at 43–46; *Amici Br.* § II.B.2., at 21–24.)

Third, the ACA prohibits the Secretary of Health and Human Services from “promulgat[ing] any regulation that creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,” or “impedes timely access to health care services.”³⁰ The IFRs clearly violate this provision by preventing women from accessing important and often medically necessary contraceptive services. (See further discussion in *CA Br.* § I.A.3., at 14; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § I.A.1.–2., at 4–6.)

(B) *The IFRs are arbitrary and capricious.*

The IFRs radically depart from prior policy without adequate or reasonable justification, as required by law. First, the IFRs do not provide sufficient justification for discarding the prior regulations’ finding of a compelling government interest in ensuring that women have contraceptive coverage even if their employers object to providing it. Five justices of the Supreme Court have expressly recognized such a compelling interest.³¹ The IFRs cite scant evidence to support the assertion that access to contraception has little effect on unintended pregnancies, and indeed, the vast majority of studies have shown precisely the opposite.³² Moreover, the IFRs ignore the other public health interests served by the contraceptive mandate—including the need for some women to avoid pregnancy, which can be hazardous or life-threatening to them due to a medical condition. (See further discussion in *CA Br.* § I.C., at 19–21; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § II.C., at 24–26.)

Second, the IFRs provide inadequate explanation for expanding the universe of employers who are exempt from compliance with the contraceptive mandate from churches, houses of worship, religious non-profits, and closely held for-profit corporations, to *any and all* non-governmental employers and *any and all* private universities. Relatedly, the IFRs fail to justify the creation of the broader religious employer exemption, rather than the narrower eligible organization accommodation, to these employers. The offered explanations for this approach is disagreement with the former Administration; but a disagreement with the previous approach is far from the reasoned and evidence-based explanation required for the evisceration of the relied-upon accommodation requirements, which balanced religious exercise and full and equal health coverage for women. (See further discussion in *CA Br.* § I.C., at 19–21; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § II.C., at 24–26.)

Third, the IFRs extend the applicability of the religious and moral exemption to insurance companies, without reasonable explanation for this entirely new expansion. In fact, the IFRs

²⁹ See Commission Decision on Coverage of Contraception, U.S. EQUAL EMPLOYMENT OPPORTUNITY COMM., 2000 WL 33407187 (Dec. 14, 2000), <http://www.eeoc.gov/policy/docs/decision-contraception.html>.

³⁰ 42 U.S.C. § 18114.

³¹ See *Hobby Lobby*, 134 S. Ct. at 2785 (Kennedy, J., concurring); *id.* at 2799 (Ginsburg, J., dissenting).

³² See, e.g., IOM Report at 102–07 (collecting studies on effects of women’s access to contraceptives).

Eric Hargan, Acting Secretary
December 5, 2017
Page 7 of 9

acknowledge that the Departments are not aware of any insurance company with such an objection—it is undoubtedly arbitrary to promulgate a rule with no intended use.

III. The IFRs Violate the Equal Protection Guarantee of the Fifth Amendment

Although the ACA requires coverage for many different types of preventive services, the IFRs single out only women’s health benefits and services. The President’s Executive Order directed the Departments to consider allowing additional “conscience-based objections” to services mandated by the WHA specifically.³³ The IFRs create vast exemptions for contraceptive coverage only, clearly targeting women’s preventive services, while leaving preventive service coverage for male employees untouched. The IFRs include a gender-based classification³⁴ and are thus subject to heightened scrutiny.

The government interest motivating both IFRs is articulated as providing protections for “sincerely held [‘religious beliefs’ or ‘moral convictions’] in certain health care contexts.”³⁵ Even if an unbounded moral conviction is found to be a compelling interest, this gender-based classification does not have an “exceedingly persuasive justification” and is not “substantially related to the achievement of those objectives.”³⁶ The IFRs fail any “means” test as the staggering breadth of the exemptions—to virtually *any* employer for virtually *any* religious or moral objection—lacks any tailoring whatsoever, and flies in the face of any reasonable interpretation of the “substantial relationship” standard. (*See* further discussion in *CA Br.* § I.E., at 25–28; *PA Br.* § I.C., at 32–34; *Amici Br.* § II.D.2., at 29–30.)

IV. The IFRs Violate the Establishment Clause

The IFRs violate the Establishment Clause because their purpose and effect is clearly the advancement of religious beliefs.³⁷ The Rules do not even bother to feign a non-religious purpose. The IFRs also violate the Establishment Clause because they allow employers to obtain religious exemptions in a manner that substantially burdens female employees who may not share the employers’ faith.³⁸ The burdens here imposed go well beyond any justified by religious exercise—they result in the potentially dramatic loss of contraceptive coverage for millions of women, with no alternative structure to obtain care. The Supreme Court relied

³³ Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017), <http://www.gpo.gov/fdsys/pkg/FR-2017-05-09/pdf/2017-09574.pdf>.

³⁴ The IFRs are also overtly discriminatory because they single out women’s health care services, including benefits that are only used by women. Aside from the reference to only women’s services, the IFRs are infused with overt references to purported “sensitive” areas of health, which all concern women’s reproductive health and rely on overly-broad generalizations of women’s health care. *See* 82 Fed. Reg. 47,838 (2017); 82 Fed. Reg. 47,813 (2017). The IFRs are also covertly discriminatory because they have a direct impact on women only. Women alone will be forced to struggle to pay for contraception themselves, forgo contraceptives, or to try to seek out services from some entity other than their employer.

³⁵ 82 Fed. Reg. 47,845 (2017); 82 Fed. Reg. 47,800 (2017).

³⁶ *Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1690 (2017).

³⁷ *See Lemon v. Kurtzman*, 403 U.S. 602, 612–13 (1971).

³⁸ *See* 42 U.S.C. § 2000bb–1(a) (the “government shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability”).

Eric Hargan, Acting Secretary
December 5, 2017
Page 8 of 9

heavily on the notification and accommodation mechanisms previously in place as necessary protections of women's ability to access contraception.³⁹ Without such accommodation, notice, and justification requirements, the burdens on women have grown dramatically, resulting in a clear violation of the Establishment Clause. (See further discussion in *CA Br.* § I.D., at 21–24; *PA Br.* § I.D., at 34–38; *Amici Br.* § II. D.1., at 27–28.)

V. Conclusion

The IFRs at issue will result in harms that are both direct and indirect, tangible and intangible. Access to contraception is fundamental to women's rights to bodily freedom and to emotional autonomy. It is a public health issue, with effects on unintended pregnancy, maternal health, and infant morbidity. It also implicates economic mobility and wage parity, educational opportunity and social equality. These far-reaching effects are too great to ignore, and are protected by the Constitution, our laws and regulations. Accordingly, we urge the Secretary to rescind the IFRs.

Respectfully submitted,
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³⁹ In *Hobby Lobby*, for example, the Court explained that the accommodation sought by closely held for-profit corporations would not violate the Establishment Clause because it has “precisely zero” effect on the women employed by Hobby Lobby. The Court noted that “these women would still be entitled to all FDA-approved contraceptives without cost sharing.” 134 S. Ct. at 2760. In his concurrence, Justice Kennedy underscored that an accommodation of religious exercise must not “unduly restrict other persons, such as employees, in protecting their own interests.” *Id.* at 2786–87 (Kennedy, J., concurring). Similarly, the Court in *Wheaton College v. Burwell* expressly noted that its order allowing employers to notify the government rather than their insurer about a religious objection would not “affect[] the ability of [Wheaton’s] employees and students to obtain, without cost, the full range of FDA approved contraceptives.” 134 S. Ct. 2806, 2807 (2014).

Eric Hargan, Acting Secretary
December 5, 2017
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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD-9840]

RIN 1545-BN92

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS-9940-F2]

RIN 0938-AT54

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, interim final rules concerning religious exemptions and accommodations regarding coverage of certain preventive services issued in the **Federal Register** on October 13, 2017. These rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an “accommodation” process as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, at (301) 492-4305 or marketreform@cms.hhs.gov for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; William Fischer, Internal Revenue Service, Department of the Treasury, at (202) 317-5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline, 1-866-444-EBSA (3272) or visit the Department of Labor’s website (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS’s website (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Executive Summary and Background
 - A. Executive Summary
 1. Purpose
 2. Summary of the Major Provisions
 - a. Expanded Religious Exemptions to the Contraceptive Coverage Requirement
 - b. Optional Accommodation
 3. Summary of Costs, Savings and Benefits of the Major Provisions
 - B. Background
- II. Overview, Analysis, and Response to Public Comments
 - A. The Departments’ Authority To Mandate Coverage and Provide Religious Exemptions
 - B. Availability and Scope of Religious Exemptions
 - C. The First Amendment and the Religious Freedom Restoration Act
 1. Discretion To Provide Religious Exemptions
 2. Requiring Entities To Choose Between Compliance With the Contraceptive Mandate or the Accommodation Violated RFRA in Many Instances
 - a. Substantial Burden
 - b. Compelling Interest
 - D. Burdens on Third Parties
 - E. Interim Final Rulemaking
 - F. Health Effects of Contraception and Pregnancy
 - G. Health and Equality Effects of Contraceptive Coverage Mandates
- III. Description of the Text of the Regulations and Response to Additional Public Comments
 - A. Restatement of Statutory Requirements of PHS Act Section 2713(a) and (a)(4) (26 CFR 54.9815-2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715-2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))
 - B. Prefatory Language of Religious Exemptions (45 CFR 147.132(a)(1))
 - C. Scope of Religious Exemptions and Requirements for Exempt Entities (45 CFR 147.132)
 - D. Plan Sponsors in General (45 CFR 147.132(a)(1)(i) prefatory text)
 - E. Houses of Worship and Integrated Auxiliaries (45 CFR 147.132(a)(1)(i)(A))
 - F. Nonprofit Organizations (45 CFR 147.132(a)(1)(i)(B))
 - G. Closely Held For-Profit Entities (45 CFR 147.132(a)(1)(i)(C))
 - H. For-Profit Entities That Are Not Closely Held (45 CFR 147.132(a)(1)(i)(D))
 - I. Other Non-Governmental Employers (45 CFR 147.132(a)(1)(i)(E))
 - J. Plans Established or Maintained by Objecting Nonprofit Entities (45 CFR 147.132(a)(1)(ii))
 - K. Institutions of Higher Education (45 CFR 147.132(a)(1)(iii))
 - L. Health Insurance Issuers (45 CFR 147.132(a)(1)(iv))
 - M. Description of the Religious Objection (45 CFR 147.132(a)(2))
 - N. Individuals (45 CFR 147.132(b))
 - O. Accommodation (45 CFR 147.131, 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A)
 - P. Definition of Contraceptives for the Purpose of These Final Rules
 - Q. Severability
 - R. Other Public Comments
 1. Items Approved as Contraceptives But Used To Treat Existing Conditions
 2. Comments Concerning Regulatory Impact
 3. Interaction With State Laws
- IV. Economic Impact and Paperwork Burden
 - A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor
 1. Need for Regulatory Action
 2. Anticipated Effects
 - a. Removal of Burdens on Religious Exercise
 - b. Notices When Revoking Accommodated Status
 - c. Impacts on Third Party Administrators and Issuers
 - d. Impacts on Persons Covered by Newly Exempt Plans
 - i. Unknown Factors Concerning Impact on Persons in Newly Exempt Plans
 - ii. Public Comments Concerning Estimates in Religious IFC
 - iii. Possible Sources of Information for Estimating Impact
 - iv. Estimates Based on Litigating Entities That May Use Expanded Exemptions
 - v. Estimates of Accommodated Entities That May Use Expanded Exemptions
 - vi. Combined Estimates of Litigating and Accommodated Entities
 - vii. Alternate Estimates Based on Consideration of Pre-ACA Plans
 - viii. Final Estimates of Persons Affected by Expanded Exemptions
 - B. Special Analyses—Department of the Treasury
 - C. Regulatory Flexibility Act
 - D. Paperwork Reduction Act—Department of Health and Human Services
 1. Wage Data
 2. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

3. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))
4. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))
5. Submission of PRA-Related Comments
- E. Paperwork Reduction Act—Department of Labor
- F. Regulatory Reform Executive Orders 13765, 13771 and 13777
- G. Unfunded Mandates Reform Act
- H. Federalism
- V. Statutory Authority

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47792), “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” (the Religious IFC). The rules are necessary to expand the protections for the sincerely held religious objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, a requirement that was created by HHS through guidance promulgated by the Health Resources and Services Administration (HRSA) (hereinafter “Guidelines”), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules maintain a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA’s Guidelines. The changes being finalized to these rules will ensure that proper respect is afforded to sincerely held religious objections in rules governing this area of health insurance and coverage, with minimal impact on HRSA’s decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Expanded Religious Exemptions to the Contraceptive Coverage Requirement

These rules finalize exemptions provided in the Religious IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held religious beliefs opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA’s Guidelines. The rules finalize exemptions to the same types of organizations and individuals for which exemptions were provided in the Religious IFC: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals. The rules also finalize the regulatory restatement in the Religious IFC of language from section 2713(a) and (a)(4) of the Public Health Service Act.

In response to public comments, various changes are made to clarify the intended scope of the language in the Religious IFC. The prefatory language to the exemptions is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to clarify that, where an exemption encompasses a plan or coverage established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, the exemption applies to each employer, organization, or plan sponsor that adopts the plan. Language is also added to clarify that the exemptions apply to non-governmental entities, including as the exemptions apply to institutions of higher education. The Departments revise the exemption applicable to health insurance issuers to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement. The Departments also restructure the

provision describing the religious objection for entities. That provision specifies that the entity objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for either: coverage or payments for some or all contraceptive services; or, a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The final rule specifies that the individual exemption ensures that the HRSA Guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. Optional Accommodation

These rules also finalize provisions from the Religious IFC that maintain the accommodation process as an optional process for entities that qualify for the exemption. Under that process, entities can choose to use the accommodation process so that contraceptive coverage to which they object is omitted from their plan, but their issuer or third party administrator, as applicable, will arrange for the persons covered by their plan to receive contraceptive coverage or payments.

In response to public comments, these final rules make technical changes to the accommodation regulations maintained in parallel by HHS, the Department of Labor, and the Department of the Treasury. The Departments modify the regulations governing when an entity, that was using or will use the accommodation, can revoke the accommodation and operate under the exemption. The modifications set forth a transitional

rule as to when entities currently using the accommodation may revoke it and use the exemption by giving 60-days notice pursuant to Public Health Service Act section 2715(d)(4) and 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), and 29 CFR 2590.715–2715(b). The modifications also express a general rule that, in plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no

sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

The Departments also modify the Religious IFC by adding a provision that existed in rules prior to the Religious IFC, namely, that if an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable contraceptive coverage requirement from HRSA's Guidelines if the issuer complies with the obligations under this section applicable to such

issuer. Likewise, the rule adds pre-existing “reliance” language deeming an issuer serving an accommodated organization compliant with the contraceptive coverage requirement if the issuer relies reasonably and in good faith on a representation by an organization as to its eligibility for the accommodation and the issuer otherwise complies with the accommodation regulation, and likewise deeming a group health plan compliant with the contraceptive coverage requirement if it complies with the accommodation regulation.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	The purpose of this provision is to ensure that the regulatory language that restates section 2713(a) and (a)(4) of the Public Health Service Act mirrors the language of the statute. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.
Expanded religious exemptions.	Expanding religious exemptions to the contraceptive coverage requirement will relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their religious beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage or using the accommodation in violation of their sincerely held religious beliefs.	We estimate there will be transfer costs where women previously receiving contraceptive coverage from employers will no longer receive that coverage where the employers use the expanded exemptions. Even after the public comment period, we have very limited data on what the scale of those transfer costs will be. We estimate that in no event will they be more than \$68.9 million. We estimate that, where entities using the accommodation revoke it to use the exemption, the cost to industry of sending notices of revocation to their policy holders will be \$112,163.
Optional accommodation regulations.	Maintaining the accommodation as an optional process will ensure that contraceptive coverage is made available to many women covered by plans of employers that object to contraceptive coverage but not to their issuers or third party administrators arranging for such coverage to be provided to their plan participants.	We estimate that, by expanding the types of organizations that may use the accommodation, some entities not currently using it will opt into it. When doing so they will incur costs of \$677 to send a self-certification or notice to their issuer or third party administrator, or to HHS, to commence operation of the accommodation. We estimate that entities that newly make use of the accommodation as the result of these rules, or their issuers or third party administrators, will incur costs of \$311,304 in providing their policy holders with notices indicating that contraceptive coverage or payments are available to them under the accommodation process.

B. Background

Over many decades, Congress has protected conscientious objections, including those based on religious beliefs, in the context of health care and human services including health coverage, even as it has sought to promote and expand access to health services.¹ In 2010, Congress enacted the

individuals and entities that object to abortion); Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any “health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan” in objecting to abortion for any reason); *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions”); *id.* at Div. E, Sec. 808 (regarding any requirement for “the provision of contraceptive coverage by health insurance plans” in the District of Columbia, “it is the intent of Congress that any

legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”); *id.* at Div. I, (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their “religious or conscientious commitment to offer only natural family planning”); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide-related treatment services for youth where the parents or legal guardians object based on “religious beliefs or moral objections”); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations

¹ See, for example, 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their “religious beliefs or moral convictions”); 42 U.S.C. 238n (protecting

Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended the PPACA. As amended by HCERA, the PPACA is known as the Affordable Care Act (ACA).

The ACA reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter “section 2713(a)(4)”), Congress provided administrative

discretion to require that certain group health plans and health insurance issuers cover certain women’s preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, “with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by” HRSA’s Guidelines.

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.² In the same time period, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, “the Departments”) ³ have promulgated regulations to guide HRSA in exercising its discretion to allow exemptions to those requirements, including issuing and finalizing three interim final regulations prior to 2017.⁴ In those

regulations, the Departments defined the scope of permissible exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Many individuals and entities brought legal challenges to the contraceptive coverage requirement and regulations (hereinafter, the “contraceptive Mandate,” or the “Mandate”) as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1 (“RFRA”). Several of those cases went to the Supreme Court. *See, for example, Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014); *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

The Departments most recently solicited public comments on these issues again in two interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017: the regulations (82 FR 47792) that are being finalized with changes here, and regulations (82 FR 47838) concerning moral objections (the Moral IFC), which are being finalized with changes in companion final rules published elsewhere in today’s **Federal Register**.

In the preamble to the Religious IFC, the Departments explained several reasons why it was appropriate to reevaluate the religious exemptions and accommodations for the contraceptive Mandate and to take into account the religious beliefs of certain employers concerning that Mandate. The Departments also sought public comment on those modifications. The Departments considered, among other things, Congress’s history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; protection of the free exercise of religion in the First Amendment and, by Congress, in RFRA; Executive Order 13798, “Promoting Free Speech and Religious Liberty” (May 4, 2017); previously submitted public comments;

80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.

and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice (now Medicare Advantage) managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on “conscience” as protected in state law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on “religious beliefs or moral convictions”); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); see also 8 U.S.C. 1182(g) (protecting vaccination objections by “aliens” due to “religious beliefs or moral convictions”); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on “moral or religious convictions”); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their “religious or moral objection”).

² The references in this document to “contraception,” “contraceptive,” “contraceptive coverage,” or “contraceptive services” generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women’s Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to “Contraceptive Methods and Counseling” as “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” <https://www.hrsa.gov/womens-guidelines/index.html>. The Guidelines as amended in December 2016 refer, under the header “Contraception,” to: “the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures,” “contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),” and “instruction in fertility awareness-based methods, including the lactation amenorrhea method.” <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

³ Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

⁴ Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at

and the extensive litigation over the contraceptive Mandate.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Religious IFC, with changes based on comments as indicated herein.⁵

II. Overview, Analysis, and Response to Public Comments

We provided a 60-day public comment period for the Religious IFC, which closed on December 5, 2017. The Departments received over 56,000 public comment submissions, which are posted at www.regulations.gov.⁶ Below, the Departments provide an overview of the general comments on the final regulations, and address the issues raised by commenters.

These rules expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules finalize the accommodation process, which was previously established in response to objections of religious organizations that were not protected by the original exemption, as an optional process for any exempt entities. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.⁷

⁵ The Department of the Treasury and the Internal Revenue Service (IRS) published proposed and temporary regulations as part of the joint rulemaking of the Religious IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules. The Department of the Treasury and IRS are finalizing their proposed regulations.

⁶ See *Regulations.gov* at <https://www.regulations.gov/search/Results?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dkid=CMS-2014-0115> and <https://www.regulations.gov/docket/Browser?rpp=25&so=DESC&sb=commentDueDate&po=7525&dct=PS&D=IRS-2017-0016>. Some of those submissions included form letters or attachments that, while not separately tabulated at *regulations.gov*, together included comments from, or were signed by, hundreds of thousands of separate persons. The Departments reviewed all of the public comments and attachments.

⁷ See, for example, Family Planning grants in 42 U.S.C. 300 *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112-74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c-8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal

A. The Departments' Authority To Mandate Coverage and Provide Religious Exemptions

The Departments received conflicting comments on their legal authority to provide the expanded exemptions and accommodation for religious beliefs. Some commenters agreed that the Departments are legally authorized to provide the expanded exemptions and accommodation, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing religious exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the exemptions that existed prior to the Religious IFC, but not to expand them.

Some commenters who argued that section 2713(a)(4) does not allow for exemptions said that the previous exemptions for houses of worship and integrated auxiliaries, and the previous accommodation process, were set forth in the ACA itself, and therefore were acceptable while the expanded exemptions in the Religious IFC were not. This is incorrect. The ACA does not prescribe (or prohibit) the previous exemptions for house of worship and the accommodation processes that the Departments issued through regulations.⁸ The Departments, therefore, find it appropriate to use the regulatory process to issue these expanded exemptions and accommodation, to better address concerns about religious exercise.

The Departments conclude that legal authority exists to provide the expanded exemptions and accommodation for religious beliefs set forth in these final rules. These rules concern section 2713 of the PHS Act, as also incorporated into ERISA and the Code. Congress has granted the Departments legal authority,

and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b-12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), and 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), and (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

⁸ The ACA also does not require that contraceptives be covered under the preventive services provisions.

collectively, to administer these statutes.⁹

Where it applies, section 2713(a)(4) requires coverage without cost sharing for “such additional” women’s preventive care and screenings “as provided for” and “supported by” Guidelines developed by HHS through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a positive grant of authority for HRSA to develop those Guidelines, thus delegating authority to HHS, as the administering agency of HRSA, and to all three agencies, as the administering agencies of the statutes by which the Guidelines are enforced, to shape that development. See 26 U.S.C. 9834; 29 U.S.C. 1191(c), 42 U.S.C. 300gg-92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency’s general supervision, see 47 FR 38,409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable Guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must “provide for” and “support” the application of Guidelines that it chooses to adopt. HRSA’s authority to support “comprehensive guidelines” involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only “as provided for in comprehensive guidelines supported by [HRSA].” That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word “as” in the phrase “as provided for,” it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase “as you like it.”¹⁰ When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. See, e.g., 42 U.S.C. 1395x (“The Secretary shall establish procedures to make beneficiaries and providers aware

⁹ 26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92.

¹⁰ See *As* (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (“[u]sed to indicate by comparison the way something happens or is done”).

of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.”) (emphasis added). Thus, the inclusion of “as” in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has been granted discretion in supporting how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word “as” is missing from the other three provisions in PHS Act section 2713(a). Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require “evidence-based” or “evidence-informed” coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA’s Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The religious objections at issue here, and in regulations providing exemptions from the inception of the Mandate in 2011, are considerations that, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA’s preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive Mandate. (See 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines “exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,” and “it

is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.” *Id.* Consistent with that longstanding view, Congress’s grant of discretion in section 2713(a)(4), and the lack of a specific statutory mandate that contraceptives must be covered or that they be covered without any exemptions or exceptions, supports the conclusion that the Departments are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The conclusions on which these final rules are based are consistent with the Departments’ interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4)’s grant of authority to include broad discretion regarding the extent to which HRSA will provide for, and support, the coverage of additional women’s preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to participants in an eligible organization’s health plan by the organization’s insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrators of self-insured church plans. See 80 FR 41323. Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation’s application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds

of employers since the Guidelines were adopted. During prior rulemakings, the Departments also disagreed with commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or as incorporated into ERISA and the Code, and who contended instead that we must enforce the Guidelines on the broadest spectrum of group health plans as possible. See, e.g., 2012 final regulations at 77 FR 8726.

The Departments’ interpretation of section 2713(a)(4) is confirmed by the ACA’s statutory structure. Congress did not intend to require coverage of preventive services for every type of plan that is subject to the ACA. See, e.g., 76 FR 46623. On the contrary, Congress carved out an exemption from PHS Act section 2713 (and from several other provisions) for grandfathered plans. In contrast, grandfathered plans do have to comply with many of the other provisions in Title I of the ACA—provisions referred to by the previous Administration as providing “particularly significant protections.” (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime and annual dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group health insurance markets, and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.¹¹ Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, “there is no legal requirement that grandfathered plans ever be phased out.” *Hobby Lobby*, 134 S. Ct. at 2764 n.10.

Some commenters argue that Executive Order 13535’s reference to

¹¹ Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2017 Annual Survey,” Henry J. Kaiser Family Foundation (Sept. 2017), <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions to the Mandate in the Guidelines. The Departments, however, believe these final regulations are consistent with Executive Order 13535. Issued upon the signing of the ACA, Executive Order 13535 specified that “longstanding Federal laws to protect conscience . . . remain intact,” including laws that protect holders of religious beliefs from certain requirements in health care contexts. While the Executive Order 13535 does not require the expanded exemptions in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws that protect religious beliefs, and are consistent with the Executive Order’s intent that the ACA would be implemented in accordance with the conscience protections set forth in those laws.

The extent to which RFRA provides authority for these final rules is discussed below in section II.C., The First Amendment and the Religious Freedom Restoration Act.

B. Availability and Scope of Religious Exemptions

Some commenters supported the expanded exemptions and accommodation in the Religious IFC, and the entities and individuals to which they applied. They asserted the expanded exemptions and accommodation are appropriate exercises of discretion and are consistent with religious exemptions Congress has provided in many similar contexts. Some further commented that the expanded exemptions are necessary under the First Amendment or RFRA. Similarly, commenters stated that the accommodation was an inadequate means to resolve religious objections, and that the expanded exemptions are needed. They objected to the accommodation process because it was another method to require compliance with the Mandate. They contended its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and that such coverage flowed in connection with the objecting organizations’ health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to the religious objections that organizations would not have with an expanded exemption.

Several other commenters asserted that the exemptions in the Religious IFC are too narrow and called for there to be no mandate of contraceptive coverage. Some of them contended that HRSA should not include contraceptives in their women’s preventive services Guidelines because fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of preventive health services. They also contended that contraceptives can pose medical risks for women and that studies do not show that contraceptive programs reduce abortion rates or rates of unintended pregnancies. Some commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacients and, therefore, violate federal conscience protections such as the Weldon Amendment, *see* section 507(d) of Public Law 115–141.

Other commenters contended that the expanded exemptions are too broad. In general, these commenters supported the inclusion of contraceptives in the Guidelines, contending they are a necessary preventive service for women. Some said that the Departments should not exempt various kinds of entities such as businesses, health insurance issuers, or other plan sponsors that are not nonprofit entities. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318). Some commenters said the Departments should not expand the exemptions, but simply expand or adjust the accommodation process to resolve religious objections to the Mandate and accommodation. Some commenters contended that even the previous regulations allowing an exemption and accommodation were too broad, and said that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible.

After consideration of the comments, the Departments are finalizing the provisions of the Religious IFC without contracting the scope of the exemptions and accommodation set forth in the Religious IFC. Since HRSA issued its Guidelines in 2011, the Departments have recognized that religious exemptions from the contraceptive Mandate are appropriate. The details of the scope of such exemptions are discussed in further detail below. In general, the Departments conclude it is

appropriate to maintain the exemptions created by the Religious IFC to avoid instances where the Mandate is applied in a way that violates the religious beliefs of certain plan sponsors, issuers, or individuals. The Departments do not believe the previous exemptions are adequate, because some religious objections by plan sponsors and individuals were favored with exemptions, some were not subjected to contraceptive coverage if they fell under the indirect exemption for certain self-insured church plans, and others had to choose between the Mandate and the accommodation even though they objected to both. The Departments wish to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage. The lack of a congressional mandate that contraceptives be covered, much less that they be covered without religious exemptions, has also informed the Departments’ decision to expand the exemptions. And Congress’s decision not to apply PHS Act section 2713 to grandfathered plans has likewise informed the Departments’ decision whether exemptions to the contraceptive Mandate are appropriate.

Congress has also established a background rule against substantially burdening sincere religious beliefs except where consistent with the stringent requirements of the Religious Freedom Restoration Act. And Congress has consistently provided additional, specific exemptions for religious beliefs in statutes addressing federal requirements in the context of health care and specifically concerning issues such as abortion, sterilization, and contraception. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive coverage Mandate by the exercise of agency discretion, that we also include exemptions for the protection of religious beliefs in certain cases. The expanded exemptions finalized in these rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. They are also consistent with the intent of Executive Order 13535 (March 24, 2010), which was issued upon the signing of the ACA and declared that, “[u]nder the Act, longstanding federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Public Law 111–8) remain intact” and that “[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.”

Some commenters argued that Congress’s failure to explicitly include

religious exemptions in PHS Act section 2713 itself is indicative of an intent that such exemptions not be included, but the Departments disagree. As noted above, Congress also failed to require contraceptive coverage in PHS Act section 2713. And the commenters' argument would negate not just these expanded exemptions, but the previous exemptions for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting religious beliefs in the context of certain federal health care requirements.

If there is to be a federal contraceptive mandate that fails to include some—or, in the views of some commenters, any—religious exemptions, the Departments do not believe it is appropriate for us to impose such a regime through discretionary administrative measures. Instead, such a serious imposition on religious liberty should be created, if at all, by Congress, in response to citizens exercising their rights of political participation. Congress did not prohibit religious exemptions under this Mandate. It did not even require contraceptive coverage under the ACA. It left the ACA subject to RFRA, and it specified that additional women's preventive services will only be required coverage as provided for in Guidelines supported by HRSA. Moreover, Congress legislated in the context of the political consensus on conscientious exemptions for health care that has long been in place. Since *Roe v. Wade* in 1973, Congress and the states have consistently offered religious exemptions for health care providers and others concerning issues such as sterilization and abortion, which implicate deep disagreements on scientific, ethical, and religious (and moral) concerns. Indeed over the last 44 years, Congress has repeatedly expanded religious exemptions in similar cases, including to contraceptive coverage. Congress did not purport to deviate from that approach in the ACA. Thus, we conclude it is appropriate to specify in these final rules, that, if the Guidelines continue to maintain a contraceptive coverage requirement, the expanded exemptions will apply to those Guidelines and their enforcement.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to

entities, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for religious beliefs in the context of certain Federal health care requirements. Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held religious beliefs to the extent the Guidelines otherwise include contraceptive coverage.¹² These exemptions do not prohibit any services, nor do they authorize employers to prohibit employees from obtaining any services. The Religious IFC and these final rules simply refrain from imposing the federal Mandate that employers and health insurance issuers cover contraceptives in their health plans where compliance with the Mandate would violate their sincerely held religious beliefs. And though not necessary to the Departments' decision here, the Departments note that the Church Amendments explicitly protect entities and that several subsequent federal conscience statutes have protected against federal mandates in health coverage.

The Departments note that their decision is also consistent with state practice. A significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.¹³ Although the practice of states is not a limit on the discretion delegated to HRSA by the ACA, nor is it a statement about what the federal government may do consistent with RFRA or other limitations or protections embodied in federal law, such state practices can inform the Departments' view that it is appropriate to protect religious liberty as an exercise of agency discretion.

The Departments decline to adopt the suggestion of some commenters to use

¹² The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. See Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

¹³ See Guttmacher Institute, "Insurance Coverage of Contraceptives", The Guttmacher Institute (June 11, 2018), <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

these final rules to revoke the contraceptive Mandate altogether, such as by declaring that HHS through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). Although previous regulations were used to authorize religious exemptions and accommodations to the imposition of the Guidelines' coverage of contraception, the issuance of the Guidelines themselves in 2011 describing what items constitute recommended women's preventive services, and the update to those recommendations in December 2016, did not occur through the regulations that preceded the 2017 Religious IFC and these final rules. The Guidelines' specification of which women's preventive services were recommended were issued, not by regulation, but directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The Departments decline to accept the invitation of some commenters to use these rules to specify whether HRSA includes contraceptives in the Guidelines at all. Instead the Departments conclude it is appropriate for these rules to continue to focus on restating the statutory language of PHS Act section 2713 in regulatory form, and delineating what exemptions and accommodations apply if HRSA lists contraceptives in its Guidelines. Some commenters said that if contraceptives are not removed from the Guidelines entirely, some entities or individuals with religious objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in the Religious IFC and these final rules cover a broad range of entities and individuals. The Departments are not aware of specific groups or individuals whose religious beliefs would still be substantially burdened by the Mandate after the issuance of these final rules.

Some commenters asserted that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions.

Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These rules focus on what religious exemptions and accommodations shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacients.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content of, and the process for developing and updating, the Guidelines, are welcome to communicate their views to HRSA, at wellwomancare@hrsa.gov.

The Departments conclude that it would be inadequate to merely attempt to amend or expand the accommodation process instead of expanding the exemption. In the past, the Departments had stated in our regulations and court briefs that the previous accommodation process required contraceptive coverage or payments in a way that is “seamless” with the coverage provided by the objecting employer. As a result, in significant respects, that previous accommodation process did not actually accommodate the objections of many entities, as many entities with religious objections have argued. The Departments have attempted to identify an accommodation process that would eliminate the religious objections of all plaintiffs, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but we stated in January 2017 that we were unable to develop such an approach at that time.¹⁴ The Departments continue to believe that, because of the nature of the accommodation process, merely amending that accommodation process without expanding the exemptions would not adequately address religious objections to compliance with the Mandate. Instead, we conclude that the

most appropriate approach to resolve these concerns is to expand the exemptions as set forth in the Religious IFC and these final rules, while maintaining the accommodation as an option for providing contraceptive coverage, without forcing entities to choose between compliance with either the Mandate or the accommodation and their religious beliefs.

Comments considering the appropriateness of exempting certain specific kinds of entities or individuals are discussed in more detail below.

C. The First Amendment and the Religious Freedom Restoration Act

Some commenters said that the Supreme Court ruled that the exemptions to the contraceptive Mandate, which the Departments previously provided to houses of worship and integrated auxiliaries, were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but exemptions beyond those are not. But in *Hobby Lobby* and *Zubik*, the Supreme Court did not decide whether the exemptions previously provided to houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate to other organizations unless RFRA prohibits the Departments from doing so. Moreover, the previous church exemption, which applied automatically to all churches whether or not they had even asserted a religious objection to contraception, 45 CFR 147.141(a), is not tailored to any plausible free-exercise concerns. The Departments decline to adopt the view that RFRA does not apply to other religious organizations, and there is no logical explanation for how RFRA could require the church exemption but not this expanded religious exemption, given that the accommodation is no less an available alternative for the former than the latter.

Commenters disagreed about the scope of RFRA’s protection in this context. Some commenters said that the expanded exemptions and accommodation are consistent with RFRA. Some also said that they are required by RFRA, as the Mandate imposes substantial burdens on religious exercise and fails to satisfy the compelling-interest and least-restrictive-means tests imposed by RFRA. Other commenters, however, contended that the expanded exemptions and accommodation are neither required by, nor consistent with, RFRA. In this vein, some argued that the Departments have

a compelling interest to deny religious exemptions, that there is no less restrictive means to achieve its goals, or that the Mandate or its accommodation process do not impose a substantial burden on religious exercise.

For the reasons discussed below, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden. Here, after further consideration of these issues and review of the public comments, the Departments have determined that a broader exemption, rather than a mere accommodation, is the appropriate response.

In addition, with respect to religious employers, the Departments conclude that, without finalizing the expanded exemptions, and therefore requiring certain religiously objecting entities to choose between the Mandate, the accommodation, or penalties for noncompliance—or requiring objecting individuals to choose between purchasing insurance with coverage to which they object or going without insurance—the Departments would violate their rights under RFRA.

1. Discretion To Provide Religious Exemptions

In the Religious IFC, we explained that even if RFRA does not compel the Departments to provide the religious exemptions set forth in the IFC, the Departments believe the exemptions are the most appropriate administrative response to the religious objections that have been raised.

The Departments received conflicting comments on this issue. Some commenters agreed that the Departments have administrative discretion to address the religious objections even if the Mandate and accommodation did not violate RFRA. Other commenters expressed the view that RFRA does not provide such discretion, but only allows exemptions when RFRA requires exemptions. They contended that RFRA does not require exemptions for entities covered by the expanded exemptions of the Religious IFC, but that subjecting those entities to the accommodation satisfies RFRA, and therefore RFRA provides the Departments with no additional authority to exempt those entities. Those commenters further contended that because, in their view, section 2713(a)(4) does not authorize the

¹⁴ See Departments of Labor, Health and Human Services, and the Treasury, “FAQs About Affordable Care Act Implementation Part 36,” (Jan. 9, 2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36-1-9-17-Final.pdf> (“the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage”).

expanded exemptions, no statutory authority exists for the Departments to finalize the expanded exemptions.

As discussed above, the Departments disagree with the suggestions of commenters that section 2713(a)(4) does not authorize the Departments to adopt the expanded exemptions. Nevertheless, the Departments note that the expanded exemptions for religious objectors also rest on an additional, independent ground: The Departments have determined that, in light of RFRA, an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*. Indeed, with respect to at least some objecting entities, an expanded exemption, as opposed to the existing accommodation, is required by RFRA. The Departments disagree with commenters who contend RFRA does not give the Departments discretion to offer these expanded exemptions.

The Departments' determination about their authority under RFRA rests in part on the Departments' reassessment of the interests served by the application of the Mandate in this specific context. Although the Departments previously took the position that the application of the Mandate to objecting employers was narrowly tailored to serve a compelling governmental interest, as discussed below the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Particularly under those circumstances, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement or instead to attempt to create an accommodation that would mitigate the burden. And here, the Departments have determined that a broader exemption rather than the existing accommodation is the appropriate response. That determination is informed by the Departments' reassessment of the relevant interests, as well as by their desire to bring to a close the more than five years of litigation over RFRA challenges to the Mandate.

Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive Mandate, pursuant to

Hobby Lobby—neither RFRA nor the ACA prescribes the remedy by which the government must eliminate that burden, where any means of doing so will require departing from the ACA to some extent (on the view of some commenters, with which the Departments disagree, that section 2713(a)(4) does not itself authorize the Departments to recognize exceptions). The prior administration chose to do so through the complex accommodation it created, but nothing in RFRA or the ACA compelled that novel choice or prohibits the current administration from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. After all, on the theory that section 2713(a)(4) allows for no exemptions, the accommodation also departed from section 2713(a)(4) in the sense that employers were not themselves offering contraceptive coverage, and the ACA did not require the Departments to choose that departure rather than the expanded exemptions as the exclusive method to satisfy their obligations under RFRA to eliminate the substantial burden imposed by the Mandate. The agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA. See 82 FR at 47798; see also *Ricci v. DeStefano*, 557 U.S. 586, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban). Indeed, if the Departments had simply adopted an expanded exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because they should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result now based merely on path dependence.

Although the foregoing analysis is independently sufficient, additional support for this view is provided by the Departments' conclusion, as explained more fully below, that an expanded exemption is required by RFRA for at least some objectors. In the Religious IFC, the Departments reaffirmed their conclusion that there is not a way to satisfy all religious objections by amending the accommodation, (82 FR at 47800), a conclusion that was confirmed by some commenters (and the continued

litigation over the accommodation).¹⁵ Some commenters agreed the religious objections could not be satisfied by amending the accommodation without expanding the exemptions, because if the accommodation requires an objecting entity's issuer or third party administrator to provide or arrange contraceptive coverage for persons covered by the plan because they are covered by the plan, this implicates the objection of entities to the coverage being provided through their own plan, issuer, or third party administrator. Other commenters contended the accommodation could be modified to satisfy RFRA concerns without extending exemptions to objecting entities, but they did not propose a method of modifying the accommodation that would, in the view of the Departments, actually address the religious objections to the accommodation.

In the Departments' view, after considering all the comments and the preceding years of contention over this issue, it is appropriate to finalize the expanded exemptions rather than merely attempt to change the accommodation to satisfy religious objections. This is because if the accommodation still delivers contraceptive coverage through use of the objecting employer's plan, issuer, or third party administrator, it does not address the religious objections. If the accommodation could deliver contraceptive coverage independent and separate from the objecting employer's plan, issuer, and third party administrator, it could possibly address the religious objections, but there are two problems with such an approach. First, it would effectively be an exemption, not the accommodation as it has existed, so it would not be a reason not to offer the expanded exemptions finalized in these rules. Second, although (as explained above) the Departments have authority to provide exemptions to the Mandate, the Departments are not aware of the authority, or of a practical mechanism, for using section 2713(a)(4) to require contraceptive coverage be provided

¹⁵ See RFI, 81 FR 47741 (July 26, 2016); Departments of Labor, Health and Human Services, and the Treasury, "FAQs, About Affordable Care Act Implementation Part 36," (Jan. 9, 2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf ("the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage").

specifically to persons covered by an objecting employer, other than by using the employer's plan, issuer, or third party administrator, which would likely violate some entities' religious objections. The Departments are aware of ways in which certain persons covered by an objecting employer might obtain contraceptive coverage through other governmental programs or requirements, instead of through objecting employers' plans, issuers, or third party administrators, and we mention those elsewhere in this rule. But those approaches do not involve the accommodation, they involve the expanded exemptions, plus the access to contraceptives through separate means.

2. Requiring Entities To Choose Between Compliance With the Contraceptive Mandate or the Accommodation Violated RFRA in Many Instances

Before the Religious IFC, the Departments had previously contended that the Mandate did not impose a substantial burden on entities and individuals under RFRA; that it was supported by a compelling government interest; and that it was, in combination with the accommodation, the least restrictive means of advancing that interest. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with sincerely held religious objections, that argument was rejected in *Hobby Lobby*, which held that the Mandate imposes a substantial burden and was not the least restrictive means of achieving any compelling governmental interest. *See* 134 S. Ct. at 2775–79. In the Religious IFC, the Departments revisited its earlier conclusions and reached a different view, concluding that requiring compliance through the Mandate or accommodation constituted a substantial burden on the religious exercise of many entities or individuals with religious objections, did not serve a compelling interest, and was not the least restrictive means of serving a compelling interest, so that requiring such compliance led to the violation of RFRA in many instances. (82 FR at 47806).

In general, commenters disagreed about this issue. Some commenters agreed with the Departments, and with some courts, that requiring entities to choose between the contraceptive Mandate and its accommodation violated their rights under RFRA, because it imposed a substantial burden on their religious exercise, did not advance a compelling government

interest, and was not the least restrictive means of achieving such an interest. Other commenters contended that requiring compliance either with the Mandate or the accommodation did not violate RFRA, agreeing with some courts that have concluded the accommodation does not substantially burden the religious exercise of organizations since, in their view, it does not require organizations to facilitate contraceptive coverage except by submitting a self-certification form or notice, and requiring compliance was the least restrictive means of advancing the compelling interest of providing contraceptive access to women covered by objecting entities' plans.

The Departments have examined further, including in light of public comments, the issue of whether requiring compliance with the combination of the contraceptive Mandate and the accommodation process imposes a substantial burden on entities that object to both, and is the least restrictive means of advancing a compelling government interest. The Departments now reaffirm the conclusion set forth in the Religious IFC, that requiring certain religiously objecting entities or individuals to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA.

a. Substantial Burden

The Departments concur with the description of substantial burdens expressed recently by the Department of Justice:

A governmental action substantially burdens an exercise of religion under RFRA if it bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice.

Because the government cannot second-guess the reasonableness of a religious belief or the adherent's assessment of the connection between the government mandate and the underlying religious belief, the substantial burden test focuses on the extent of governmental compulsion involved. In general, a government action that bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, will qualify as a substantial burden on the exercise of religion.¹⁶

The Mandate and accommodation under the previous regulation forced

certain non-exempt religious entities to choose between complying with the Mandate, complying with the accommodation, or facing significant penalties. Various entities sincerely contended, in litigation or in public comments, that complying with either the Mandate or the accommodation was inconsistent with their religious observance or practice. The Departments have concluded that withholding an exemption from those entities has imposed a substantial burden on their exercise of religion, either by compelling an act inconsistent with that observance or practice, or by substantially pressuring the adherents to modify such observance or practice. To this extent, the Departments believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing substantial burden, to the burdens that an entity faces when it opposes, on the basis of its religious beliefs, complying with the Mandate or participating in the accommodation process, and is subject to penalties or disadvantages that would have applied in this context if it chose neither. *See also Sharpe Holdings*, 801 F.3d at 942. Likewise, reconsideration of these issues has also led the Departments to conclude that the Mandate imposes a substantial burden on the religious beliefs of an individual employee who opposes coverage of some (or all) contraceptives in his or her plan on the basis of his or her religious beliefs, and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because the Mandate requires that employer or issuer to provide a plan that covers all FDA-approved contraceptives. The Departments disagree with commenters that contend the accommodation did not impose a substantial burden on religiously objecting entities, and agree with other commenters and some courts and judges that concluded the accommodation can be seen as imposing a substantial burden on religious exercise in many instances.

b. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have concluded, after reassessing the relevant interests and, in light of the public comments received, that it does not. This is based on several independent reasons.

First, as discussed above, the structure of section 2713(a)(4) and the ACA evince a desire by Congress to

¹⁶ *See* Federal Law Protections for Religious Liberty, 82 FR 49668, 49669 (Oct. 26, 2017).

grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4). This informs the Departments' assessment of whether the interest in mandating the coverage constitutes a compelling interest, as doing so imposes a substantial burden on religious exercise. As the Department of Justice has explained, "[t]he strict scrutiny standard applicable to RFRA is exceptionally demanding," and "[o]nly those interests of the highest order can outweigh legitimate claims to the free exercise of religion, and such interests must be evaluated not in broad generalities but as applied to the particular adherent."¹⁷

Second, since the day the contraceptive Mandate came into effect in 2011, the Mandate has not applied in many circumstances. To begin, the ACA does not apply the Mandate, or any part of the preventive services coverage requirements, to grandfathered plans. To continue, the Departments under the last Administration provided exemptions to the Mandate and expanded those exemptions through multiple rulemaking processes. Those rulemaking processes included an accommodation that effectively left employees of many non-exempt religious nonprofit entities without contraceptive coverage, in particular with respect to self-insured church plans exempt from ERISA. Under the previous accommodation, once a self-insured church plan filed a self-certification or notice, the accommodation relieved it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would generally have transferred the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments recognized that they lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to health insurance issuers, but does not apply to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church

plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs of those plans to provide such coverage, led to significant disparity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

Third party administrators for some, but not all, religious nonprofit organizations were subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they administer a self-insured church plan. Notably, many of those nonprofit organizations were not houses of worship or integrated auxiliaries. Under section 3(33)(C) of ERISA, organizations whose employees participate in self-insured church plans need not be churches so long as they are controlled by or "share[] common religious bonds and convictions with" a church or convention or association of churches. The effect is that many similar religious organizations were being treated differently with respect to their employees receiving contraceptive coverage based solely on whether organization employees participate in a church plan.

This arrangement encompassed potentially hundreds of religious nonprofit organizations that were not covered by the exemption for houses of worship and integrated auxiliaries. For example, the Departments were sued by two large self-insured church plans—Guidestone and Christian Brothers.¹⁸ Guidestone is a plan organized by the Southern Baptist convention that covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not. Christian Brothers is a plan that covers Catholic churches and integrated auxiliaries and has said in litigation that it covers about 500 additional entities that are not exempt as churches. In several other lawsuits challenging the Mandate, the previous Administration took the position that some plans established and maintained by houses of worship but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government "has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time." *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

¹⁸ The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

Third, the Departments now believe the administrative record on which the Mandate rested was—and remains—insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. The Mandate is not narrowly tailored to advance the government's interests and appears both overinclusive and underinclusive. It includes some entities where a contraceptive coverage requirement seems unlikely to be effective, such as religious organizations of certain faiths, which, according to commenters, primarily hire persons who agree with their religious views or make their dedication to their religious views known to potential employees who are expected to respect those views. The Mandate also does not apply to a significant number of entities encompassing many employees and for-profit businesses, such as grandfathered plans. And it does not appear to target the population defined, at the time the Guidelines were developed, as being the most at-risk of unintended pregnancy, that is, "women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority."¹⁹ Rather than focusing on this group, the Mandate is a broad-sweeping requirement across employer-provided coverage and the individual and group health insurance markets.

The Department received conflicting comments on this issue. Some commenters agreed that the government does not have a compelling interest in applying the Mandate to objecting religious employers. They noted that the expanded exemptions will impact only a small fraction of women otherwise affected by the Mandate and argued that refusing to provide those exemptions would fail to satisfy the compelling interest test. Other commenters, however, argued that the government has a broader interest in the Mandate because all women should be considered at-risk of unintended pregnancy. But the Institute of Medicine (IOM), in discussing whether contraceptive coverage is needed, provided a very specific definition of the population of women most at-risk of unintended pregnancy.²⁰ The Departments believe it is appropriate to consider the government's interest in

¹⁹ Institute of Medicine, "Clinical Preventive Services for Women: Closing the Gaps" at 102 (2011).

²⁰ Id.

¹⁷ Id. at 49670.

the contraceptive coverage requirement using the definition that formed the basis of that requirement and the justifications the Departments have offered for it since 2011. The Mandate, by its own terms, applies not just to women most at-risk of unintended pregnancy as identified by the IOM, but applies to any non-grandfathered “group health plan and a health insurance issuer offering group or individual health insurance coverage.” PHS Act section 2713(a). Similarly, the exemptions and accommodation in previous rules, and the expanded exemptions in these rules, do not apply only to coverage for women most at-risk of unintended pregnancy, but to plans where a qualifying objection exists based on sincerely held religious beliefs without regard to the types of women covered in those plans. Seen in this light, the Departments believe there is a serious question whether the administrative record supports the conclusion that the Mandate, as applied to religious objectors encompassed by the expanded exemptions, is narrowly tailored to achieve the interests previously identified by the government. Whether and to what extent it is certain that an interest in health is advanced by refraining from providing expanded religious exemptions is discussed in more detail below in section II.F., Health Effects of Contraception and Pregnancy.

Fourth, the availability of contraceptive coverage from other possible sources—including some objecting entities that are willing to provide some (but not all) contraceptives, or from other governmental programs for low-income women—detracts from the government’s interest to refuse to expand exemptions to the Mandate. The Guttmacher Institute recently published a study that concluded, “[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,” and “there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.”²¹ In discussing why they did not see such an effect from the Mandate, the authors suggested that “[p]rior to the

implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use. In addition, cost is not the only barrier to accessing a full range of method options,” and “[t]he fact that income is not associated with use of most other methods [besides male sterilization and withdrawal] obtained through health care settings may reflect broader access to affordable and/or free contraception made possible through programs such as Title X.”

Fifth, the Departments previously created the accommodation, in part, as a way to provide for payments of contraceptives and sterilization in a way that is “seamless” with the coverage that eligible employers provide to their plan participants and their beneficiaries. (80 FR 41318). As noted above, some commenters contended that seamlessness between contraceptive coverage and employer sponsored insurance is important and is a compelling governmental interest, while other commenters disagreed. Neither Congress, nor the Departments in other contexts, have concluded that seamlessness, as such, is a compelling interest in the federal government’s delivery of contraceptive coverage. For example, the preventive services Mandate itself does not require contraceptive coverage and does not apply to grandfathered plans, thereby failing to guarantee seamless contraceptive coverage. The exemption for houses of worship and integrated auxiliaries, and the application of the accommodation to certain self-insured church plans, also represents a failure to achieve seamless contraceptive coverage. HHS’s Title X program provides contraceptive coverage in a way that is not necessarily seamless with beneficiaries’ employer sponsored insurance plans. After reviewing the public comments and reconsidering this issue, the Departments no longer believe that if a woman working for an objecting religious employer receives contraceptive access in ways that are not seamless to her employer sponsored insurance, a compelling government interest has nevertheless been undermined. Therefore the Departments conclude that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides

employers’ religious objections to the contraceptive Mandate.

Some commenters contended that obtaining contraceptive coverage from other sources could be more difficult or more expensive for women than obtaining it from their group health plan or health insurance plan. The Departments do not believe that such differences rise to the level of a compelling interest or make it inappropriate for us to issue the expanded exemptions set forth in these final rules. Instead, after considering this issue, the Departments conclude that the religious liberty interests that would be infringed if we do not offer the expanded exemptions are not overridden by the impact on those who will no longer obtain contraceptives through their employer sponsored coverage as a result. This is discussed in more detail in following section, II.D., Burdens on Third Parties.

D. Burdens on Third Parties

The Departments received a number of comments on the question of burdens that these rules might impose on third parties. Some commenters asserted that the expanded exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might not otherwise receive contraceptive coverage with no cost-sharing. These included commenters agreeing with the Departments’ explanations in the Religious IFC, stating that unintended pregnancies were decreasing before the Mandate was implemented, and asserting that any benefit that third parties might receive in getting contraceptive coverage does not justify forcing religious persons to provide such products in violation of their beliefs. Other commenters disagreed, asserting that the expanded exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more unintended pregnancies,²² births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as those found in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as

²¹ M.L. Kavanaugh et al., Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, 97 *Contraception* 14, 14–21 (2018), available at [http://www.contraceptionjournal.org/article/S0010-7824\(17\)30478-X/pdf](http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf).

²² Some commenters attempted to quantify the costs of unintended pregnancy, but failed to persuasively estimate the population of women that this exemption may affect.

prioritizing religious liberty of exempted entities over the religious liberty, conscience, or choices of women who would not receive contraceptive coverage where an exemption is used.

The Departments note that the exemptions in the Religious IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these final rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. HHS exercised discretion granted to HRSA by the Congress to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits. But Congress did not create a right to receive contraceptive coverage from other private citizens through PHS Act section 2713, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to benefit other private parties, does not prevent the government from relieving some or all of the burden of its Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Religious IFC and these rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third-party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not

ultimately benefit, notwithstanding any expanded exemptions—including through grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris v. McRae*, 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the Government refrain from requiring private citizens, in violation of their religious beliefs, to cover contraception for other citizens. *Cf. Rust v. Sullivan*, 500 U.S. 173, 192–93 (1991) (“A refusal to fund protected activity, without more, cannot be equated with the imposition of a ‘penalty’ on that activity.”). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting religious objections to such governmental mandates, especially where, as here, the mandate is not an explicit statutory requirement.²³ The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these final rules.

As the Department of Justice has observed, the fact that exemptions may relieve a religious adherent from conferring a benefit on a third party “does not categorically render an exemption unavailable,” and RFRA still applies.²⁴ The Departments conclusion on this matter is consistent with the Supreme Court’s observation that RFRA may require exemptions even from laws requiring claimants “to confer benefits on third parties.” *See Hobby Lobby*, 134 S. Ct. at 2781 n.37. Here, no law contains such a requirement, but the Mandate is derived from an administrative exercise of discretion that Congress charged HRSA and the Departments with exercising. Burdens that may affect third parties as a result of revisiting the exercise of agency discretion may be relevant to the RFRA analysis, but they cannot be dispositive. “Otherwise, for example, the

Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).” *Id.*

When government relieves burdens on religious exercise, it does not violate the Establishment Clause; rather, “it follows the best of our traditions.” *Zorach v. Clauson*, 343 U.S. 306, 314 (1952). The Supreme Court’s cases “leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice.” *Board of Educ. of Kiryas Joel Village Sch. Dist. v. Grumet*, 512 U.S. 687, 705 (1994). Rather, the Supreme Court “has long recognized that the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause.” *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334 (1987) (quoting *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136, 144–45 (1987)). “[T]here is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.” *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005) (internal quotation omitted). Thus, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII’s prohibition against discrimination in employment on the basis of religion, *see Amos*, 483 U.S. at 335–39; a state property tax exemption for religious organizations, *see Walz v. Tax Comm’n of City of New York*, 397 U.S. 664, 672–80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach*, 343 U.S. at 315.

Before 2012 (when HRSA’s Guidelines went into effect), there was no federal women’s preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA’s Guidelines, and it did not require any preventive services required under PHS

²³ *See, for example, Planned Parenthood Ariz., Inc. v. Am. Ass’n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (“[A] woman’s right to an abortion or to contraception does not compel a private person or entity to facilitate either.”).

²⁴ *See Federal Law Protections for Religious Liberty*, 82 FR at 49670.

Act section 2713 to be covered by grandfathered plans. Many States do not impose contraceptive coverage mandates, or they offer religious exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or State courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters said that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others said that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to states or local governments. We are not aware of instances where the various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage (other than through the Religious and Moral IFCs), have been determined to cause a cognizable injury to state or local governments. Some states that were opposed to the IFCs submitted comments objecting to the potential impacts on their programs resulting

from the expanded exemptions, but they did not adequately demonstrate that such impacts would occur, and they did not explain whether, or to what extent, they were impacted by the other kinds of instances mentioned above in which no federal mandate of contraceptive coverage has applied to certain plans. The Departments find no legal prohibition on finalizing these rules based on the speculative suggestion of an impact on state or local governments, and we disagree with the suggestion that once we have exercised our discretion to deny exemptions—no matter how recently or incompletely—we cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, these expanded exemptions apply only to a small fraction of entities to which the Mandate would otherwise apply—those with qualifying religious objections. Public comments did not provide reliable data on how many entities would use these expanded religious exemptions, in which states women in such plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would have to cover. As mentioned above, at least one study, published by the Guttmacher Institute, concluded the Mandate has caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the expanded exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates.

In the discussion below concerning estimated economic impacts of these rules, the Departments explain there is not reliable data available to accurately estimate the number of women who may lose contraceptive coverage under these rules, and the Departments set forth various reasons why it is difficult to know how many entities will use these exemptions or how many women will be impacted by those decisions.

Solely for the purposes of determining whether the rules have a significant economic impact under Executive Order 12,866, and in order to estimate the broadest possible impact so as to determine the applicability of the procedures set forth in that Executive Order, the Departments propose that the rules will affect no more than 126,400 women of childbearing age who use contraceptives covered by the Guidelines, and conclude the economic impact falls well below \$100 million. As explained below, that estimate assumes that a certain percentage of employers which did not cover contraceptives before the ACA will use these exemptions based on sincerely held religious beliefs. The Departments do not actually know that such entities will do so, however, or that they operate based on sincerely held religious beliefs against contraceptive coverage. The Departments also explain that other exemptions unaffected by these rules may encompass many or most women potentially affected by the expanded exemptions. In other words, the houses of worship and integrated auxiliaries exemption, the accommodation's failure to require contraceptive coverage in certain self-insured church plans, the non-applicability of PHS Act section 2713 to grandfathered plans, and the permanent injunctive relief many religious litigants have received against section 2713(a)(4), may encompass a large percentage of women potentially affected by religious objections, and therefore many women in those plans may not be impacted by these rules at all. In addition, even if 126,400 women might be affected by these rules, that number constitutes less than 0.1% of all women in the United States.²⁵ This suggests that if these rules have any impact on state or local governments, it will be statistically de minimus. The Departments conclude that there is insufficient evidence of a potential negative impact of these rules on state and local governments to override the appropriateness of deciding to finalize these rules.

Some commenters contended that the expanded exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions

²⁵ U.S. Census Bureau, "Quick Facts: Population Estimates, July 1, 2017" (estimating 325,719,178 persons in the U.S., 50.8% of which are female), available at <https://www.census.gov/quickfacts/fact/table/US/PST045217>.

would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these final rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The expanded exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead they allow entities that have sincerely held religious objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

These commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII “does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women”). Second, these rules create no disparate impact. The women's preventive services mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inures to the specific benefit of women—men are denied any benefit from that section. Both before and after these final rules, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or male contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions are expanded to encompass religious objections. The previous regulations, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that few women of childbearing age in the

country will be affected by these expanded exemptions.²⁶ In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters observed that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some objected to the suggestion in the Religious IFC that many forms of contraceptives are available for around \$50 per month and other forms, though they bear a higher one-time cost, cost a similar amount over the duration of use. But some of those commenters cited sources maintaining that birth control pills can cost up to \$600 per year (that is, \$50 per month), and said that IUDs, which can last three to six years or more,²⁷ can cost \$1,100 (that is, less than \$50 per month over the duration of use). Some commenters said that, for lower income women, contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or

because the programs were not intended to absorb privately insured individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, pointing out that some government programs that provide family planning have income and eligibility thresholds, so that women earning certain amounts above those levels would need to pay full cost for contraceptives if they were no longer covered in their health plans.

The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules. In addition, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed regulation to amend the regulations governing its Title X family planning program. The proposed regulation would amend the definition of “low income family”—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions (see 83 FR 25502). If that regulation is finalized as proposed, it could further reduce any potential effect of these final rules on women's access to contraceptives. That proposal also demonstrates that the government has other means available to it for increasing women's access to contraception. Some of those means are less restrictive of religious exercise than imposition of the contraceptive Mandate on employers with sincerely held religious objections to providing such coverage.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS “shall not promulgate any regulation” that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,” “impedes timely access to health care services,” “interferes with communications regarding a full range of treatment options between the patient and the provider,” “restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,” “violates the principles of informed consent and the ethical standards of health care professionals,” or “limits the

²⁶ Below, the Departments estimate that no more than 126,400 women of childbearing age will be affected by the expanded exemptions. As noted above, this is less than 0.1% of the over 165 million women in the United States. The Departments previously estimated that, at most 120,000 women of childbearing age would be affected by the expanded exemptions. *See Religious IFC*, 82 FR 47,823–84.

²⁷ *See, for example*, Planned Parenthood, “IUD,” <https://www.plannedparenthood.org/learn/birth-control/iud>.

availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. 18114. Such commenters urged, for example, that the Religious IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections. The Departments, which administer both ACA section 1554 and PHS Act section 2713, did not conclude that the exemptions or accommodations in those regulations violated section 1554. Moreover, the decision not to impose a governmental mandate is not the "creation" of a "barrier," especially when that mandate requires private citizens to provide services to other private citizens. Nor, in any event, are the exemptions from the Mandate unreasonable. Section 1554 of the ACA does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 prohibit the Departments from providing exemptions for burdens on religious exercise, or, as is the case here, from refraining to impose the Mandate in cases where religious exercise would be burdened by it. In light of RFRA and the First Amendment, providing religious exemptions is a reasonable administrative response in the context of this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts. Religious exemptions from federal mandates in sensitive health contexts have existed in federal laws for decades, and President Obama referenced them when he issued Executive Order 13535 (March 24, 2010), declaring that, under the ACA, "longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a-7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111-8) remain intact," and that "[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS." While the text of Executive Order 13535 does not require the expanded exemptions issued in these rules, the expanded exemptions are, as explained

below, consistent with longstanding federal laws to protect religious beliefs.

In short, the Departments do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

Members of the public have widely divergent views on whether expanding the exemptions is good public policy. Some commenters said the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind expanding the exemptions and arguing that the exemptions would not interfere with the physician-patient relationship. For all the reasons explained at length in this preamble, the Departments have determined that these rules are good policy. Because of the importance of the religious liberty values being accommodated, the limited impact of these rules, and uncertainty about the impact of the Mandate overall according to some studies, the Departments do not believe these rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

E. Interim Final Rulemaking

The Departments received several comments about their decision to issue the Religious IFC as interim final rules with requests for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Religious IFC in that way, agreeing that the Departments had explicit statutory authority to do so, good cause under the Administrative Procedure Act (APA), or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe legal authority existed to issue the Religious IFC as interim final rules.

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Religious IFC, the Departments issued three interim final rules implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Religious IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Religious IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules are being issued after receiving and thoroughly considering public comments as requested in the Religious IFC. These final rules therefore comply with the APA's notice and comment requirements.

F. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause or are associated with an increased risk of depression,²⁸ venous thromboembolic

²⁸ Commenters cited Charlotte Wessel Skovlund et al., "Association of Hormonal Contraception with Depression," 73 *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) ("Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression,

disease,²⁹ fatal pulmonary embolism,³⁰ thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),³¹ hypertension,³² HIV-1 acquisition and transmission,³³ and

suggesting depression as a potential adverse effect of hormonal contraceptive use.”).

²⁹ Commenters cited the Practice Committee of the American Society for Reproductive Medicine, “Hormonal Contraception: Recent Advances and Controversies,” 82 *Fertility and Sterility* S20, S26 (2004); V.A. Van Hylckama et al., “The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,” 339 *Brit. Med. J.* 339b2921 (2009); Y. Vinogradova et al., “Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,” 350 *Brit. Med. J.* 350h2135 (2015) (“Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.”); Ø. Lidegaard et al., “Hormonal contraception and risk of venous thromboembolism: national follow-up study,” 339 *Brit. Med. J.* b2890 (2009); M. de Bastos et al., “Combined oral contraceptives: venous thrombosis,” *Cochrane Database Syst. Rev.* (no. 3, 2014). CD010813. doi: 10.1002/14651858.CD010813.pub2, available at <https://www.ncbi.nlm.nih.gov/pubmed/?term=24590565>; L.J. Havrilesky et al., “Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,” Agency for Healthcare Research and Quality, Report No. 13-E002-EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocustp.html>; and Robert A. Hatcher et al., *Contraceptive Technology* 405-07 (Ardent Media 18th rev. ed. 2004).

³⁰ Commenters cited N.R. Poulter, “Risk of Fatal Pulmonary Embolism with Oral Contraceptives,” 355 *Lancet* 2088 (2000).

³¹ Commenters cited Ø. Lidegaard et al., “Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception,” 366 *N. Eng. J. Med.* 2257, 2257 (2012) (risks “increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 µg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 µg”); Practice Committee of the American Society for Reproductive Medicine, “Hormonal Contraception”; M. Vessey et al., “Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,” 362 *Lancet* 185, 185-91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, “Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,” 349 *Lancet* 1202, 1202-09(1997); K.M. Curtis et al., Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review, 73 *Contraception* 73179, 179-88 (2006); L.A. Gillum et al., “Ischemic stroke risk with oral contraceptives: A meta analysis,” 284 *JAMA* 72, 72-78 (2000), available at <https://www.ncbi.nlm.nih.gov/pubmed/10872016>; and Robert A. Hatcher et al., *Contraceptive Technology* 404-05, 445 (Ardent Media 18th rev. ed. 2004).

³² Commenters cited Robert A. Hatcher et al., *Contraceptive Technology* 407, 445 (Ardent Media 18th rev. ed. 2004).

³³ Commenters cited Renee Heffron et al., “Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study,” 12 *Lancet Infectious Diseases* 19, 24 (2012) (“Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV-1 acquisition by women and HIV-1 transmission from women to men.”); and “Hormonal Contraception Doubles HIV Risk, Study Suggests,” *Science Daily* (Oct. 4, 2011),

breast, cervical, and liver cancers.³⁴ Some commenters also observed that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that contraceptive access does not reduce unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 IOM Report’s discussions of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality.³⁵ Commenters also said studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer,³⁶ and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory

<https://www.sciencedaily.com/releases/2011/10/111003195253.htm>.

³⁴ Commenters cited “Oral Contraceptives and Cancer Risk” (Mar. 21, 2012, National Cancer Institute (reviewed Feb. 22, 2018), <https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet>; L.J. Havrilesky et al., “Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,” Agency for Healthcare Research and Quality, Report No. 13-E002-EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocustp.html>; S.N. Bhupathiraju et al., “Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses’ Health Study,” 106 *Am. J. Pub. Health* 1631, 1631-37 (2016); The World Health Organization Department of Reproductive Health and Research, “The Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment”, World Health Organization (Sept. 2005), http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf; and the American Cancer Society, “Known and Probably Human Carcinogens,” American Cancer Society (rev. Nov. 3, 2016), <https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html>.

³⁵ Citing, e.g., Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. *JAMA* 2006;295:1809-23, and John Hopkins Bloomberg Public Health School of Health, Contraception Use Averts 272,000 Maternal Deaths Worldwide, <https://www.jhsph.edu/news/news-releases/2012/ahmed-contraception.html>.

³⁶ Citing, e.g., Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. *International Journal of Endocrinology and Metabolism*, 11 (1), 41-47.

disease.³⁷ Some commenters said that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters said that, in the Religious IFC, the Departments made incorrect statements concerning scientific studies. For example, some commenters argued there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Religious IFC for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality Report No.: 13-E002-EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR at 47804, the 2013 Agency for Healthcare Research and Quality study, and others, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to take into account both of those studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,³⁸ the purpose for the Departments’ reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or, more specifically, the part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some

³⁷ Citing, e.g., id., and American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women. (2015, January). Committee Opinion Number 615: Access to Contraception. As discussed below, to the extent that contraceptives are prescribed to treat existing health conditions, and not for preventive purposes, the Mandate would not be applicable.

³⁸ 82 FR at 47803-04.

commenters agreed with the quotation, in the Religious IFC, of FDA materials³⁹ that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Religious IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Religious IFC that some persons believe those possible effects are “abortifacient.”

The objection on this issue appears to be partially one of semantics. People disagree about whether to define “conception” or “pregnancy” to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items “abortifacient”—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother’s body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby*, 134 U.S. at 2765 (“The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.”).

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have

sincere religious objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of a sincerely held religious belief under RFRA.⁴⁰ Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA’s statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer expanded religious exemptions with respect to this Mandate.

The Departments also received comments about their discussion of the uncertain effects of the expanded exemptions on teen sexual activity. In this respect, the Departments stated, “With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that ‘[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.’”⁴¹ Some commenters agreed with

⁴⁰ “Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.” *Hobby Lobby*, 134 S. Ct. at 2762–63. “The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.” *Id.* at 2765–66.

⁴¹ Citing J.S. Santelli & A.J. Melnikas, “Teen fertility in transition: recent and historic trends in the United States,” 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at <http://public.econ.duke.edu/~psarcidi/addicted13.pdf>. See also K. Buckles & D. Hungerman, “The Incidental Fertility Effects of School Condom Distribution Programs,” *Nat’l Bureau of Econ. Research Working Paper No. 22322* (June 2016), available at <http://www.nber.org/papers/w22322> (“access to condoms in schools increases teen fertility by about 10 percent” and increased sexually transmitted infections).

this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that denying expanded exemptions to the Mandate is not a narrowly tailored way to advance the Government’s interests in reducing teen pregnancy, and suggesting there are means of doing so that are less restrictive of religious exercise.⁴² Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.⁴³

Many commenters opposing the Religious IFC misunderstood the Departments’ discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, we note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments’ conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including but not limited to reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline), and concluded “that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.”⁴⁴ One

⁴² See Helen Alvaré, “No Compelling Interest: The ‘Birth Control’ Mandate and Religious Freedom,” 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

⁴³ See, for example, Lindberg L., Santelli J., “Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,” 59 *J. Adolescent Health* 577–83 (Nov. 2016), <https://doi.org/10.1016/j.jadohealth.2016.06.024>; see also Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, www.regulations.gov (discussing teen pregnancy data from Colorado).

⁴⁴ Kearney MS and Levine PB, “Investigating recent trends in the U.S. birth rate,” 41 *J. Health*

³⁹ FDA’s guide “Birth Control: Medicines To Help You,” specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and “may also work . . . by preventing attachment (implantation) to the womb (uterus)” of a human embryo after fertilization. Available at <https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm>.

study found that during the teen pregnancy decline between 2007–2012, teen sexual activity was also decreasing.⁴⁵ One study concluded that falling unemployment rates in the 1990s accounted for 85% of the decrease in rates of first births among 18–19 year-old African Americans.⁴⁶ Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.⁴⁷ One study concluded that an “increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.”⁴⁸ Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.⁴⁹ Some commenters also cited studies, which are not limited to the issue of teen pregnancy, that have found many women who have abortions report that they were using contraceptives when they became pregnant.⁵⁰

Econ. 15–29 (2015), available at <https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041>.

⁴⁵ See, for example, K. Ethier et al., “Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,” 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at <http://dx.doi.org/10.15585/mmwr.mm665152a1> (“Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall. . . .”).

⁴⁶ Colen CG, Geronimus AT, and Phipps MG, “Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,” 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at <https://www.sciencedirect.com/science/article/pii/S027795360600205X>.

⁴⁷ Atkins DN and Wilkins VM, “Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,” 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at <https://academic.oup.com/jpart/article-abstract/23/4/771/963674>.

⁴⁸ E. Collins & B. Herchbein, “The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,” *U. Mich. Pop. Studies Ctr. Report* 11–737 (May 2011), available at <https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf> (“[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women”).

⁴⁹ See D. Paton & L. Wright, “The effect of spending cuts on teen pregnancy,” 54 *J. Health Econ.* 135, 135–46 (2017), available at <https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551> (“Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates”).

⁵⁰ Commenters cited, for example, Guttmacher Institute, “Fact Sheet: Induced Abortion in the United States” (Jan. 2018) (“Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant”), available at https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women’s preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of the public comments has reinforced the Departments’ conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing religious exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments for implementing the ACA.

G. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promotes the health and equality of women, especially low income women and promotes female participation and equality in the workforce. Other commenters contended that there was insufficient evidence that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed the study quoted above, published and revised by the Guttmacher Institute in October 2017, concluding that through 2014 there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy, that there was no significant shift from less

effective to more effective methods, and that it was “unclear” whether this Mandate impacted contraceptive use because there was no significant increase in the use of contraceptive methods the Mandate covered.⁵¹ These commenters also noted that, in the 29 States where contraceptive coverage mandates have been imposed statewide,⁵² those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.⁵³ Other commenters, however, disputed the significance of these state statistics, noting that of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the expanded exemptions in these rules might have on the Mandate more broadly. The state mandates apply to a very large number of plans and plan participants, notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups are, and have been, exempt from the federal Mandate prior to the Religious IFC. The exemptions as set forth in the Religious IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might

⁵¹ Kavanaugh, 97 *Contraception* at 14–21.

⁵² See Guttmacher Institute, “Insurance Coverage of Contraceptives” (June 11, 2018); Kaiser Family Foundation, “State Requirements for Insurance Coverage of Contraceptives,” Henry J Kaiser Family Foundation (Jan. 1, 2018), <https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

⁵³ See Michael J. New, “Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,” 13 *Ave Maria L. Rev.* 345 (2015), available at <http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf>.

result from a broad contraceptive coverage mandate.

Some commenters expressed concern that providing exemptions to the Mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, PHS Act section 2713(a)(2) requires coverage of “immunizations,” and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting religious beliefs from certain health care mandates concerning issues such as sterilization, abortion and birth control.

Some commenters took issue with the conclusion set forth in the Religious IFC, which is similar to that asserted in the 2017 Guttmacher study, that “[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.” They observed that more women have coverage of contraceptives and contraception counseling under the Mandate and that more contraceptives are provided without co-pays than before. Still other commenters argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of

women delay or forego health care overall under the ACA⁵⁴ and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also argued that studies show that decreases in unintended pregnancies are due to broader access of contraceptives. Finally, some commenters argued that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on our review, it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women’s preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, we conclude that the Religious IFC and these final rules—which merely withdraw the Mandate’s requirement from what appears to be a small group of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. We also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, are an appropriate exercise of the Departments’ discretion.

Moreover, we conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules will provide tangible protections for religious liberty, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise. The Departments view the

provision of those protections to preserve religious exercise in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for religious exercise set forth in the Religious IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

III. Description of the Text of the Regulations and Response to Additional Public Comments

Here, the Departments describe the regulatory text set forth prior to the Religious IFC, the regulations from that IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments’ response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. As noted above, various members of the public provided comments that were supportive, or critical, of the Religious IFC overall, or of significant policies pertaining to those regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

A. Restatement of Statutory Requirements of PHS Act Section 2713(a) and (a)(4) (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified these restatements to more closely align them with the text of PHS Act section 2713(a) and (a)(4).

Previous versions of these rules had varied from the statutory language. PHS Act section 2713(a) and (a)(4) require group health plans and health insurance issuers offering coverage to provide coverage without cost sharing for “such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines” supported by HRSA. In comparison, the previous version of regulatory restatements of this language (as drawn from 45 CFR 147.130(a)(1)

⁵⁴ Citing, for example, Adelle Simmons et al., “The Affordable Care Act: Promoting Better Health for Women,” Table 1, Assistant Secretary for Planning and Evaluation (June 14, 2016), <https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf>.

and (a)(1)(iv)) stated the coverage must include “evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by” HRSA. The Religious IFC amended this language to state, parallel to the language in section 2713(a)(4), that the coverage must include “such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by” HRSA.

These rules adopt as final, without change, the provisions in the Religious IFC amending 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). In this way, the regulatory text better conforms to the statutory language. In paragraph (a)(1) of the final regulations, instead of saying “must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements . . . with respect to those items and services:”, the regulation now tracks the statutory language by saying “must provide coverage for and must not impose any cost-sharing requirements . . . for—”. By eliminating the language “coverage for all of the following items and services,” and “with respect to those items and services,” the Departments do not intend that coverage for specified items and services will not be required, but we simply intend to simplify the text of the regulation to track the statute and avoid duplicative language.

By specifying that paragraph (a)(1)(iv) concerning the women’s preventive services Guidelines encompasses “such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132,” the regulatory text also better tracks the statutory language that the Guidelines are for “such additional” preventive services as HRSA may “provide[] for” and “support[].” This text also eliminates language, not found in the statute, that the Guidelines are “evidence-informed” and “binding.” Congress did not include the word “binding” in PHS Act section 2713, and did include the words “evidence-based” or “evidence-informed” in section 2713(a)(1) and (a)(3), but omitted such terms from section 2713(a)(4). In this way, the regulatory text better comports with the scope of the statutory text. This text of paragraph (a)(1)(iv) also

acknowledges that the Departments have decided Guidelines issued under section 2713(a)(4) will not be provided for or supported to the extent they exceed the exemptions and accommodation set forth in 45 CFR 147.131 and 147.132. Previous versions of the regulation placed that limit in 45 CFR 147.130(a)(1), but did not reiterate it in § 147.130(a)(1)(iv). To clearly set forth the applicability of the exemptions and accommodation, the Departments adopt as final the Religious IFC language, which included the language “subject to §§ 147.131 and 147.132” in both § 147.130(a)(1) and § 147.130(a)(1)(iv). Because these final rules adopt as final the Religious IFC language which includes the exemptions and accommodation in both §§ 147.131 and 147.132, and not just in § 147.131 as under the previous rules, the Departments correspondingly included references to both sections in this part.

Some commenters supported restoring the statutory language from PHS Act section 2713(a) and (a)(4) in the regulatory restatements of that language. Other commenters opposed doing so, asserting that Guidelines issued pursuant to section 2713(a)(4) must be “evidence-informed” and “binding.” The Departments disagree with the position that, even though Congress omitted those terms from section 2713(a)(4), their regulatory restatement of the statutory requirement should include those terms. Instead, the Departments conclude that it is more appropriate for the regulatory restatements of section 2713(a)(4) to track the statutory language in this regard, namely, “as provided for in comprehensive guidelines supported by [HRSA] for purposes of” that paragraph.

B. Prefatory Language of Religious Exemptions (45 CFR 147.132(a)(1))

These final rules adopt as final, with changes based on comments as set forth below, the regulatory provision in the Religious IFC that moved the religious exemption from 45 CFR 147.131(a) to 45 CFR 147.132.

In the previous regulations, the exemption stated, at § 147.131(a), that HRSA’s Guidelines “may establish an exemption” for the health plan or coverage of a “religious employer,” defined as “an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code.” The Religious IFC moved the exemption to a new § 147.132, in which paragraph (a) discussed objecting entities, paragraph (b) discussed objecting individuals,

paragraph (c) set forth a definition, and paragraph (d) discussed severability. The prefatory language to § 147.132(a)(1) stated that HRSA’s Guidelines “must not provide for or support the requirement of coverage or payments for contraceptive services” for the health plan or coverage of an “objecting organization,” and thus that HRSA “will exempt” such an organization from the contraceptive coverage requirements of the Guidelines. The remainder of paragraph (a)(1), which is discussed in greater detail below, describes what entities are included as objecting organizations.

This language not only specifies that certain entities are “exempt,” but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women’s preventive services coverage only “as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.” To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are “exempt” by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as “exempt,” and in referring to the “exemption” encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer’s employees. This explanation is consistent with how prior regulations have worked by means of similar language. When sections § 147.132(a)(1) and (a)(1)(i) specify that “[a] group health plan,” “health insurance coverage provided in connection with a group health plan,” and “health insurance coverage offered or arranged by an objecting organization” are exempt “to the extent” of the objections “as specified in paragraph (a)(2),” that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv)), the plan

sponsor, issuer, and plan covered in the exemption of § 147.132(a)(1) and (a)(1)(i) would face no penalty as a result of omitting certain contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while the objection of a plan sponsor (or entity that arranges coverage under the plan, as applicable) removes penalties from that plan's issuer, it only does so for that plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.132(a)(1)(iii) is included below.

The exemptions in § 147.132(a)(1) apply “to the extent” of the objecting entities’ sincerely held religious convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters said it was unclear whether the plans of entities or individuals that religiously object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite religious objection against some but not all contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects, and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules, the Departments finalize the prefatory language of § 147.132(a) with the following change, so that the final rules state that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, “to the extent of the objections specified below.”

The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying “to the extent” of the objection(s).

C. Scope of Religious Exemptions and Requirements for Exempt Entities (45 CFR 147.132)

In 45 CFR 147.132(a)(1)(i) through (iii) and (b), the Religious IFC expands the exemption to plans of additional entities and individuals not encompassed by the exemption set forth in the regulations

prior to the Religious IFC. Specific entities to which the expanded exemptions apply are discussed below.

The exemptions contained in previous regulations, at § 147.131(a), did not require exempt entities to submit any particular self-certification or notice, either to the government or to their issuer or third party administrator, in order to obtain or qualify for the exemption. Similarly, under the expanded exemptions in § 147.132, the Religious IFC did not require exempt entities to comply with a self-certification process. We finalize that approach in this respect without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.⁵⁵ Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosure documents must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported the expanded exemption's approach which maintained the policy of the previous exemption in not requiring exempt entities to comply with a self-certification process. They suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to religious objections to the self-certification process itself. Commenters also stated that requiring an exemption form for

exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters, however, favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process. Some commenters asked that the government publish a list of entities that claim the exemption.

The Departments believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption. The Departments believe the approach under the previous exemption is appropriate for the expanded exemption. Adding a self-certification or notice to the exemption process would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices were to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries in plans that reduce or eliminate contraceptive benefits as a result of the exemption will know whether their health plan claims an exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these rules to continue to not require notices or self-certifications for using the exemption.

⁵⁵ See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 102–3, & 104b–3(d), and 29 CFR 2590.715–2715. See also 45 CFR 147.200 (requiring disclosure of the “exceptions, reductions, and limitations of the coverage,” including group health plans and group and individual issuers).

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these rules. The expanded exemptions in these rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. The rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (Below, these rules discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that, where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed below, the Departments are including, in these final rules, language from the previous regulations protecting issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in and derived from the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship

between exempt entities and their issuers or third party administrators.

Regarding the Religious IFC's expansion of the exemption to other kinds of entities and individuals in general, commenters disagreed about the likely effects of the exemptions on the health coverage market. Some commenters said that expanding the exemptions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or offer only some contraceptives—to houses of worship and integrated auxiliaries; some commenters and litigants said that issuers were doing so. These cases where plans did not need to comply with the Mandate, and the Departments' previous accommodation process allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.⁵⁶

Concerning the prospect raised by commenters of different risk pools between men and women, PHS Act section 2713(a) itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage would be required. These rules do not require issuers to offer products that satisfy religiously objecting entities or individuals; they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to religious entities has been in continual

flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

D. Plan Sponsors in General (45 CFR 147.132(a)(1)(i) Prefatory Text)

With respect to employers and others that sponsor group health plans, in § 147.132(a)(1)(i), the Religious IFC provided exemptions for non-governmental plan sponsors that object to coverage of all, or a subset of, contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs. The Departments finalize the prefatory text of § 147.132(a)(1)(i) without change.

The expanded exemptions covered any kind of non-governmental employer plan sponsor with the requisite objections, stating the exemption encompassed “[a] group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section.” For the sake of clarity, the expanded exemptions also stated that “[s]uch non-governmental plan sponsors include, but are not limited to, the following entities,” followed by an illustrative, non-exhaustive list of non-governmental organizations whose objections qualify the plans they sponsor for an exemption. Each type of such entities, and comments specifically concerning them, are discussed below.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.132(a)(1)(i). Some commenters suggested that the expanded religious exemptions should include government entities. Others disagreed. The Departments are not aware of reasons why it would be appropriate or necessary to offer a religious exemption to governmental employer plan sponsors with respect to the contraceptive Mandate. We are unaware of government entities that would attempt to assert a religious exemption to the Mandate, and it is not clear to us that a governmental entity could do so. Accordingly, we conclude that it is appropriate for us to not further expand the religious exemption to include governmental entities in the religious plan-sponsor exemption.

Nevertheless, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and, thus, to provide

⁵⁶ See also *Real Alternatives v. Sec'y, Dep't of Health & Human Servs.*, 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) (“Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.” (citation and internal quotation marks omitted)).

health coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union, or a sponsor of a multiemployer plan) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization. Some commenters objected to extending the exemption to such entities, arguing that they could not have the same kind of religious objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite religious objection. The Departments conclude that it is appropriate, where the plan sponsor of a union, multiemployer, or similar plan adopts a religious objection using the same procedures that such a plan sponsor might use to make other decisions, that the expanded exemptions should respect that decision by providing an exemption from the Mandate.

E. Houses of Worship and Integrated Auxiliaries (45 CFR 147.132(a)(1)(i)(A))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only “an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.” Section 6033(a)(3)(A)(i) or (iii) of the Code encompasses “churches, their integrated auxiliaries, and conventions or associations of churches,” and “the exclusively religious activities of any religious order.”

The Religious IFC expanded the exemption to include, in § 147.132(a)(1)(i)(A), plans sponsored by “[a] church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.” Most commenters did not oppose the exemptions continuing to include these entities, although some contended that the Departments have no authority to exempt any entity or plan from the Mandate, an objection to which the

Departments respond above. Notably, this exemption exempts “a religious order,” and not merely “the exclusively religious activities of any religious order.” In addition, section 6033(a)(3)(A)(i) specifies that it covers churches, not merely “the exclusively religious activities” of a church. Some religious people might express their beliefs through a church, others might do so through a religious order, and still others might do so through religious bodies that take a different form, structure, or nomenclature based on a different cultural or historical tradition. Cf. *Hosanna-Tabor Evangelical Lutheran Church and School v. E.E.O.C.*, 565 U.S. 171, 198 (2012) (Alito and Kagan, JJ., concurring) (“The term ‘minister’ is commonly used by many Protestant denominations to refer to members of their clergy, but the term is rarely if ever used in this way by Catholics, Jews, Muslims, Hindus, or Buddhists.”). For the purposes of respecting the exercise of religious beliefs, which the expanded exemptions in these rules concern, the Departments find it appropriate that this part of the exemption encompasses religious orders and churches similarly, without limiting the scope of the protection to the exclusively religious activities of either kind of entity. Based on all these considerations, the Departments finalize § 147.132(a)(1)(i)(A) without change.

Moreover, the Departments also finalize the regulatory text to exempt plans “established or maintained by” a house of worship or integrated auxiliary on a plan, not employer, basis. Under previous regulations, the Departments stated that “the availability of the exemption or accommodation [was to] be determined on an employer by employer basis, which the Departments . . . believe[d] best balance[d] the interests of religious employers and eligible organizations and those of employees and their dependents.” (78 FR 39886 (emphasis added)). Therefore, under the prior exemption, if an employer participated in a house of worship’s plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not covered by the exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a “plan established or maintained by a [house of worship].” Upon further consideration, in the Religious IFC, the Departments changed their view on this issue and expanded the exemption for houses of worship and integrated auxiliaries. Under these rules, the Departments intend that,

when this regulation text exempts a plan “established or maintained by” a house of worship or integrated auxiliary, such exemption will no longer “be determined on an employer by employer basis,” but will be determined on a plan basis—that is, by whether the plan is a “plan established or maintained by” a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices, but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the requirement of being integrated auxiliaries. Under this interpretation, houses of worship would not be faced with the potential of having to include, in the plans that they have established and maintained, coverage for services to which they have a religious objection for employees of an affiliated employer participating in the plans.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted to participate in its health plan but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior regulation where with respect to self-insured church plans, hundreds of nonprofit religious entities participating in those plans were provided a mechanism by which their plan participants would not receive contraceptive coverage through the plan or third party administrator.⁵⁷

Therefore, the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

F. Nonprofit Organizations (45 CFR 147.132(a)(1)(i)(B))

The exemption under previous regulations did not encompass nonprofit religious organizations beyond one that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code. The Religious IFC expanded the exemption to include plans sponsored by any other

⁵⁷ See *supra* at II.A.3.

“nonprofit organization.”

§ 147.132(a)(1)(i)(B), if it has the requisite religious objection under § 147.132(a)(2) (see § 147.132(a)(1)(i) introductory text). The Religious IFC also specified in § 147.132(a)(1)(i)(A), as under the prior exemption, that the exemption covers “a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.” (Hereinafter “houses of worship and integrated auxiliaries.”) These rules finalize, without change, the text of § 147.132(a)(1)(i)(A) and (B).

The Departments received comments in support of, and in opposition to, this expansion. Some commenters supported the expansion of the exemptions beyond houses of worship and integrated auxiliaries to other nonprofit organizations with religious objections (referred to herein as “religious nonprofit” organizations, groups or employers). They said that religious belief and exercise in American law has not been limited to worship, that religious people engage in service and social engagement as part of their religious exercise, and, therefore, that the Departments should respect the religiosity of nonprofit groups even when they are not houses of worship and integrated auxiliaries. Some public commenters and litigants have indicated that various religious nonprofit groups possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Other commenters did not support the expansion of exemptions to nonprofit organizations. Some of them described churches as having a special status that should not be extended to religious nonprofit groups. Some others contended that women at nonprofit religious organizations may support or wish to use contraceptives and that if the exemptions are expanded, it would deprive all or most of the employees of various religious nonprofit organizations of contraceptive coverage.

After evaluating the comments, the Departments continue to believe that an expanded exemption is the appropriate administrative response to the substantial burdens on sincere religious beliefs imposed by the contraceptive Mandate, as well as to the litigation objecting to the same. We agree with the comments that religious exercise in this country has long been understood to encompass actions outside of houses of worship and their integrated auxiliaries. The Departments’ previous assertion that the exemptions were intended to respect a certain sphere of church autonomy (80 FR 41325) is not, in itself,

grounds to refuse to extend the exemptions to other nonprofit entities with religious objections. Respect for churches does not preclude respect for other religious entities. Among religious nonprofit organizations, the Departments no longer adhere to our previous assertion that “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.” (78 FR 39874.) It is not clear to the Departments that the percentage of women who work at churches that oppose contraception, but who support contraception, is lower than the percentage of woman who work at nonprofit religious organizations that oppose contraception on religious grounds, but who support contraception. In addition, public comments and litigation reflect that many nonprofit religious organizations publicly describe their religiosity. Government records and those groups’ websites also often reflect those groups’ religious character. If a person who desires contraceptive coverage works at a nonprofit religious organization, the Departments believe it is sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit religious organization that opposes contraceptive coverage to hire a person who the organization knows disagrees with the organization’s view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.⁵⁸

In addition, it is not at all clear to the Departments that expanding the exemptions would, as some commenters asserted, remove contraceptive coverage from employees of many large religious nonprofit organizations. Many large religious nonprofit employers, including but not limited to some Catholic hospitals, notified the Department under the last Administration that they had opted into the accommodation and expressed no objections to doing so. We also received public comments from organizations of similar nonprofit

employers indicating that the accommodation satisfied their religious objections. These final rules leave the accommodation in place as an optional process. Thus, it is not clear to the Departments that all or most of such large nonprofit employers will choose to use the expanded exemption instead of the accommodation. If they continue to use the accommodation, their insurers or third party administrators would continue to be required to provide contraceptive coverage to the plan sponsors’ employees through such accommodation.

Given the sincerely held religious beliefs of many nonprofit religious organizations, some commenters also contended that continuing to impose the contraceptive Mandate on certain nonprofit religious objectors might also undermine the Government’s broader interests in ensuring health coverage by causing some entities to stop providing health coverage entirely.⁵⁹ Although the Departments do not know the extent to which that effect would result from not extending exemptions, we wish to avoid that potential obstacle to the general expansion of health coverage.

G. Closely Held For-Profit Entities (45 CFR 147.132(a)(1)(i)(C))

The previous regulations did not exempt plans sponsored by closely held for-profit entities; however, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(C), “[a] closely held for-profit entity.” These rules finalize § 147.132(a)(1)(i)(C) without change.

Some commenters supported including these entities in the exemption, saying owners of such entities exercise their religious beliefs through their businesses and should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise religion or should not have their religious opposition to contraceptive coverage protected by the exemption. Some said the entities should not be able to impose their beliefs about contraceptive coverage on their employees, and that doing so constitutes discrimination.

As set forth in the Religious IFC, the Departments believe it is appropriate to expand the exemptions to include closely held for-profit employers in

⁵⁸ Notably, “the First Amendment simply does not require that every member of a group agree on every issue in order for the group’s policy to be ‘expressive association.’” *Boy Scouts of America v. Dale*, 530 U.S. 640, 655 (2000).

⁵⁹ See, e.g., Manya Brachear Pashman, “Wheaton College ends coverage amid fight against birth control mandate,” *Chicago Tribune*, July 29, 2015; Laura Bassett, “Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,” *HuffPost*, May 15, 2012.

order to protect the religious exercise of those entities and their owners. The ACA did not apply the preventive services mandate to the many grandfathered health plans among closely held as well as publicly traded for-profit entities, encompassing tens of millions of women. As explained below, we are not aware of evidence showing that the expanded exemptions finalized here will impact such a large number of women. And, in the Departments' view, the decision by Congress to not apply the preventive services mandate to grandfathered plans did not constitute improper discrimination or an imposition of beliefs. We also do not believe RFRA or the large number of other statutory exemptions Congress has provided for religious beliefs (including those exercised for profit) in certain health contexts such as sterilization, contraception, or abortion have been improper.

Including closely held for-profit entities in the exemption is also consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization, and rejected the previous Administration's argument to the contrary. 134 S. Ct. at 2768–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.⁶⁰

H. For-Profit Entities That Are Not Closely Held (45 CFR 147.132(a)(1)(i)(D))

The previous regulations did not exempt for-profit entities that are not closely held. However, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(D), “[a] for-profit entity that is not closely held.” These rules finalize § 147.132(a)(1)(i)(D) without change.

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. Some commenters supported including such entities, including publicly traded businesses, in the scope of the exemption. Some of them said that publicly traded entities have historically taken various positions on important public concerns beyond merely (and exclusively) seeking the

company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to exercise religious views against contraceptive coverage. They also said that other protections for religious beliefs in federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines “persons,” protected under RFRA, to include corporations at 1 U.S.C. 1. Other commenters opposed including publicly traded companies in the expanded exemptions. Some of these commenters stated that such companies could not exercise religious beliefs, and opposed the effects on women if they could. These commenters also objected that including such employers, along with closely held businesses, would extend the exemptions to all or virtually all employers.

The Departments conclude it is appropriate to include entities that are not closely held within the expanded exemptions for entities with religious objection. RFRA prohibits the federal government from “substantially burden[ing] a person's exercise of religion . . .” unless it demonstrates that the application of the burden to the person “is the least restrictive means to achieve a compelling governmental interest.” 42 U.S.C. 2000bb–1(a) & (b). As commenters noted, the definition of “person” applicable in RFRA is found at 1 U.S.C. 1, which defines “person” as including “corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.” Accordingly, the Departments' decision to extend the religious exemption to publicly traded for profit corporations is supported by the text of RFRA. The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held religious beliefs, is a matter of well-established State law with respect to corporate decision-making,⁶¹ and the Departments expect that application of such laws would cabin the scope of this exemption.

As to the impact of so extending the religious exemption, the Departments are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief. As noted above, before the ACA, a substantial majority of

employers covered contraceptives. Some commenters opposed to including publicly traded entities in these exemptions noted that there did not appear to be any known religiously motivated objections to the Mandate from publicly traded for-profit corporations. These comments support our estimates that including publicly traded entities in the exemptions will have little, if any effect, on contraceptive coverage for women. We likewise agree with the Supreme Court's statement in *Hobby Lobby* that it is unlikely that many publicly traded companies will adopt religious objections to offering women contraceptive coverage. *See* 134 S. Ct. at 2774. Some commenters contended that, because many closely held for-profit businesses expressed religious objections to the Mandate, or took advantage of the accommodation, it is likely that many publicly traded businesses will do so. The Departments agree it is possible that publicly traded businesses may use the expanded exemption. But while scores of closely held for-profit businesses filed suit against the Mandate, no publicly traded entities did so, even though they were not authorized to seek the accommodation. Based on these data points, we believe the impact of the extension of the exemption to publicly traded for-profit organizations will not be significant. Below, based on limited data, but on years of receiving public comments and defending litigation brought by organizations challenging the Mandate on the basis of their religious objections, our best estimate of the anticipated effects of these rules is that no publicly traded employers will invoke the religious exemption.

In the Departments' view, such estimate does not lead to the conclusion that the religious exemption should not be extended to publicly traded corporations. The Departments are generally aware that, in a country as large as the U.S., comprised of a supermajority of religious persons,⁶² some publicly traded entities might claim a religious character for their company, or the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.⁶³ Thus we consider

⁶⁰ See Jennifer Haberkorn, “Two years later, few Hobby Lobby copycats emerge,” *Politico* (Oct. 11, 2016), <http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627>.

⁶¹ Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which the organization is incorporated or organized.

⁶² For example, in 2017, 74 percent of Americans said that religion is fairly important or very important in their lives, and 87 percent of Americans said they believe in God. Gallup, “Religion,” available at <https://news.gallup.com/poll/1690/religion.aspx>.

⁶³ See, for example, Kapitall, “4 Publicly Traded Religious Companies if You're Looking to Invest in

it possible that a publicly traded company might have religious objections to contraceptive coverage. Moreover, as noted, there are many closely held for-profit corporations that do have religious objections to covering some or all contraceptives. The Departments do not want to preclude such a closely held corporation from having to decide between relinquishing the exemption or financing future growth by sales of stock, which would be the effect of denying it the exemption if it changes its status and became a publicly traded entity. The Departments also find it relevant that other federal conscience statutes, such as those applying to hospitals or insurance companies, do not exclude publicly traded businesses from protection.⁶⁴ As a result, the Departments continue to consider it appropriate not to exclude such entities from these expanded exemptions.

I. Other Non-Governmental Employers (45 CFR 147.132(a)(1)(i)(E))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. The Religious IFC included, in its list of exempt plan sponsors at § 147.132(a)(1)(i)(E), “[a]ny other non-governmental employer.” These rules finalize § 147.132(a)(1)(i)(E) without change.

Some commenters objected to extending the exemption to other nongovernmental employers, asserting that it is not clear such employers should be protected, nor that they can assert religious objections. The Departments, however, agree with other commenters that supported that provision of the Religious IFC. The Departments believe it is appropriate that any nongovernmental employer asserting the requisite religious objections should be protected from the Mandate in the same way as other plan sponsors. Such other employers could include, for example, association health plans.⁶⁵ The reasons discussed above for providing the exemption to various specific kinds of employers, and for their ability to assert sincerely held religious beliefs using ordinary mechanisms of corporate decision-

making, generally apply to other nongovernmental employers as well, if they have sincerely held religious beliefs opposed to contraceptive coverage and otherwise meet the requirements of these rules. We agree with commenters who contend there is not a sufficient basis to exclude other nongovernmental employers from the exemption.

J. Plans Established or Maintained by Objecting Nonprofit Entities (45 CFR 147.132(a)(1)(ii))

Based on the expressed intent in the Religious IFC, as discussed above, to expand the exemption to encompass plans established or maintained by nonprofit organizations with religious objections, and on public comments received concerning those exemptions, these rules finalize new language in § 147.132(a)(1)(ii) to better clarify the scope and application of the exemptions.

The preamble to the Religious IFC contained several discussions about the Departments’ intent to exempt plans established or maintained by certain religious organizations that have the requisite objection to contraceptive coverage, including instances in which the plans encompass multiple employers. For example, as noted above, the Departments intended that the exemption for houses of worship and integrated auxiliaries be interpreted to apply on a plan basis, instead of on an employer-by-employer basis. In addition, the Departments discussed at length the fact that, under the prior regulations, where an entity was enrolled in a self-insured church plan exempt from ERISA under ERISA section 3(33) and the accommodation in the previous regulations was used, that accommodation process provided no mechanism to impose, or enforce, the accommodation requirement of contraceptive coverage against a third party administrator of such a plan. As a result, the prior accommodation served, in effect, as an exemption from requirements of contraceptive coverage for all organizations and employers covered under a self-insured church plan.

In response to these discussions in the Religious IFC, some commenters, including some church plans, supported the apparent intent to exempt such plans on a plan basis, but suggested that additional clarification is needed in the text of the rule to effect this intent. They observed that some plans are established or maintained by religious nonprofit entities that might not be houses of worship or integrated auxiliaries, and that some employers

that adopt or participate in such plans may not be the “plan sponsors.” They recommended, therefore, that the final rules specify that the exemption applies on a plan basis when plans are established or maintained by houses of worship, integrated auxiliaries, or religious nonprofits, so as to shield employers that adopt such plans from penalties for noncompliance with the Mandate.

The text of the prefatory language of § 147.132(a)(1), as set forth in the Religious IFC, declared that the Guidelines would not apply “with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization.” We intended this language to exempt a plan and/or coverage where the entity that established or maintained a plan was an objecting organization, and not just to look at the views or status of individual employers (or other entities) participating in such plan. The Departments agree with commenters who stated that additional clarity is needed and appropriate in these final rules, in order to ensure that such plans are exempt on a plan basis, and that employers joining or adopting those plans are exempt by virtue of the plan itself being exempt. Doing so will make the application of the expanded exemption clearer, and protect employers (and other entities) participating in such plans from penalties for noncompliance with the Mandate. Clearer language will better realize the intent to exempt plans and coverage “established or maintained by an objecting organization,” and make the operation of that exemption simpler by specifying that the exemption applies based on the objection of the entity that established or maintains the plan. Such language would also resolve the anomaly that, under the previous rules, only self-insured church plans (not insured church plans) under ERISA section 3(33) were, in effect, exempt—but only indirectly through the Departments’ inability to impose, or enforce, the accommodation process against the third party administrators of such plans, instead of being specifically exempt in the rules.

We believe entities participating in plans established or maintained by an objecting organization usually share the views of those organizations. Multiple lawsuits were filed against the Departments by churches that established or maintained plans, or the church plans themselves, and they generally declared that the entities or individuals participating in their plans

Faith” (Feb. 7, 2014), <http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665>.

⁶⁴ See, for example, 42 U.S.C. 300a–7, 42 U.S.C. 238n, Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d), Public Law 115–141, and *id.* at Div. E, Sec. 808.

⁶⁵ See 29 CFR 2510.3–5.

are usually required to share their religious affiliation or beliefs. In addition, because, as we have stated before, “providing payments for contraceptive services is cost neutral for issuers” (78 FR 39877), we do not believe this clarification would produce any financial incentive for entities that do not have religious objections to contraceptive coverage to enter into plans established or maintained by an organization that does have such objections.

Therefore, the Departments finalize the text of § 147.132(a)(1) of the Religious IFC with the following change: adding a provision that makes explicit this understanding, in a new paragraph at § 147.132(a)(1)(ii). This language now specifies that the exemptions encompassed by § 147.132(a)(1) include: “[a] group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan[.]”

K. Institutions of Higher Education (45 CFR 147.132(a)(1)(iii))

The previous regulations did not exempt student health plans arranged by institutions of higher education, although it did, for purposes of the accommodation, treat plans arranged by institutions of higher education similar to the way in which the regulations treated plans of nonprofit religious employers. See 80 FR at 41347. The Religious IFC included in its list of exemptions, at § 147.132(a)(1)(ii), “[a]n institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ‘plan participants and beneficiaries’ will be interpreted as references to student enrollees and their covered dependents.” These rules

finalize this language with a change to clarify their application, as discussed below, and by redesignating the paragraph as § 147.132(a)(1)(iii).

These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.132(a)(1)(iii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held religious beliefs, to their arrangement of student health insurance coverage in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer.

Some commenters supported including, in the expanded exemptions, institutions of higher education that provide health coverage for students through student health plans but have religious objections to providing certain contraceptive coverage. They said that religious exemptions allow freedom for certain religious institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemptions would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result among those women.

In the Departments’ view, the reasons for extending the exemptions to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. Only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities.⁶⁶ It is necessarily true that

an even smaller number receive such coverage from religious schools, and from religious or other private schools that object to arranging contraceptive coverage. Religious institutions of higher education are private entities with religious missions. Various commenters asserted the importance, to many of those institutions, of being able to adhere to their religious tenets. Indeed, many students who attend such institutions do so because of the institutions’ religious tenets. No student is required to attend such an institution. At a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans they arrange. Some students wish to receive contraceptive coverage from a health plan arranged by an institution of higher education. But other students wish to attend an institution of higher education that adheres to its religious mission about contraceptives in health insurance. And still other students favor contraception, but are willing to attend a religious university without forcing it to violate its beliefs about contraceptive coverage. Exempting religious institutions that object to contraceptive coverage still allows contraceptive coverage to be provided by institutions of higher education more broadly. The exemption simply makes it legal under federal law for institutions to adhere to religious beliefs that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation’s higher education system, and makes it more possible for students to attend institutions of higher education that hold those views.

In addition, under the previous exemption and accommodation, it was possible for self-insured church plans exempt from ERISA that have religious objection to certain contraceptives to avoid any requirement that either they or their third party administrators provide contraceptive coverage. As seen

documents/Networks/Coalitions/Why_SHIPs_Matter.pdf. We assume for the purposes of this estimate that those plans covered 2,100,000 million students. Data from the Department of Education shows that in 2014, there were 20,207,000 students enrolled in degree-granting postsecondary institutions. National Center for Education Statistics, Table 105.20, “Enrollment in elementary, secondary, and degree-granting postsecondary institutions, by level and control of institution, enrollment level, and attendance status and sex of student: Selected years, fall 1990 through fall 2026,” available at https://nces.ed.gov/programs/digest/d16/tables/dt16_105.20.asp?current=yes.

⁶⁶ The American College Health Association estimates that, in 2014, student health insurance plans at colleges and universities covered “more than two million college students nationwide.” “Do You Know Why Student Health Insurance Matters?” available at <https://www.acha.org/>

in some public comments and litigation statements, some such self-insured church plans provide health coverage for students at institutions of higher education covered by those church plans. In order to avoid the situation where some student health plans sponsored by institutions with religious objections are effectively exempt from the contraceptive Mandate, and other student health plans sponsored by other institutions with similar religious objections are required to comply with the Mandate, the Departments consider it appropriate to extend the exemption, so that religious colleges and universities with objections to the Mandate would not be treated differently in this regard.

The Departments also note that the ACA does not require institutions of higher education to provide student health insurance coverage. As a result, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student health insurance plans, rather than comply with the Mandate or be subject to the accommodation.⁶⁷ Extending the exemption in these rules removes an obstacle to such entities deciding to offer student health insurance plans, thereby giving students another health insurance option.

As noted above, it is not clear that studies discussing various effects of birth control access clearly and specifically demonstrate a negative impact to students in higher education because of the expanded exemption in these final rules. The Departments consider these expanded exemptions to be an appropriate and permissible policy choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these expanded exemptions.

Finally, the Religious IFC specified that the plan sponsor exemption applied to “non-governmental” plan sponsors (§ 147.132(a)(1)(i)), including “[a]ny other non-governmental employer” (§ 147.132(a)(1)(i)(E)). Then, in § 147.132(a)(1)(ii), the rule specified that the institution of higher education exemption applicable to the arrangement of student health insurance coverage applied “in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan

established or maintained by a plan sponsor that is an employer.” Consequently, the Religious IFC’s expanded exemptions only applied to non-governmental institutions of higher education, including for student health insurance coverage, not to governmental institutions of higher education. Nevertheless, the term “non-governmental,” while appearing twice in § 147.132(a)(1)(i) concerning plan sponsors, was not repeated in § 147.132(a)(1)(ii). To more clearly specify that this limitation was intended to apply to § 147.132(a)(1)(ii), we finalize this paragraph with a change by adding the phrase “which is non-governmental” after the phrase “An institution of higher education as defined in 20 U.S.C. 1002”.

L. Health Insurance Issuers (45 CFR 147.132(a)(1)(iv))

The previous regulations did not exempt health insurance issuers. However, the Religious IFC included in its list of exemptions at § 147.132(a)(1)(iii), “[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]” These rules finalize this exemption with technical changes to clarify the language based on public comments, and redesignate the paragraph as § 147.132(a)(1)(iv).

The Religious IFC extends the exemption to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services. Under this exemption, the only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on their objection. An exempt issuer can then offer an exempt health insurance product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies

that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless it is also exempt from that requirement.

Under these rules, issuers that hold their own objections, based on sincerely held religious beliefs, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their religious beliefs, or on their moral convictions under the companion final rules published elsewhere in today’s **Federal Register**. Likewise, issuers with sincerely held moral convictions, that are exempt under those companion final rules, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments provided a similar exemption for issuers in the context of moral objections, but we used slightly different operative language. There, in the second sentence, instead of saying “the plan remains subject to any requirement to provide coverage for contraceptive services,” the exemption stated, “the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services.” Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. Consequently, these rules finalize the issuer exemption paragraph from the Religious IFC with minor technical changes so that the final language will mirror language from the Moral IFC, stating that the exemption encompasses: “[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iv) of this section, the group health plan established or maintained by the plan sponsor with

⁶⁷ See, e.g., Manya Brachear Pashman, “Wheaton College ends coverage amid fight against birth control mandate,” *Chicago Tribune*, July 29, 2015; Laura Bassett, “Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,” *HuffPost*, May 15, 2012.

which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]”

Some commenters supported including this exemption for issuers in these rules, both to protect the religious exercise of issuers, and so that in the future religious issuers that may wish to specifically serve religious plan sponsors would be free to organize. Other commenters objected to including an exemption for issuers. Some objected that issuers cannot exercise religious beliefs, while others objected that exempting issuers would threaten contraceptive coverage for women. Some commenters said that it was arbitrary and capricious for the Departments to provide an exemption for issuers if we do not know that issuers with qualifying religious objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage. The issuer exemption therefore serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors and plans that independently qualify for an exemption, will remove a possible obstacle to religious issuers being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers from being required to issue policies that cover contraception in violation of the issuers’ sincerely held religious beliefs, and from being required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus

subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise religious beliefs. First, since RFRA protects the religious exercise of corporations as persons, the religious exercise of health insurance issuers—which are generally organized as corporations—is protected by RFRA. In addition, many federal health care conscience laws and regulations specifically protect issuers or plans. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment specifically protects, among other entities, provider-sponsored organizations, health maintenance organizations (HMOs), health insurance plans, and “any other kind of health care facilit[ies], organization[s], or plan[s]” as a “health care entity” from being required to pay for, or provide coverage of, abortions. *See for example*, Consolidated Appropriations Act of 2018, Public Law 115–141, Div. H, Sec. 507(d), 132 Stat. 348, 764 (Mar. 23, 2018).⁶⁸ Congress also declared this year that “it is the intent of Congress” to include a “conscience clause” which provides exceptions for religious beliefs if the District of Columbia requires “the provision of contraceptive coverage by health insurance plans.” *See id.* at Div. E, Sec. 808, 132 Stat. at 603. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these final rules, and their third party administrators, as

claims processors, are under no obligation under section 2713(a)(4) to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments’ understanding that third party administrators are not typically designated as plan administrators, and, therefore, would not normally act as plan administrators, under section 3(16) of ERISA. Therefore, to the Departments’ knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or decline to continue, contracts as third party administrators of such plans.

M. Description of the Religious Objection (45 CFR 147.132(a)(2))

The previous regulations did not specify what, if any, religious objection applied to its exemption; however, the Religious IFC set forth the scope of the religious objection of objecting entities in § 147.132(a)(2), as follows: “The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.” These rules finalize this description with technical changes to clarify the scope of the objection as intended in the Religious IFC, and based on public comments.

Throughout the exemptions for objecting entities, the rules specify that they apply where the entities object as specified in § 147.132(a)(2) of the Religious IFC. That paragraph describes the religious objection by specifying that exemptions for objecting entities will apply to the extent that an entity described in paragraph (a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

⁶⁸ ACA section 1553 protects an identically defined group of “health care entities,” including provider-sponsored organizations, HMOs, health insurance plans, and “any other kind of . . . plan,” from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(a)(2), provided a similar description of the scope of the objection based on moral convictions rather than religious beliefs, but we used slightly different operative language. There, instead of saying the entity “objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services,” the paragraph stated the entity “objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.” Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. The Religious IFC explained that the intent of the expanded exemptions was to encompass entities that objected to providing or arranging for contraceptive coverage in their plans, and to encompass entities that objected to the previous accommodation process, by which their issuers or third party administrators were required to provide contraceptive coverage or payments in connection with their plans. In other words, an entity would be exempt from the Mandate if it objected to complying with the Mandate, or if it objected to complying with the accommodation. The language in the Religious IFC encompassed both circumstances by encompassing an objection to providing “coverage [or] payments” for contraceptive services, and by encompassing an objection to “a plan that provides” coverage or payments for contraceptive services. But the language describing the objection set forth in the Moral IFC does so more clearly, and restructuring the sentence could make it clearer still. Questions by commenters about the scope of the description suggests that we should restructure the description, in a non-substantive way, to provide more clarity. The Departments do this by breaking some of the text out into subparagraphs, and rearranging clauses so that it is clearer which words they modify. The new

structure specifies that it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) coverage or payments for contraceptive services, and it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) a plan, issuer, or third party administrator that provides contraceptive coverage. This more clearly encompasses objections to complying with either the Mandate or the accommodation. Consequently, these rules finalize the paragraph describing the religious objection in the Religious IFC with minor technical changes so that the final language will essentially mirror language from the Moral IFC. The introductory phrase of the religious objection set forth in paragraph (a)(2) is finalized to state the exemption “will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable)”. The remainder of the paragraph is broken into two subparagraphs, regarding either “coverage or payments for some or all contraceptive services,” or “a plan, issuer, or third party administrator that provides or arranges such coverage or payments.”

Some commenters observed that by allowing exempt groups to object to “some or all” contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators. The Departments have concluded, however, that, just as the exemption under the previous regulations allowed entities to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. Notably, even where an entity or individual qualifies for an exemption under these rules, these rules do not require the issuer or third party administrator to contract with that entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual variation of a plan. These rules simply remove the federal Mandate that, in some cases, could have led to penalties for an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence

of a qualifying religious objection. Similarly, under the previous exemption, the plans of houses of worship and integrated auxiliaries were exempt from offering some or all contraceptives, but the previous regulations did not require issuers and third party administrators to contract with those exempt entities if they chose not to do so.

N. Individuals (45 CFR 147.132(b))

The previous regulations did not provide an exemption for objecting individuals. However, the Religious IFC expanded the exemptions to encompass objecting individuals (referred to here as the “individual exemption”), at § 147.132(b). These rules finalize the individual exemption from the Religious IFC with changes, which reflect both non-substantial technical revisions, and changes based on public comments to more clearly express the intent of the Religious IFC.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Religious IFC described what may be offered to objecting individuals as “a separate benefit package option, or a separate policy, certificate or contract of insurance,” the Moral IFC said a willing issuer and plan sponsor may offer “a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects” under the individual exemption. Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of “a separate group health plan,” as set forth in the version found in § 147.133(b), because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee’s objection. Consequently, these rules finalize the individual

exemption by making a technical change to the language to adopt the formulation, “a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects” under the individual exemption.

Some commenters supported the individual exemption as providing appropriate protections for the religious beliefs of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to contraceptive coverage but is willing (and, as applicable, the issuer is also willing) to provide coverage that is consistent with an individual’s religious objections. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage. Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. As discussed in the Religious IFC, the individual exemption only operates in the case where the group health plan sponsor or group or individual market health insurance issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and

issuers are willing to offer particular options in individual cases.

In addition, Congress has provided several protections for individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. *See for example*, Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–141, 132 Stat. 348, 593–94 (Mar. 23, 2018). While some commenters proposed to construe this provision narrowly, Congress likewise provided that, if the District of Columbia requires “the provision of contraceptive coverage by health insurance plans,” “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions”. *Id.* at Div. E, Sec. 808, 132 Stat. at 603. A religious exemption for individuals would not be effective if the government simultaneously made it illegal for issuers and group health plans to provide individuals with policies that comply with the individual’s religious beliefs.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan’s or issuer’s obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers.

By its terms, the individual exemption would also apply with respect to individuals in plans arranged by institutions of higher education, if the issuers offering those plans were willing to provide plans complying with the individuals’ objections. Because federal law does not require institutions of higher education to arrange such plans, the institutions would not be required by these rules to arrange a plan compliant with an individual’s

objection if the institution did not wish to do so.

As an example, in one lawsuit brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees’ religious beliefs, or against the individual employees who accept such offers. *See Wieland*, 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these final rules do not affect such other laws or terms.

Some individuals commented that they welcomed the individual exemption so that their religious beliefs were not forced to be in tension with their desire for health coverage. The Departments believe the individual exemption may help to meet the ACA’s goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.⁶⁹ At the same time, this individual exemption “does not undermine the governmental interests furthered by the contraceptive

⁶⁹ See also, for example, *Wieland*, 196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to “forgo health insurance altogether.”

coverage requirement,”⁷⁰ because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives. Other commenters expressed concern that there might be multiple variations in the kinds of contraceptive coverage to which individuals object, and this might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the religious beliefs of an exempt individual. As discussed above, where the individual exemption applies, it only affects the coverage of an individual. If an individual only objects to some contraceptives, and the individual’s issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons they can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Religious IFC implied this conclusion, by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, this was different than the language applicable to the exemptions under § 147.132(a), which specifies that the exemptions apply “to the extent” of the religious objections, so that, as discussed above, the exemptions include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b) with the following change, by adding the following sentence at the end of the paragraph: “Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the individual with a separate policy, certificate or contract of insurance or a separate group health plan or benefit

package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.”

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held religious beliefs objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to this employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under a policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees’ plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with clarifying changes to reflect the Departments’ intent.

O. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations set forth an accommodation process at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, as an alternative method of compliance with the Mandate. Under the accommodation, if a religious nonprofit entity, or a religious closely held for-profit business, objected to coverage of some or all contraceptive services in its health plan, it could file a notice or fill out a form expressing this objection and describing its objection to its plan and

issuer or third party administrator. Upon doing so, the plan would not cover some or all contraceptive services, and the issuer or third party administrator would be responsible for providing or arranging for persons covered by the plan to receive coverage or payments of those services (except in the case of self-insured church plans exempt from ERISA, in which case no such obligation was imposed on the third party administrator). The accommodation was set forth in regulations of each of the Departments. Based on each Department’s regulatory authority, HHS regulations applied to insured group health plans, and DOL and Treasury regulations applied to both insured group health plans and self-insured group health plans.

The Religious IFC maintained the accommodation process. Nevertheless, by virtue of expanding the exemptions to encompass all entities that were eligible for the accommodation process under the previous regulations, in addition to other newly exempt entities, the Religious IFC rendered the accommodation process optional. Entities could choose not just between the Mandate and the accommodation, but between the Mandate, the exemption, and the accommodation. These rules finalize the optional accommodation process and its location in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, but the Departments do so with several changes based on public comments.

Many commenters supported keeping the accommodation as an optional process, including some commenters who otherwise supported creating the expanded exemptions. Some commenters opposed making the accommodation optional, but asked the Departments to return to the previous regulations in which entities that did not meet the narrower exemption could only choose between the accommodation process or direct compliance with the Mandate. Some commenters believed there should be no exemptions and no accommodation process.

The Departments continue to consider it appropriate to make the accommodation process optional for entities that are otherwise also eligible for the expanded exemptions—that is, to keep it in place as an option that exempt entities can choose. The accommodation provides contraceptive access, which is a result many opponents of the expanded exemptions said they desire. The accommodation involves some regulation of issuers and third party administrators, but the previous

⁷⁰ 78 FR 39874.

regulations had already put that regulatory structure in place. These rules for the most part merely keep it in place and maintain the way it operates. The Religious IFC adds some additional paperwork burdens as a result of the new interaction between the accommodation and the expanded exemptions; those are discussed below.

Above, the Departments discussed public comments concerning whether we should have merely expanded the accommodation rather than expanding the exemptions. The Religious IFC and these final rules expand the kinds of entities that may use the optional accommodation, by expanding the exemptions and allowing any exempt entities to opt to make use of the accommodation. Consequently, under these rules, objecting employers may make use of the exemption or may choose to utilize the optional accommodation process. If an eligible organization uses the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

Some commenters asked that these final rules create an alternative payment mechanism to cover contraceptive services for third party administrators obligated to provide or arrange such coverage under the accommodation. These rules do not concern the payment mechanism, which is set forth in separate rules at 45 CFR 156.50. The Departments do not view an alternative payment mechanism as necessary. As discussed below, although the Departments do not know how many entities will use the accommodation, it is reasonably likely that some entities previously using it will continue to do so, while others will choose the expanded exemption, leading to an overall reduction in the use of the accommodation. The Departments have reason to believe that these final rules will not lead to a significant expansion of entities using the accommodation, since nearly all of the entities of which the Departments are aware that may be interested in doing so were already able to do so prior to the Religious IFC. Moreover, it is still the case under these rules that if an entity serving as a third party administrator does not wish to satisfy the obligations it would need to satisfy under an accommodation, it could choose not to contract with an entity that opts into the accommodation. This conflict is even less likely now that entities eligible for the accommodation are also eligible for the exemption. For these reasons, the Departments do not

find it necessary to add an additional payment mechanism for the accommodation process.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these rules, and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation. Some commenters suggested HHS has not yet issued guidance on the revocation process, but CCIIO provided guidance concerning this process on November 30, 2017.⁷¹ These rules supersede that guidance, and adopt or modify its specific guidelines as explained below. As a result, these rules delete references, set forth in the Religious IFC's accommodation regulations, to "guidance issued by the Secretary of the Department of Health and Human Services."

The guidance stated that an entity that was using the accommodation under the previous rules, or an entity that adopts the accommodation maintained by the IFCs, could revoke its use of the accommodation and use the exemption. This guideline applies under the final rules. This revocation process applies both prospectively to eligible organizations that decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that invoked the accommodation prior to the effective date of the Religious IFC either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies.

The guidance stated that, when the accommodation is revoked by an entity using the exemption, the issuer of the eligible organization must provide participants and beneficiaries written notice of such revocation. These rules adopt that guideline. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. The

guidance further stated that the notice may be provided by the organization itself, its group health plan, or its third party administrator, as applicable. The guidance stated that, under the regulation at 45 CFR 147.200(b), "[t]he notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section," and (a)(4) has detailed rules on when electronic notice is permitted. These guidelines still apply under the final rules. These rules adopt those guidelines.

The guidance further specified that the revocation of the accommodation would be effective notice on the first day of the first plan year that begins on or after 30 days after the date of the revocation, or alternatively, whether or not the objecting entity's group health plan or issuer listed the contraceptive benefit in its Summary of Benefits of Coverage (SBC), the group health plan or issuer could revoke the accommodation by giving at least 60-days prior notice pursuant to section 2715(d)(4) of the PHS Act (incorporated into ERISA and the Code)⁷² and applicable regulations thereunder to revoke the accommodation. The guidance noted that, unlike the SBC notification process, which can effectuate a modification of benefits in the middle of a plan year, provided it is allowed by State law and the contract of the policy, the 30 day notification process under the guidance can only effectuate a benefit modification at the beginning of a plan year. This part of the guidance is adopted in part and changed in part by these final rules, as follows, based on public comments on the issue.

Some commenters asked that revocations only be permitted to occur on the first day of the next plan year, or no sooner than January 2019, to avoid burdens on plans and because some states do not allow for mid-year plan changes. The Departments believe that providing 60-days notice pursuant to section 2715(d)(4) of the PHS Act, where applicable, is a mechanism that already exists for making changes in health benefits covered by a group health plan during a plan year; that process already takes into consideration any applicable state laws. However, in response to public comments, these rules change the accommodation provisions from the Religious IFC to indicate that, as a transitional rule, providing 60-days notice for revoking an accommodation is only available, if applicable, to plans that are using the accommodation at the time of the

⁷¹ See Randy Pate, "Notice by Issuer or Third Party Administrator for Employer/Plan Sponsor of Revocation of the Accommodation for Certain Preventive Services," CMS (Nov. 30, 2017), <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf>.

⁷² See also 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

publication of these final rules. As a general rule, for plans that use the accommodation in future plan years, the Departments believe it is appropriate to allow revocation of an accommodation only on the first day of the next plan year. Based on the objections of various litigants and public commenters, we believe that some entities already using the accommodation may have been doing so only because previous regulations denied them an exemption. For them, access to the transitional 60-days notice procedure (if applicable) is appropriate in the period immediately following the finalization of these rules. In future plan years, however—plan years that begin after the effective date of these final rules—plans and entities that qualify as exempt under these rules will have been on notice that they qualify for an exemption or the accommodation. If they have opted to enter or remain in the accommodation in those future plan years, when they could have chosen the exemption, the Departments believe it is appropriate for them to wait until the first day of the following plan year to change to exempt status.⁷³

This change is implemented in the following manner. In the Religious IFC, the accommodation provisions addressing revocation were found at 45 CFR 147.131(c)(4), 26 CFR 54.9815–2713AT(a)(5),⁷⁴ and 29 CFR 2590.715–2713A(a)(5).

The provisions in the Religious IFC (with technical variations among the HHS, Labor, and Treasury rules) state that a written notice of revocation must be provided “as specified in guidance issued by the Secretary of the

Department of Health and Human Services.” On November 30, 2017, HHS issued the guidance regarding revocation. These final rules incorporate this guidance, with certain clarifications, and state that the revocation notice must be provided “as specified herein.” The final rule incorporates the two sets of directions for revoking the accommodation initially set forth in the interim guidance in the following manner. The first, designated as subparagraph (1) as a “[t]ransitional rule,” explains that if contraceptive coverage is being offered through the accommodation process on the date on which these final rules go into effect, 60-days notice may be provided to revoke the accommodation process, or they revocation may occur “on the first day of the first plan year that begins on or after 30 days after the date of the revocation” consistent with PHS Act section 2715(d)(4), 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), or 29 CFR 2590.715–2715(b). The second direction, set forth in subparagraph (ii), explains the “[g]eneral rule” that, in plan years beginning after the date on which these final rules go into effect, revocation of the accommodation will be effective on “the first day of the first plan year that begins on or after 30 days after the date of the revocation.”

The Religious IFC states that if an accommodated entity objects to some, but not all, contraceptives, an issuer for an insured group health plan that covers contraceptives under the accommodation may, at the issuer’s option, choose to provide coverage or payments for all contraceptive services, instead of just for the narrower set of contraceptive services to which the entities object. Some commenters supported this provision, saying that it allows flexibility for issuers that might otherwise face unintended burdens from providing coverage under the accommodation for entities that object to only some contraceptive items. The Departments have maintained this provision in these final rules. Note that this provision is consistent with the other assertions in the rules saying that an entity’s objection applies “to the extent” of the entity’s religious beliefs, because in this instance, under the accommodation, the plan participant or beneficiary still receives coverage or payments for all contraceptives, and this provision simply allows issuers more flexibility in choosing how to help provide that coverage.

Some commenters asked that the Departments retain the “reliance” provision, contained in the previous accommodation regulations, under

which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. The Departments omitted this provision from the Religious IFC, on the grounds that this provision was less necessary where any organization eligible for the optional accommodation is also exempt. Nevertheless, in order to respond to concerns in public comments, and to prevent any risk to issuers of a mistake or misrepresentation by an organization seeking the accommodation process, the Departments have finalized the Religious IFC with an additional change that restores this clause. The clause uses the same language that was in the regulations prior to the Religious IFC, and it is inserted at 45 CFR 147.131(f), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e). As a result, these rules renumber the subsequent paragraphs in each of those sections.

P. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under “Contraceptive methods and counseling,” “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” The previous regulations concerning the exemption and the accommodation used the terms contraceptive services and contraceptive coverage as catch-all terms to encompass all of those Guidelines’ requirements. The 2016 update to the Guidelines are similarly worded. Under “Contraception,” they include the “full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,” “instruction in fertility awareness-based methods,” and “[c]ontraceptive care” to “include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).”⁷⁵

To more explicitly state that the exemption encompasses any of the contraceptive or sterilization services, items, or information that have been required under the Guidelines, the Religious IFC included a definition at 45

⁷³ These final rules go into effect 60 days after they are published in the **Federal Register**. Some entities currently using the accommodation may have a plan year that begins less than 30 days after the effective date of these final rules. In such cases, they may be unable, after the effective date of these final rules, to provide a revocation notice 30 days prior to the start of their next plan year. However, these final rules will be published at least 60 days prior to the start of that plan year. Therefore, entities exempt under these final rules that have been subject to the accommodation on the date these final rules are published, that wish to revoke the accommodation, and whose next plan years start after these final rules go into effect, but less than 30 days thereafter, may submit their 30 day revocation notices after these final rules are published, before these final rules are in effect, so that they will have submitted the revocation at least 30 days before their next plan year starts. In such cases, even though the revocation notice will be submitted before these final rules are in effect, the actual revocation will not occur until after these final rules are in effect, and plan participants will have been provided with 30 days’ notice of the revocation.

⁷⁴ The Department of the Treasury’s rule addressing the accommodation is being finalized at 26 CFR 54.9815–2713A, superseding its temporary regulation at 26 CFR 54.9815–2713AT.

⁷⁵ <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713AT(e), and 29 CFR 2590.715–2713A(e). These rules finalize those definitions without change, but renumber them as 45 CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e), respectively.

Q. Severability

The Departments finalize without change (except for certain paragraph redesignations), the severability clauses in the interim final rules, namely, at paragraph (g) of 26 CFR 54.9815–2713A, the redesignated paragraph (g) of 29 CFR 2590.715–2713A, and 45 CFR 147.132(d).

R. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to “preventive” care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to “preventive” services or care.⁷⁶ The requirement in the Guidelines concerning “contraception” specifies several times that it encompasses “contraceptives,” that is, medical products, methods, and services applied for “contraceptive” uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines’ inclusion of contraceptive services requires coverage

of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage, without cost-sharing, of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.⁷⁷ The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans’ decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use, or for another use. Section 2713(a)(4), however, draws a distinction between preventive care and screenings and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of contraceptive methods or care unless such methods or care is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are

⁷⁷ The Departments previously cited the IOM’s listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that “there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.” 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act 2713(a)(4) or the Guidelines require coverage of “contraceptive” methods when prescribed for an exclusively non-contraceptive, non-preventive use. Instead, it was an observation that such drugs—generally referred to as “contraceptives”—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the reference prior to the Religious IFC to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage for contraceptive use. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules also do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply to the extent the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that under section 2713(a)(4), exempt organizations must provide coverage for drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments’ statement in the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the expanded exemptions could take contraceptive coverage away from many or most women. Still others opposed expanding the exemptions and contended that accurately determining the number of women affected by the expanded exemptions is not possible.

After reviewing the public comments, the Departments agree with commenters who said that estimating the impact of these final rules is difficult based on the limited data available to us, and with commenters who agreed with the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women. The Departments do not find the estimates of large impacts submitted by some commenters more reliable than the estimates set forth in the Religious and Moral IFCs. Even certain commenters that “strongly oppos[ed]” the Religious IFC commented that merely “thousands” would be impacted, a number consistent with the Departments’ estimate of the number of women who may be affected by the rule. The Departments’ estimates of the impact of these final rules are discussed in more detail in the following section. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious IFC are still the best estimates available. Our estimates are discussed in more detail in the following section.

3. Interaction With State Laws

Some commenters asked the Departments to discuss the interaction between these final rules and state laws that either require contraceptive

⁷⁶ *Id.*

coverage or provide religious exemptions from those and other requirements. Some commenters argued that providing expanded exemptions in these rules would negate state contraceptive requirements or narrower state religious exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage. The Department agrees that these rules concern only the applicability of the Federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state religious exemptions. If a plan is exempt under the Religious IFC and these rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the religious exemptions to declare that the Federal contraceptive Mandate will still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.⁷⁸

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. See 29 U.S.C. 1144(a) & (b)(1). These rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include

⁷⁸ Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the Federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. Elsewhere in this preamble, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

contraceptives, nor that the Guidelines must force entities with religious objections to cover contraceptives.

IV. Economic Impact and Paperwork Burden

The Departments have examined the impacts of the Religious IFC and the final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with

economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding their anticipated effects, the Religious IFC and these rules are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These final rules adopt as final and further change the amendments made by the Religious IFC, which amended the Departments’ July 2015 final regulations. The Religious IFC and these final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held religious beliefs, and they revise the accommodation process to make it optional for eligible organizations. The expanded exemption applies to certain individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action has been taken, among other reasons discussed above, to provide for participation in the health insurance market by certain entities or individuals, by freeing them from penalties they could incur if they follow their sincerely held religious beliefs against contraceptive coverage.

2. Anticipated Effects

a. Removal of Burdens on Religious Exercise

Regarding entities and individuals that are extended an exemption by the Religious IFC and these final rules, without that exemption the Guidelines would require many of them to either pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which

some entities also believe entangles them in the provision of such objectionable coverage; or pay tax penalties, or be subject to other adverse consequences, for non-compliance with these requirements. These final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections to, and exempting them on the basis of such objections from, the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

b. Notices When Revoking Accommodated Status

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption, a notice will need to be sent to enrollees (either by the objecting entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during the current plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of the entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be \$302,036.

c. Impacts on Third Party Administrators and Issuers

The Departments estimate that these final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their new exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation to which they were not previously provided access. Reduced

burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations for serving the fewer number of entities that will now opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation. While these rules make it legal for issuers to offer insurance coverage that omits contraceptives to exempt entities and individuals, these final rules do not require issuers to do so.

The Departments anticipate that the effect of these rules on adjustments made to the federally facilitated Exchange user fees under 45 CFR 156.50 will be that fewer overall adjustments will be made using the accommodation process, because there will be more entities who previously were reluctant users of the accommodation that will choose to operate under the newly expanded exemption than there will be entities not previously eligible to use the accommodation that will opt into it. The Departments' estimates of each number of those entities is set forth in more detail below.

d. Impacts on Persons Covered by Newly Exempt Plans

These final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. As discussed in the Religious IFC, the Departments did not have sufficient data on a variety of relevant factors to precisely estimate how many women would be impacted by the expanded exemptions or any related costs they may incur for contraceptive coverage or the results associated with any unintended pregnancies.

i. Unknown Factors Concerning Impact on Persons in Newly Exempt Plans

As referenced above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- How many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- Which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby*, several objecting entities have still

provided coverage for 14 of the 18 FDA-approved women's contraceptive or sterilization methods, 134 S. Ct. at 2766).

- How many women will be covered by plans of entities using their newly exempt status.
 - Which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
 - Whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
 - The degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
 - The degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
 - The degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
 - The extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.
- ii. Public Comments Concerning Estimates in Religious IFC
- In the public comments, some commenters agreed with the Departments' estimate that, at most, the economic impact would lead to a potential transfer cost, from employers (or other plan sponsors) to affected women, of \$63.8 million. Some commenters said the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women.
- These general comments do not, however, substantially assist us in

estimating how many women would be affected by these expanded exemptions specifically, or among them, how many unintended pregnancies would result, or how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the transfer costs the Departments estimate, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives. The Departments conclude, therefore, that our estimates of the anticipated effect in the Religious IFC are still the best estimates we have based on the limited data available to make those estimates. We do not believe that the higher estimates submitted by various public commenters sufficiently took into consideration, or analyzed, the various factors that suggest the small percentage of entities that will now use the expanded exemptions out of the large number of entities subject to the Mandate overall. Instead, the Departments agree with various public commenters providing comment and analysis that, for a variety of reasons, the best estimate of the impact of the expanded exemptions finalized in these rules is that most women receiving contraceptive coverage under the Mandate will not be affected. We agree with such commenters that the number of women covered by entities likely to make use of the expanded exemptions in these rules is likely to be very small in comparison to the overall number of women receiving contraceptive coverage as a result of the Mandate.

iii. Possible Sources of Information for Estimating Impact

The Departments have access to the following general sources of information that are relevant to this issue, but these sources do not provide a full picture of the impact of these final rules. First, the regulations prior to the Religious IFC already exempted certain houses of worship and their integrated auxiliaries and, as explained elsewhere, effectively did not apply contraceptive coverage requirements to various entities in self-insured church plans. The effect of those previous exemptions or limitations are not included as effects of these rules, which leave those impacts in place. Second, in the Departments' previous regulations creating or expanding exemptions and the accommodation process we concluded that no significant burden or costs would result. 76 FR 46625; 78 FR 39889. Third, some entities, including some for-profit entities, object to only some but not all contraceptives, and in some

cases will cover 14 of 18 FDA-approved women's contraceptive and sterilization methods.⁷⁹ See *Hobby Lobby*, 134 S. Ct. at 2766. The effects of the expanded exemptions will be mitigated to that extent. No publicly traded for-profit entities sued challenging the Mandate, and the public comments did not reveal any that specifically would seek to use the expanded exemptions. Consequently, the Departments agree with the estimate from the Religious IFC that publicly traded companies would not likely make use of these expanded exemptions.

Fourth, HHS previously estimated that 209 entities would make use of the accommodation process. To arrive at this number, the Departments used, as a placeholder, the approximately 122 nonprofit entities that brought litigation challenging the accommodation process, and the approximately 87 closely held for-profit entities that filed suit challenging the Mandate in general. The Departments' records indicate, as noted in the Religious IFC, that approximately 63 entities affirmatively submitted notices to HHS to use the accommodation,⁸⁰ and approximately 60 plans took advantage of the

⁷⁹ By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, <https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf>, Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). See 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives ("the Pill"—combined pill); oral contraceptives ("the Pill"—extended/continuous use/combined pill); oral contraceptives ("the Mini Pill"—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and "[t]he pill and female sterilization have been the two most commonly used methods since 1982." See Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁸⁰ This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. In addition, the Departments have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or the Departments were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage.

contraceptive user fees adjustments, in the 2015 plan year, to obtain reimbursement for contraceptive service payments made for coverage of such services for women covered by self-insured plans that were accommodated. Overall, while recognizing the limited data available, the Departments assumed that, under an expanded exemption and accommodation, approximately 109 previously accommodated entities would use an expanded exemption, and about 100 would continue their accommodated status. We also estimated that another 9 entities would use the accommodation where the entities were not previously eligible to do so.

These sources of information were outlined in the Religious IFC. Some commenters agreed with the Departments' estimates based on those sources, and while others disagreed, the Departments conclude that commenters did not provide information that allows us to make better estimates.

iv. Estimates Based on Litigating Entities That May Use Expanded Exemptions

Based on these and other factors, the Departments considered two approaches in the Religious IFC to estimate the number of women affected among entities using the expanded exemptions. First, following the use in previous regulations of litigating entities to estimate the effect of the exemption and accommodation, the Departments attempted to estimate the number of women covered by plans of litigating entities that could be affected by expanded exemptions. Based on papers filed in litigation, and public sources, the Departments estimated in the Religious IFC that approximately 8,700 women of childbearing age could have their contraception costs affected by plans of litigating entities using these expanded exemptions. The Departments believe that number is lower based upon the receipt, by many of those litigating entities, of permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate, which have been entered by federal district courts since the issuance of the Religious IFC.⁸¹ As a result, these final rules will not affect whether such entities will be subject to the contraceptive Mandate. Subtracting those entities from the total, the Departments estimate that the remaining litigating entities employ

⁸¹ See, for example, *Catholic Benefits Ass'n LCA v. Hargan*, No. 5:14-cv-00240-R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll. v. Burwell*, No. 5:13-cv-04100 (N.D. Iowa order filed June 12, 2018).

approximately 49,000 persons, male and female. The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent.⁸² This amounts to approximately 29,000 employees covered under those plans. EBSA estimates that for each employee policyholder, there is approximately one dependent.⁸³ This amounts to approximately 58,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15 to 44—compose 20.2 percent of the general population.⁸⁴ Furthermore, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.⁸⁵ Therefore, the Departments estimate that approximately 5,200 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that might be affected by these final rules. The Departments also estimate that, for the educational institutions that brought litigation challenges objecting to the Mandate as applied to student coverage that they arranged—where (1) the institutions were not exempt under the prior rule, (2) their student plans were not self-insured, and (3) they have not received permanent injunctions preventing the application of the previous regulations—such student plans likely covered approximately 2,600 students. Thus, the Departments estimate the female members of those plans is 2,600 women.⁸⁶ Assuming, as

referenced above, that 43.6 percent of such women use contraception covered by the Guidelines, the Departments estimate that 1,150 of those women would be affected by these final rules.

Together, this leads the Departments to estimate that approximately 6,400 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted previously, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do the Departments know how many would have alternative contraceptive access from a parent's or spouse's plan, or from federal, state, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

v. Estimates of Accommodated Entities That May Use Expanded Exemptions

In the Religious IFC, the Departments also examined data concerning user-fee reductions to estimate how many women might be affected by entities that are using the accommodation and would use the expanded exemptions under these final rules. Under the accommodation, HHS has received information from issuers that seek user fees adjustments under 45 CFR 156.50(d)(3)(ii), for providing contraceptive payments for self-insured plans that make use of the accommodation. HHS receives requests for fees adjustments both where Third Party Administrators (TPAs) for those self-insured accommodated plans are themselves issuers, and where the TPAs use separate issuers to provide the payments and those issuers seek fees

adjustments. Where the issuers seeking adjustments are separate from the TPAs, the TPAs are asked to report the number of persons covered by those plans. Some users do not enter all the requested data, and not all the data for the 2017 plan year is complete. Nevertheless, HHS has reviewed the user fees adjustment data received for the 2017 plan year. HHS's best estimate from the data is that there were \$38.4 million in contraception claims sought as the basis for user fees adjustments for plans, and that these claims were for plans covering approximately 1,823,000 plan participants and beneficiaries of all ages, male and female.

This number fluctuates from year to year. It is larger than the estimate used in the Religious IFC because, on closer examination of the data, this number better accounts for plans where TPAs were also issuers seeking user fees adjustments, in addition to plans where the TPA is separate from the issuer seeking user fees adjustments. The number of employers using the accommodation where user fees adjustments were sought cannot be determined from HHS data, because not all users are required to submit that information, and HHS does not necessarily receive information about fully insured plans using the accommodation. Therefore, the Departments still consider our previous estimate of 209 entities using the accommodation as the best estimate available.

As noted in the Religious IFC, HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly tens of thousands of persons each and are proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

The Departments continue to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.⁸⁷

⁸² See Kaiser Family Foundation and Health Research and Educational Trust, "Employer Health Benefits: 2018 Annual Survey" at 62, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018>.

⁸³ Employee Benefits Security Administration, "Health Insurance Coverage Bulletin" Table 4, page 21, Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>.

⁸⁴ United States Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at <https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf>. The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." <https://www.hrsa.gov/womensguidelines/>; also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁸⁵ See <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states> (reporting that of 61,491,766 women aged 15–44, 26,809,555 use women's contraceptive methods covered by the Guidelines).

⁸⁶ On average, the Departments expect that approximately half of those students (1,300) are

female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. The Departments expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, the Departments assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 2,600. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, the Departments assume they are. Therefore, for the purposes of this estimate, the Departments assume that the effect of these expanded exemptions on student plans of litigating entities includes 2,600 women.

⁸⁷ See, e.g., <https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule> ("HHS has now established an accommodation that will allow our ministries to continue offering health

Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.⁸⁸ As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.⁸⁹ (The Departments take no view on the status of these particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.) Nevertheless, considering all these factors, it generally seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations, the Religious IFC and these final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.”). In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it “is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia.” Comments on CMS–9968–ANPRM (dated June 15, 2012).

⁸⁸ See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, Advocate Health Care Network, Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) (“CHA members have relied for decades that the ‘church plan’ exemption contained in” ERISA.).

⁸⁹ See <https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf>; see, for example, *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

vi. Combined Estimates of Litigating and Accommodated Entities

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these final rules. In addition to the estimate of 6,400 women of childbearing age that use contraception covered by the Guidelines, who will be affected by use of the expanded exemption among litigating entities, the Departments calculate the following number of women who we estimate to be affected by accommodated entities using the expanded exemption. As noted above, approximately 1,823,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2017. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, the Departments do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, the Departments assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans.⁹⁰ Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in

plans using the accommodation under the previous regulations.

Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans. The data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems and other entities likely to continue using the accommodation constitute over 60 percent of plans using the accommodation, and encompass more than 90 percent of the persons covered in accommodated plans.⁹¹ In other words, plans sponsored by such entities appear to be a majority of plans using the accommodation, and also have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. Moreover, as cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these final rules would not impact the contraceptive coverage their employees receive.

The Departments do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons

⁹⁰ “Health Insurance Coverage Bulletin” Table 3A, page 14. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>.

⁹¹ The data also reflects a religious university using the accommodation that has publicly affirmed the accommodation is consistent with its religious views, and two houses of worship that are using the accommodation despite already qualifying for the previous exemption. We assume for the purposes of this estimate these three entities will also continue using the accommodation instead of the expanded exemption.

previously covered in accommodated plans.

Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, women of childbearing age comprise 20.2 percent of the population, which means that approximately 147,000 women of childbearing age are covered in previously accommodated plans that the Departments estimate will use the expanded exemption. As noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that the Departments expect approximately 64,000 women that use contraception covered by the Guidelines will be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 6,400 women in plans of litigating entities that may be affected by these rules. In order to more broadly estimate the possible effects of these rules, the Departments assume there is no overlap between the two numbers, and therefore that these final rules would affect the contraceptive costs of approximately 70,500 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these final rules is approximately 0.1 percent of the 55.6 million women in private plans that HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated in 2015 received preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the previous accommodation process, the total amount of contraceptive claims sought for self-insured plans for the 2017 benefit year was \$38.5 million.⁹² These adjustments covered the cost of contraceptive coverage provided to women. As also discussed above, the Departments estimate that amount corresponded to plans covering

1,823,000 persons. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age, and of those, approximately 43.6 percent use women's contraceptive methods covered by the Guidelines. This amounts to approximately 161,000 women. Therefore, entities using contraceptive user fees adjustments received approximately \$239 per year per woman of childbearing age that used contraception covered by the Guidelines and covered in their plans. But in the Religious IFC, we estimated that the average annual cost of contraception per woman per year is \$584. As noted above, public commenters cited similar estimates of the annual cost of various contraceptive methods, if calculated for the life of the method's effectiveness. Therefore, to estimate the annual transfer effects of these final rules, the Departments will continue to use the estimate of \$584 per woman per year. With an estimated impact of these final rules of 70,500 women per year, the financial transfer effects attributable to these final rules on those women would be approximately \$41.2 million.

Some commenters suggested that the Departments' estimate of women affected among litigating entities was too low, but they did not support their proposed higher numbers with citations or specific data that could be verified as more reliable than the estimates in the Religious IFC. Their estimates appeared to be overinclusive, for example, by counting all litigating entities and not just those that may be affected by these rules because they are not in church plans, or by counting all plan participants and not just women of childbearing age that use contraception. Moreover, since the Religious IFC was issued, additional entities have received permanent injunctions against enforcement of any regulations implementing the contraceptive Mandate and so will not be affected by these final rules. Taking all of these factors into account, the Departments are not aware of a better method of estimating the number of women affected by these expanded exemptions.

vii. Alternate Estimates Based on Consideration of Pre-ACA Plans

To account for uncertainty in the estimates above, the Departments conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these final rules.

In 2015, ASPE estimated that 55.6 million women aged 15 to 64 were covered by private insurance had

preventive services coverage under the Affordable Care Act.⁹³ The Religious IFC used this estimate in this second analysis of the possible impact of the expanded exemptions in the interim final rules. ASPE has not issued an update to its report. Some commenters noted that a private organization published a fact sheet in 2017 claiming to make similar estimates based on more recent data, in which it estimated that 62.4 million aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.⁹⁴ The primary difference between these numbers appears to be a change in the number of persons covered by grandfathered plans.

The methodology of both reports do not fully correspond to the number the Departments seek to estimate here for the purposes of *Executive Orders 12866 and 13563*. These final rules will not affect all women aged 15 to 64 who are covered by private insurance and have coverage of preventive services under the Affordable Care Act. This is partly because the Departments do not have evidence to suggest that most employers will have sincerely held religious objections to contraceptive coverage and will use the expanded exemptions. In addition, both reports include women covered by plans that are not likely affected by the expanded exemptions for other reasons. For example, even though the estimates in those reports do not include enrollees in public plans such as Medicare or Medicaid, they do include enrollees in plans obtained on the health insurance marketplaces, purchased in the individual market, obtained by self-employed persons, or offered by government employers. Women who purchase plans in the marketplaces, the individual market, or as self-employed persons are not required to use the exemptions in these rules. Government employers are also not affected by the exemptions in these rules.

In response to public comments citing the more recent report, the Departments offer the following estimates based on more recent data than used in the Religious IFC. Data from the U.S. Census Bureau indicates that 167.6 million individuals, male and female, under 65 years of age, were covered by

⁹³ Available at <https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf>.

⁹⁴ The commenters cited the National Women's Law Center's Fact Sheet from September 2017, available at <https://nwlcl-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf>.

⁹² The amount of user fees adjustments provided was higher than this, since an additional administrative amount was added to the amount of contraceptive costs claimed.

employment-based insurance in 2017.⁹⁵ Of those, 50.1 percent were female, that is, 84 million.⁹⁶ The most recent Health Insurance Coverage Bulletin from EBSA states that, within employer-sponsored insurance, 76.5% are covered by private sector employers.⁹⁷ As noted above, these expanded exemptions do not apply to public sector employers. Assuming the same percentage applies to the Census data for 2017, 64.2 million women under 65 years of age were covered by private sector employment based insurance. EBSA's bulletin also states that, among those covered by private sector employer sponsored insurance, 5% receive health insurance coverage from a different primary source.⁹⁸ We assume for the purposes of this estimate that an exemption claimed by an employer under these rules need not affect contraceptive coverage of a person who receives health insurance coverage from a different primary source. Again assuming this percentage applies to the 2017 coverage year, we estimate that 61 million women under 65 years of age received primary health coverage from private sector, employment-based insurance. In conducting this analysis, the Departments also observed that for 3.8 percent of those covered by private sector employment sponsored insurance, the plan was purchased by a self-employed person, not by a third party employer. Self-employed persons who direct firms are not required to use the exemptions in these final rules, but if they do, they would not be losing contraceptive coverage that they want to have, since they would be using the exemption based on their sincerely held religious beliefs. If those persons have employees, the employees would be included in this estimate in the number of people who receive employer sponsored insurance from a third party. Assuming this percentage applies to the 2017 coverage year, we estimate that 58.7 million women under 65 years of age received primary health coverage

from private sector insurance from a third party employer plan sponsor.

The Kaiser Family Foundation's Employer Health Benefits Annual Survey 2018 states that 16% of covered workers at all firms are enrolled in a plan grandfathered under the ACA (and thus not subject to the preventive services coverage requirements), but that only 14% of workers receiving coverage from state and local government employer plans are in grandfathered plans.⁹⁹ Using the data cited above in EBSA's bulletin concerning the number of persons covered in public and private sector employer sponsored insurance, this suggests 16.6% of persons covered by private sector employer sponsored plans are in grandfathered plans, and 83.4% in non-grandfathered plans.¹⁰⁰ Applying this percentage to the Census data, 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based, non-grandfathered plans. Census data indicates that among women under age 65, 46.7% are of childbearing age (aged 15 to 44).¹⁰¹ Therefore, we estimate that 22.9 million women aged 15–44 received primary health insurance coverage from private sector, third party employment based, non-grandfathered insurance plans.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.¹⁰² The 6 percent may have included approximately 1.37 million of the women aged 15 to 44 primarily covered by employer-sponsored insurance plans in the private sector. And as noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore, the Departments estimate that 599,000

women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.¹⁰³

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for religious or other reasons. Despite the lack of information about their motives, the Departments attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, the Departments estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby*, where the Court observed that "HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable." 134 S. Ct. at 2774. The Departments are aware of several federal health care conscience

¹⁰³ Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these final rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these final rules.

⁹⁵ See U.S. Census Bureau Current Population Survey Table HI-01, "Health Insurance Coverage in 2017: All Races," available at https://www2.census.gov/programs-surveys/cps/tables/hi-01/2018/hi01_1.xls.

⁹⁶ *Id.*

⁹⁷ Table 1A, page 5 (stating that in coverage year 2015, 177.5 million persons of all ages were covered by employer sponsored insurance, with 135.7 million of those being covered by private sector employers), available at <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>.

⁹⁸ *Id.* at Table 1C, page 8 (168.7 million persons received health insurance coverage from employer sponsored insurance as their primary source, compared to 177.5 million persons covered by employer sponsored insurance overall).

⁹⁹ "Employer Health Benefits: 2018 Annual Survey" at 211, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018>.

¹⁰⁰ EBSA's bulletin shows 168.7 million persons with primary coverage from employer sponsored insurance, with 131.6 million in the private sector and 37.1 million in the public sector. 16% of 168.7 million is 26.9 million. 14% of 37.1 million is 5.2 million. 26.9 million – 5.2 million is 21.8 million, which is 16.6% of the 131.6 million persons with primary coverage from private sector employer sponsored insurance.

¹⁰¹ U.S. Census Bureau, Table S0101 "Age and Sex" (available at https://data.census.gov/cedsci/results?table=S0101.%20AGE%20AND%20SEX&ps=table*currentPage@1).

¹⁰² Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2010 Annual Survey" at 196, available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf>.

laws¹⁰⁴ that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but the Departments are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while the Departments consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those reasons used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions, the Departments agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.¹⁰⁵ That means that only approximately 411,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, because these final rules build on previous regulations that already exempted houses of worship and integrated auxiliaries and, as explained above, effectively eliminated obligations to provide contraceptive coverage within objecting self-insured church plans, the Departments attempt to estimate the number of such employers whose employees would not be affected by these rules. In attempting to estimate the number of such employers, the Departments consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the United States,¹⁰⁶ 197 Catholic

dioceses,¹⁰⁷ 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.¹⁰⁸ Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so the Departments use the number of schools as an estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention covering 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.¹⁰⁹ Christian Brothers is a plan that covers Catholic organizations including Catholic churches and integrated auxiliaries, which are estimated above, but has also said in litigation that it covers about 500 additional entities that are not exempt as churches.¹¹⁰ In total, therefore, without having certain data on the number of entities exempt under the previous rules, the Departments estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous regulations. The Departments do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include “churches, mission-sending agencies, hospitals, educational institutions and other related ministries.” Using that ratio, the Departments estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 women would be of childbearing age, and 32,100 may use contraceptives covered by the Guidelines.

Taking all of these factors into account, the Departments estimate that

the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines. But to estimate the likely actual transfer impact of these final rules, the Departments must estimate not just the number of such women covered by those entities, but how many of those entities would actually qualify for, and use, the expanded exemptions.

The Departments do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, the Departments believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. Consequently, as explained below, the Departments believe that the potential impact of these final rules falls substantially below the \$100 million threshold for an economically significant major rule.

First, as mentioned, the Departments are not aware of information, or of data from public comments, that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or, specifically, religious beliefs, as opposed to having done so for other reasons. It would seem reasonable to assume that many of those entities did not do so based on sincerely held religious beliefs. According to a 2016 poll, only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective).¹¹¹ In addition,

¹⁰⁴ For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

¹⁰⁵ John Asker, et al., “Corporate Investment and Stock Market Listing: A Puzzle?” 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at <https://doi.org/10.1093/rfs/hhu077>. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, “The number of publicly-traded US companies is down 46% in the past two decades,” *Yahoo! Finance* (Aug. 8, 2016), available at <https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html>.

¹⁰⁶ Roman Catholic Diocese of Reno, “Diocese of Reno Directory: 2016–2017,” available at <http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf>.

¹⁰⁷ Wikipedia, “List of Catholic dioceses in the United States,” available at https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.

¹⁰⁸ National Catholic Educational Association, “Catholic School Data,” available at http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.

¹⁰⁹ Guidestone Financial Resources, “Who We Serve,” available at <https://www.guidestone.org/AboutUs/WhoWeServe>.

¹¹⁰ The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

¹¹¹ Pew Research Center, “Where the Public Stands on Religious Liberty vs. Nondiscrimination”

various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage, such as avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.¹¹² Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees and, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

It may not be the case that all entities that objected on religious grounds to contraceptive coverage before the ACA brought suit against the Mandate. However, it is worth noting that, while less than 100 for-profit entities challenged the Mandate in court (and an unknown number joined two newly formed associational organizations bringing suit on their behalf), there are more than 3 million for-profit private sector establishments in the United States that offer health insurance.¹¹³ Six

percent of those would be 185,000, and one third of that number would be 62,000. The Departments consider it unlikely that tens or hundreds of thousands of for-profit private sector establishments omitted contraceptive coverage pre-ACA specifically because of sincerely held religious beliefs, when, after six years of litigation and multiple public comment periods, the Departments are aware of less than 100 such entities. The Departments do not know how many additional nonprofit entities would use the expanded exemptions, but as noted above, under the rules predating the Religious IFC, tens of thousands were already exempt as churches or integrated auxiliaries, or were covered by self-insured church plans that are not penalized if no contraceptive coverage is offered.

Finally, among entities that omitted contraceptive coverage based on sincerely held conscientious objections as opposed to other reasons, it is likely that some, albeit a minority, did so based on moral objections that are non-religious, and therefore would not be compassed by the expanded exemptions in these final rules.¹¹⁴ Among the general public, polls vary about religious beliefs, but one prominent poll shows that 13 percent of Americans say they do not believe in God or have no opinion on the question.¹¹⁵ Therefore, the Departments estimate that, of the entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, a small fraction did so based on sincerely held non-religious moral convictions, and therefore would not be affected by the expanded exemption provided by these final rules for religious beliefs.

For the reasons stated above, the Departments believe it would be incorrect to assume that all or even most of the plans that did not cover contraceptives before the ACA did so on the basis of religious objections. Instead, without data available on the reasons those plans omitted contraceptive coverage before the ACA, we assume that no more than one third of those plans omitted contraceptive coverage based on sincerely held religious beliefs. Thus, of the estimated 379,000 women aged 15 to 44 that use contraceptives

covered by the Guidelines, who received primary coverage from plans of private, non-publicly traded, third party employers that did not cover contraception pre-Affordable Care Act, and whose plans were neither exempt nor omitted from mandatory contraceptive coverage under the previous regulations, we estimate that no more than 126,400 women would be in plans that will use these expanded exemptions.

viii. Final Estimates of Persons Affected by Expanded Exemptions

Based on the estimate of an average annual expenditure on contraceptive products and services of \$584 per user, the effect of the expanded exemptions on 126,400 women would give rise to approximately \$73.8 million in potential transfer impact. It is possible, however, that premiums would adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As referenced elsewhere in this analysis, such women may make up approximately 8.8 percent of the covered population,¹¹⁶ in which case the offset would also be approximately 8.8 percent, yielding a potential transfer of \$67.3 million.

Thus, in their most expansive estimate, the Departments conclude that no more than approximately 126,400 women would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. The Departments estimate this financial transfer to be approximately \$67.3 million. This falls substantially below the \$100 million threshold for an economically significant and major rule.

As noted above, the Departments view this alternative estimate as being the highest possible bound of the transfer effects of these rules, but believe the number of establishments that will actually exempt their plans as the result of these rules will be far fewer than contemplated by this estimate. The Departments make these estimates only for the purposes of determining whether the rules are economically significant under Executive Orders 12866 and 13563.

After reviewing public comments, both those supporting and those disagreeing with these estimates and similar estimates from the Religious IFC, and because the Departments do not have sufficient data to precisely

at page 26 (Sept. 28, 2016), available at <http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf>.

¹¹² On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered “yes” or “don’t know” to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule’s effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

¹¹³ Tables I.A.1 and I.A.2, Medical Expenditure Panel Survey, “Private-Sector Data by Firm Size, Industry Group, Ownership, Age of Firm, and Other Characteristics: 2017,” HHS Agency for Healthcare Research and Quality (indicating total number of for-profit incorporated, for-profit unincorporated, and non-profit establishments in the United States, and the percentage of each that offer health insurance), available at https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia1.htm and https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia2.htm. 2523.

¹¹⁴ Such objections may be encompassed by companion final rules published elsewhere in today’s **Federal Register**. Those final rules, however, are narrower in scope than these final rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

¹¹⁵ Gallup, “Religion,” available at <https://news.gallup.com/poll/1690/religion.aspx>.

¹¹⁶ As cited above, women of childbearing age are 20.2 percent of woman aged 15–65, and 43.6 percent of women of childbearing age use contraceptives covered by the Guidelines.

estimate the amount by which these factors render our estimate too high, or too low, the Departments simply conclude that the financial transfer falls substantially below the \$100 million threshold for an economically significant rule based on the calculations set forth above.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. The Religious IFC was an interim final rule with comment period, and in these final rules, the Departments adopt the Religious IFC as final with certain changes. These final rules are, thus, being issued after a notice and comment period.

The Departments also carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866 and do not expect that these final

rules will have a significant economic effect on a substantial number of small entities. These final rules will not result in any additional costs to affected entities, and, in many cases, may relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization—businesses and organizations that would otherwise be faced with the dilemma of complying with the Mandate (and violating their religious beliefs) or following their beliefs (and incurring potentially significant financial penalties for noncompliance)—the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires

that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. In the October 13, 2017 (82 FR 47792) interim final rules, we solicited public comment on each of these issues for the following sections of the rule containing information collection requirements (ICRs). A description of the information collection provisions implicated in these final rules is given in the following section with an estimate of the annual burden. The burden related to these ICRs received emergency review and approval under OMB control number 0938–1344. They have been resubmitted to OMB in conjunction with these final rules and are pending re-approval. The Departments sought public comments on PRA estimates set forth in the Religious IFC, and are not aware of significant comments submitted that suggest there is a better way to estimate these burdens.

1. Wage Data

Average labor costs (including 100 percent fringe benefits and overhead) used to estimate the costs are calculated using data available derived from the Bureau of Labor Statistics.¹¹⁷

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupational code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Executive Secretaries and Executive Administrative Assistants	43–6011	\$27.84	\$27.84	\$55.68
Compensation and Benefits Manager	11–3111	61.01	61.01	122.02
Legal Counsel	23–1011	67.25	67.25	134.50
Senior Executive	11–1011	93.44	93.44	186.88
General and Operations Managers	11–1021	58.70	58.70	117.40

2. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under these final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all

or a subset of contraceptive services. Specifically, these final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations (80 FR 41318).

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party

¹¹⁷ May 2016 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm.

administrator). As explained above, HHS assumes that, among the 209 entities the Departments estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.¹¹⁸ HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$55.68 per hour, 10 minutes for a compensation and benefits manager at a cost of \$122.02 per hour, 5 minutes for legal counsel at a cost of \$134.50 per hour, and 5 minutes by a senior executive at a cost of \$186.88 per hour) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost of approximately \$74.96 for a total hour burden of approximately 7.5 hours and an associated equivalent cost of approximately \$675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so that each will account for approximately 3.75 burden hours with an equivalent cost of approximately \$337.

HHS estimates that each self-certification or notice to HHS will require \$0.50 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be \$0.55. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for

sending the self-certifications or notices to HHS by mail is approximately \$2.75 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so that each will account for \$1.38 of the cost burden.

3. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations (80 FR 41318), a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language previously provided by HHS or substantially similar language.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$55.68 per hour) and 15 minutes of management review (at \$117.40 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an associated cost of approximately \$85.03. The total burden for all 109 issuers or third party administrators will be 136 hours, with an associated cost of approximately \$9,268. As DOL and HHS share jurisdiction, they are splitting the burden each will account for 68 burden hours with an associated cost of \$4,634, with approximately 55 respondents.

The Departments estimate that approximately 2,180,000 plan participants and beneficiaries will be

covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. We reach this estimate using calculations set forth above, in which we used 2017 data available to HHS for contraceptive user fees adjustments to estimate that approximately 2,907,000 plan participants and beneficiaries were covered by plans using the accommodation. We further estimated that the 100 entities that previously used the accommodation and will continue doing so will cover approximately 75 percent of the persons in all accommodated plans, based on HHS data concerning accommodated self-insured plans that indicates plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As noted above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans. The Departments do not have specific data on which plans of which employer sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data.

Based on these assumptions and without better data available, the Departments estimate that previously accommodated entities encompassed approximately 2,907,000 persons; the estimated 100 entities that previously used the accommodation and continue to use it will account for 75 percent of those persons (that is, approximately 2,180,000 persons); and the estimated 109 entities that previously used the accommodation and will now use their exempt status will account for 25 percent of those persons (that is, approximately 727,000 persons). It is not known how many persons will be covered in the plans of the 9 entities we estimate will newly use the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity as the 100 entities encompassing 2,180,000

¹¹⁸ For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

persons, the Departments estimate that all 109 accommodated entities will encompass approximately 2,376,000 covered persons.

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.¹¹⁹ For 109 entities, the total number of notices will be 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.¹²⁰ Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require \$0.50 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.55. The total cost for sending approximately 551,254 notices by mail will be approximately \$303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for \$151,595 of the cost burden.

4. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization that now wishes to take advantage of the

expanded exemption may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to send the notification; the issuer or third party administrator can send the notice on behalf of the entity. For the purpose of calculating the ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke their use of the accommodation fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of \$117.40 per hour, 30 minutes for legal counsel at a cost of \$134.50 per hour, 1 hour for clerical staff at a cost of \$55.68 per hour). The burden per respondent will be 2 hours with an associated cost

of approximately \$182; for 109 entities, the total hour burden will be 218 hours with an associated cost of approximately \$19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an associated cost of approximately \$9,899.

As discussed above, HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.¹²¹ As before, the Departments use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require \$0.50 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.55. The total cost for sending approximately 168,579 notices by mail is approximately \$93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately \$46,772.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB Control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total cost (\$)
Self-Certification or Notices to HHS	0938–1344	* 5	5	0.83	3.75	\$89.95	\$337	\$339
Notice of Availability of Separate Payments for Contraceptive Services	0938–1344	* 55	595,307	1.25	68.13	68.02	4,634	156,229
Notice of Revocation of Accommodation ..	0938–1344	* 55	182,051	2.00	109	90.82	9,899	56,671
Total		* 115	777,363		180.88		14,870	213,239

* The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

¹¹⁹ “Health Insurance Coverage Bulletin” Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>.

¹²⁰ According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic

disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

¹²¹ In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the

number of women in accommodated plans affected by these final rules overlap with the number of women in plans offered by litigating entities that will be affected by these final rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

5. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

The Religious final rules amended the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer revokes their accommodation; these final rules confirm as final the Religious IFC provisions on the accommodation process. DOL submitted the ICRs to OMB in order to obtain OMB approval under the PRA for the regulatory revision. In an effort to consolidate the number of information collection requests, DOL is combining the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150 and discontinuing OMB control number 1210–0152. Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur \$0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services.

These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur \$0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 1,190,613 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke their use of the accommodation (in favor of the expanded exemption) and will therefore be required to cause the Notice of Revocation of Accommodation to be sent, with the issuer or third party administrator able to send the notice on behalf of the entity. These entities will spend approximately two hours in preparation time and incur \$0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 364,102 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114 ¹²² (combined with HHS total is 227).

Total Responses: 777,362 (combined with HHS total is 1,554,724).

Frequency of Response: On occasion.

Estimated Total Annual Burden

Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: \$197,955 (combined with HHS total is \$395,911).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, “[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall

¹²² Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” In addition, agencies are directed to “take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the states more flexibility and control to create a freer and open healthcare market.” These final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these final rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.¹²³ However, in order to avoid double-counting with the Religious IFC, which has already been tallied as an Executive Order 13771 deregulatory action, this finalization of the IFC’s policy is not considered a deregulatory action under the Executive Order.

¹²³ Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB’s guidance on E.O. 13771 implementation (Dominic J. Mancini, “Guidance Implementing Executive Order 13771, Titled ‘Reducing Regulation and Controlling Regulatory Costs,’” Office of Mgmt. & Budget (Apr. 5, 2017), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf>) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this final rule’s medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104-4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.” In 2018, that threshold after adjustment for inflation is \$150 million. For purposes of the Unfunded Mandates Reform Act, the Religious IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of \$150 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These final rules do not have any federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

V. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code, and Public Law 103-141, 107 Stat. 1488 (42 U.S.C. 2000bb-2000bb-4).

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-

200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111-148, 124 Stat. 119, as amended by Public Law 111-152, 124 Stat. 1029; Pub. L. 103-141, 107 Stat. 1488 (42 U.S.C. 2000bb-2000bb-4); Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended; and Title I of the Affordable Care Act, sections 1301-1304, 1311-1312, 1321-1322, 1324, 1334, 1342-1343, 1401-1402, 1412, Public Law 111-148, 124 Stat. 119 (42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701); and Public Law 103-141, 107 Stat. 1488 (42 U.S.C. 2000bb-2000bb-4).

List of Subjects*26 CFR Part 54*

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY**Internal Revenue Service**

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ 2. Section 54.9815-2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815-2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 54.9815-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 3. Section 54.9815-2713A is revised to read as follows:

§ 54.9815-2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the

Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(b) *Optional accommodation—self-insured group health plans*—(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services) will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide

administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not

apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of

Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the

eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be

incorrect, the issuer is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 54.9815–2713T [Removed]

■ 4. Section 54.9815–2713T is removed.

§ 54.9815–2713AT [Removed]

■ 5. Section 54.9815–2713AT is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor adopts as final the interim final rules amending 29 CFR part 2590 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read, as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L.

110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713A is amended by:

- a. Revising paragraph (a)(5);
- b. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g); and
- c. Adding new paragraph (e).

The revision and addition read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) * * *

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided).

Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization’s revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 8. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 9. Section 147.131 is amended by:

- a. Revising paragraph (c)(4);
- b. Redesignating paragraphs (f) and (g) as (g) and (h); and
- c. Adding new paragraph (f).

The revision and addition read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

* * * * *

(c) * * *

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after January 14, 2019, if

contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(f) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

■ 10. Section 147.132 is amended by:

- a. Revising paragraph (a)(1) introductory text;
- b. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (iii) and (iv);
- c. Adding new paragraph (a)(1)(ii);
- d. Revising newly designated paragraph (a)(1)(iii);
- e. Revising newly designated paragraph (a)(1)(iv); and
- f. Revising paragraphs (a)(2) and (b).

The revisions and addition read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or

maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide

coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD-9841]

RIN 1545-BN91

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS-9925-F]

RIN 0938-AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, the interim final rules issued in the **Federal Register** on October 13, 2017 concerning moral exemptions and accommodations regarding coverage of certain preventive services. These rules finalize expanded exemptions to protect moral beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an optional “accommodation” process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu at (301) 492-4305 or marketreform@cms.hhs.gov for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
Amber Rivers or Matthew Litton at (202) 693-8335 for Employee Benefits Security Administration (EBSA), Department of Labor (DOL).
William Fischer at (202) 317-5500 for Internal Revenue Service, Department of the Treasury.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit DOL’s website (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS’s website (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Executive Summary and Background
 - A. Executive Summary
 1. Purpose
 2. Summary of the Major Provisions
 3. Summary of Costs, Savings and Benefits of the Major Provisions
 - B. Background
- II. Overview of the Final Rules and Public Comments
 - A. Moral Exemptions and Accommodation in General
 1. The Departments’ Authority to Mandate Coverage or Provide Exemptions
 2. Congress’s History of Protecting Moral Convictions
 - a. The Church Amendments’ Protection of Moral Convictions
 - b. Court Precedents Relevant to These Expanded Exemptions
 - c. Conscience Protections in Other Federal and State Contexts
 - d. Founding Principles
 - e. Executive Orders Relevant to These Expanded Exemptions
 - f. Litigation Concerning the Mandate
 3. Whether Moral Exemptions Should Exist, and Whom They Should Cover
 4. The Departments’ Rebalancing of Government Interests
 5. Burdens on Third Parties
 6. Interim Final Rulemaking
 7. Health Effects of Contraception and Pregnancy
 8. Health and Equality Effects of Contraceptive Coverage Mandates
 9. Other General Comments
 - B. Text of the Final Rules
 1. Restatement of Statutory Requirements of Section 2713(a) and (a)(4) of the PHS Act (26 CFR 54.9815-2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715-2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv)).

2. Exemption for Objecting Entities Based on Moral Convictions (45 CFR 147.133(a))
3. Exemption for Certain Plan Sponsors (45 CFR 147.133(a)(1)(i))
 - a. Plan sponsors in general (45 CFR 147.133(a)(1)(i) prefatory text)
 - b. Nonprofit organizations (45 CFR 147.133(a)(1)(i)(A))
 - c. For-Profit Entities (45 CFR 147.133(a)(1)(i)(B))
4. Institutions of Higher Education (45 CFR 147.133(a)(1)(ii))
5. Health Insurance Issuers (45 CFR 147.133(a)(1)(iii))
6. Description of the Moral Objection (45 CFR 147.133(a)(2))
7. Individuals (45 CFR 147.133(b))
8. Accommodation (45 CFR 147.131, 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A)
9. Definition of Contraceptives for the Purpose of These Final Rules
10. Severability
- C. Other Public Comments
 1. Items Approved as Contraceptives But Used to Treat Existing Conditions
 2. Comments Concerning Regulatory Impact
- III. Economic Impact and Paperwork Burden
 - A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor
 1. Need for Regulatory Action
 2. Anticipated Effects
 - B. Special Analyses—Department of the Treasury
 - C. Regulatory Flexibility Act
 - D. Paperwork Reduction Act—Department of Health and Human Services
 - E. Paperwork Reduction Act—Department of Labor
 - F. Regulatory Reform Executive Orders 13765, 13771 and 13777
 - G. Unfunded Mandates Reform Act
 - H. Federalism
- IV. Statutory Authority

I. Executive Summary and Background**A. Executive Summary****1. Purpose**

The primary purpose of these final rules is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47838), “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” (the Moral IFC). The rules are necessary to protect sincerely held moral objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their moral beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, which was created by HHS through guidance promulgated by the Health Resources and Services

Administration (HRSA), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules finalize references to these moral exemptions in the previously created accommodation process that permit entities with certain objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's guidelines. The changes to the rules being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Moral Exemptions

These rules finalize exemptions provided in the Moral IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held moral convictions opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's guidelines. As in the Moral IFC, the exemptions include plan sponsors that are nonprofit organization plan sponsors or for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The exemptions also continue to include institutions of higher education in their arrangement of student health insurance coverage; health insurance issuers (but only with respect to plans that are otherwise also exempt under the rules); and objecting

individuals with respect to their own coverage, where their health insurance issuer and plan sponsor, as applicable, are willing to provide coverage complying with the individual's moral objection. After considering public comments, the Departments have decided not to extend the moral exemptions to non-federal governmental entities at this time, although individuals receiving employer-sponsored insurance from a governmental entity may use the individual exemption if the other terms of the individual exemption apply, including that their employer is willing to offer them a plan consistent with their moral objection.

In response to public comments, various changes are made to clarify the intended scope of the language in the Moral IFC's exemptions. The prefatory exemption language is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to specify that the exemption for institutions of higher education applies to non-governmental entities. The Departments also modified language describing the moral objection applicable to the exemptions, to specify that the entity objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable) either: Coverage or payments for some or all contraceptive services; or a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The clarification is made to ensure that the HRSA guidelines do not prevent a willing health insurance issuer offering group or

individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. References to Moral Exemptions in Accommodation Regulations and in Regulatory Restatement of Statutory Language

These rules finalize without change the references to the moral exemptions that were inserted by the Moral IFC into the rules that regulatorily restate the statutory language from section 2713(a) and (a)(4) of the Public Health Service Act. Similarly, these rules finalize without change from the Moral IFC references to the moral exemptions that were inserted into the regulations governing the optional accommodation process. These references operationalize the effect of the moral exemptions rule, and they allow contraceptive services to be made available to women if any employers with non-religious moral objections to contraceptive coverage choose to use the optional accommodation process.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and Benefits	Costs
Finalizing insertion of references to moral exemptions into restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	These provisions, finalized without change, are for the purpose of inserting references to the moral exemptions into the regulatory restatement of section 2713(a) and (a)(4) of the Public Health Service Act, which already references the religious exemptions. This operationalizes the moral exemptions in each of the tri-agencies' rules. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.

Provision	Savings and Benefits	Costs
Finalized moral exemptions	The moral exemptions to the contraceptive coverage requirement are finalized with technical changes. Their purpose is to relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their moral beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage in violation of their sincerely held moral beliefs.	We estimate there will be only a small amount of costs for these exemptions, because they will primarily be used by organizations and individuals that do not want contraceptive coverage. To the extent some other employers will use the exemption where there will be transfer costs for women previously receiving contraceptive coverage who will no longer receive that coverage, we expect those costs to be minimal due to the small number of entities expected to use the exemptions with non-religious moral objections. We estimate the transfer costs will amount to \$8,760.
Finalizing insertion of references to moral exemptions into optional accommodation regulations.	These provisions, finalized without change, will allow organizations with moral objections to contraceptive coverage on the basis of sincerely held moral convictions to use the accommodation as an optional process. These provisions will allow contraceptive coverage to be made available to women covered by plans of employers that object to contraceptive coverage but do not object to their issuers or third party administrators arranging for such coverage to be provided to persons covered by their plans.	We do not estimate any entities with non-religious moral objections to use the accommodation process at this time.

B. Background

Over many decades, Congress has protected conscientious objections including based on moral convictions in the context of health care and human services, and including health coverage, even as it has sought to promote access to health services.¹ In 2010, Congress

¹ See, for example, 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their “religious beliefs or moral convictions”); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any “health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan” in objecting to abortion for any reason); *Id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions”); *Id.* at Div. E, Sec. 808 (regarding any requirement of “the provision of contraceptive coverage by health insurance plans” in the District of Columbia, “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”); *Id.* at Div. K, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their “religious or conscientious commitment to offer only natural family planning”); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on “religious beliefs or moral objections”); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice, now Medicare Advantage, managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on “conscience” as protected in State law concerning

enacted the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended PPACA. As amended by HCERA, PPACA is known as the Affordable Care Act (ACA).

The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and

advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on “religious beliefs or moral convictions”); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by “aliens” due to “religious beliefs or moral convictions”); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on “moral or religious convictions”); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their “religious or moral objection”).

health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter “section 2713(a)(4)”), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women’s preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, “with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported” by HRSA (the “Guidelines”).

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.² In the same

² The references in this document to “contraception,” “contraceptive,” “contraceptive coverage,” or “contraceptive services” generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women’s Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to “Contraceptive Methods and Counseling” as “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” <https://www.hrsa.gov/womens-guidelines/index.html>. The Guidelines as amended in December 2016 refer, under the header “Contraception,” to: “the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family

time period, the administering agencies—HHS, the Department of Labor, and the Department of the Treasury (collectively, “the Departments”³)—exercised discretion to allow exemptions to those requirements by issuing rulemaking various times, including issuing and finalizing three interim final regulations prior to 2017.⁴ In those regulations, the Departments crafted exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Public comments were submitted on various iterations of the regulations issued before 2017, and some of those comments supported expanding the exemptions to include those who oppose the contraceptive coverage mandate for either religious “or moral” reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.⁵

planning practices, and sterilization procedures,” “contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),” and “instruction in fertility awareness-based methods, including the lactation amenorrhea method.” <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

³ Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

⁴ Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.

⁵ See, for example, Denise M. Burke, Re: file code CMS-9968-P, *Regulations.gov* (posted May 5, 2013), <http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115>; Comment, *Regulations.gov* (posted Oct. 26, 2016), <https://www.regulations.gov/document?D=CMS-2016-0123-54142>; David Sater, Re: CMS-9931-NC: Request for Information, *Regulations.gov* (posted Oct. 26, 2016), <https://www.regulations.gov/document?D=CMS-2016-0123-54218>; Comment, *Regulations.gov* (posted Oct. 26, 2016), <https://www.regulations.gov/document?D=CMS-2016-0123-54218>.

During the period when the Departments were publishing and modifying the regulations, organizations and individuals filed dozens of lawsuits challenging the contraceptive coverage requirement and regulations (hereinafter, the “contraceptive Mandate,” or the “Mandate”). Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. For-profit entities with religious objections won various court decisions leading to the Supreme Court’s ruling in *Burwell v. Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.⁶ Later, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On May 16, 2016, the Supreme Court issued a per curiam decision, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments’ favor—and remanding the cases “in light of the substantial clarification and refinement in the positions of the parties” that had been filed in supplemental briefs. *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would “allow the parties sufficient time to resolve any outstanding issues between them.” *Id.*

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations stated that they believe some methods classified by the Food and Drug Administration (FDA) as contraceptives may have an abortifacient effect and, therefore, in their view, are morally equivalent to abortion to which they

www.regulations.gov/document?D=CMS-2016-0123-46220.

⁶ The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

have a moral objection. Under regulations preceding October 2017, these organizations neither received an exemption from the Mandate nor qualified for the accommodation. For example, March for Life filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, 77 FR 8727, March for Life argued that the Departments’ stated interests behind the Mandate were only advanced among women who “want” the coverage so as to prevent “unintended” pregnancy. March for Life contended that, because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments’ interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and, therefore, was arbitrary and capricious in violation of the APA. March for Life further contended that, because the Departments concluded the government’s interests were not undermined by exempting houses of worship and integrated auxiliaries (based on the assumption that such entities are relatively more likely than other nonprofits with religious objections to have employees that share their views against certain contraceptives), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and, therefore, violated their right of equal protection under the Due Process Clause.

March for Life’s employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violated their rights under RFRA by making it impossible for them to obtain health coverage consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate’s requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real*

Alternatives, Inc. v. Burwell, 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims, while not specifically ruling on the APA claim, and issued a permanent injunction against the Departments that is still in place. *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, federal district and appellate courts in Pennsylvania disagreed with the reasoning in *March for Life*, and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives*, 150 F. Supp. 3d 419, affirmed by 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives v. Sec'y of HHS* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. 867 F.3d 338, 367 (3d Cir. 2017) (Jordan, J., dissenting).

The Departments most recently solicited public comments on these issues again in two interim final regulations with request for comments published in the **Federal Register** on October 13, 2017: The regulations (82 FR 47838) (the Moral IFC) that are being finalized with changes here, and the regulations (82 FR 47792) (the Religious IFC) published on the same day as the Moral IFC, which are being finalized with changes in the companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Moral IFC, the Departments explained several reasons why, after exercising our discretion to reevaluate the exemptions and accommodations for the contraceptive Mandate, we sought public comment on whether to protect moral convictions in the Moral IFC and these final rules. The Departments noted that we considered, among other things, Congress's history of providing protections for moral convictions regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017); previously submitted public comments; and the extensive litigation over the contraceptive Mandate. The Departments concluded that it was appropriate that HRSA take into account

the moral convictions of certain employers, individuals and health insurance issuers where the coverage of contraceptive services is concerned. Comments were requested on the interim final regulations.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Moral IFC, with changes based on comments as indicated herein.⁷

II. Overview of the Final Rules and Public Comments

During the 60-day comment period for the Moral IFC, which closed on December 5, 2017, the Departments received over 54,000 public comment submissions, which are posted to www.regulations.gov.⁸ Below, the Departments provide an overview of the final rules and address the issues raised in the comments we received.

A. Moral Exemptions and Accommodation in General

These rules expand exemptions to protect certain entities and individuals with moral convictions that oppose contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also make available to exempt organizations the accommodation process, which was previously established in response to some objections of religious organizations, as an optional process for exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and

counseling for women at risk of unintended pregnancy.⁹

1. The Departments' Authority To Mandate Coverage or Provide Exemptions

The Departments received conflicting comments on their legal authority to provide exemptions and accommodations to the Mandate. Some commenters agreed that the Departments are legally authorized to provide expanded exemptions and an accommodation for moral convictions, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing moral exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the religious exemptions that existed prior to the 2017 IFCs, but not to protect moral convictions.

The Departments conclude that we are legally authorized to provide the exemption and accommodation for moral convictions set forth in the Moral IFC and these final rules. These rules concern section 2713 of the PHS Act, as incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92).

Where it applies, section 2713(a)(4) requires coverage without cost sharing for "such additional" women's preventive care and screenings "as provided for" and "supported by" guidelines developed by HHS acting through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a

⁷ The Department of the Treasury and Internal Revenue Service published proposed and temporary regulations as part of the joint rulemaking of the Moral IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules in these final rules. The Department of the Treasury and Internal Revenue Service are finalizing their regulations.

⁸ See [Regulations.gov](https://www.regulations.gov) at <https://www.regulations.gov/search/Results?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dkid=CMS-2017-0133> and <https://www.regulations.gov/docket/Browser?rpp=25&so=ASC&sb=postedDate&po=100&D=IRS-2017-0015>. Some of those submissions included form letters or attachments that, while not separately tabulated at [regulations.gov](https://www.regulations.gov), together included comments from, or were signed by, possibly over a hundred thousand separate persons. The Departments reviewed all of the public comments and attachments.

⁹ See, for example, Family Planning grants in 42 U.S.C. 300, *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112-74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c-8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b-12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS to shape that development, as the administering agency of HSRA, and to all three agencies as the administering agencies of the statutes by which the Guidelines are enforced. *See* 26 U.S.C. 9833; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HSRA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38409 (August 31, 1982). Thus, nothing prevented HSRA from creating an exemption from otherwise-applicable guidelines or prevented HHS and the other agencies from directing that HSRA create such an exemption.

Congress did not specify the extent to which HSRA must “provide for” and “support” the application of Guidelines that it chooses to adopt. HSRA's authority to support “comprehensive guidelines” involves determining both the types of coverage and scope of that coverage. Section 2713(a)(4) requires coverage for preventive services only “as provided for in comprehensive guidelines supported by [HSRA].” That is, services are required to be included in coverage only to the extent that the Guidelines supported by HSRA provide for them. Through use of the word “as” in the phrase “as provided for,” it requires that HSRA support how those services apply—that is, the manner in which the support will happen, such as in the phrase “as you like it.”¹⁰ When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See for example*, 42 U.S.C. 1395x (“The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.”) (emphasis added). Thus, the inclusion of “as” in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HSRA has discretion whether to support how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word “as” is missing from the other three provisions in section 2713(a) of the PHS Act. Rather, this difference

mirrors other distinctions within that section that demonstrate that Congress intended HSRA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require “evidence-based” or “evidence-informed” coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HSRA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The moral objections at issue here, like the religious objections prompting exemptions dating back to the inception of the Mandate in 2011, may, consistent with the statutory provision, permissibly inform what HHS, through HSRA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HSRA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive-coverage Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HSRA Guidelines “exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,” and “it is appropriate that HSRA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.” *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a mandate that contraceptives be covered or that they be covered without any exemptions or exceptions, lead the Departments to conclude that we are legally authorized to exempt certain entities or plans from a contraceptive

Mandate if HSRA decides to otherwise include contraceptives in its Guidelines.

The Departments' conclusions are consistent with our interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4) to grant broad discretion to decide the extent to which HSRA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments created an exemption to the contraceptive Mandate when that Mandate was announced in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to plan participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrator of self-insured church plans (*see* 80 FR 41323). Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. In doing so, the Departments have been acting contrary to commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or its incorporation into ERISA and the Code, and who contended instead that the Departments must enforce Guidelines on the broadest spectrum of group health plans as possible, even including churches (*see, for example*, 2012 final regulations at 77 FR 8726).

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (*see for*

¹⁰ *See* As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (“[u]sed to indicate by comparison the way something happens or is done”).

example, 76 FR 46623). On the contrary, Congress carved out an exemption from section 2713 of the PHS Act (and from several other provisions) for grandfathered plans. In contrast, the grandfathering exemption is not applicable to many of the other provisions in Title I of the ACA—provisions previously referred to by the Departments as providing “particularly significant protections.” (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.¹¹ Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, “there is no legal requirement that grandfathered plans ever be phased out.” *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

Some commenters argue that Executive Order 13535’s reference to implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions in the Guidelines. The Departments, however, believe that they are acting consistent with Executive Order 13535 by creating exemptions using HRSA’s authority under section 2713(a)(4), and the Departments’ administrative authority over the implementation of section 2713(a) of the PHS Act. Executive Order 13535, issued upon the signing of the ACA, specified that “longstanding Federal laws to protect conscience . . . remain intact,”

including laws that protect holders of religious beliefs or moral convictions from certain requirements in health care contexts. Although the text of Executive Order 13535 does not require the expanded exemptions confirmed in these final rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect conscience objections, based on religious beliefs or moral convictions regarding certain health matters, and are consistent with the intent that the ACA be implemented in accordance with the conscience protections set forth in those laws.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities instead of to individuals, and should not be construed to prohibit procedures. But those comments mistake the Departments’ position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for sincerely held moral convictions in sensitive healthcare contexts.¹² Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held moral convictions to the extent the Departments otherwise impose a contraceptive Mandate. These exemptions do not prohibit any services, nor authorize employers to prohibit employees from obtaining any services. The exemptions in the Moral IFC and these final rules simply refrain from imposing a federal mandate that employers cover contraceptives in their health plans even if they have sincerely held moral convictions against doing so.

Some commenters stated that the Supreme Court ruled that the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but that exemptions beyond those are not. But the Supreme Court did not rule on the question whether the

exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate unless RFRA prohibits us from doing so.

The appropriateness of including exemptions to protect moral convictions is informed by Congress’s long history of providing exemptions for moral convictions, especially in certain health care contexts.

2. Congress’s History of Protecting Moral Convictions

The Department received numerous comments about its decision in the Moral IFC to exercise its discretion to provide moral exemptions to, and an accommodation under, the contraceptive Mandate. Some commenters agreed with the Departments’ decision in the Moral IFC, arguing that it is appropriate to exercise the Departments’ discretion to protect moral convictions in light of Congress’s history of protecting moral convictions in various contexts, especially concerning health care. Other commenters disagreed, saying that existing conscience statutes protecting moral convictions do not require these exemptions and, therefore, the exemptions should not be offered. Some commenters stated that because Congress has provided conscience protections, but did not specifically provide them in section 2713(a)(4), conscience protections are inappropriate in the implementation of that section. Still other commenters went further, disagreeing with conscience protections regarding contraceptives, abortions, or health care in general.

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on the most recent statements of Congress, along with nearly 50 years of statutes and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health coverage. Most recently, Congress expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.” Consolidated Appropriations Act, 2018, Div. E, section 808, Public Law 115–141, 132 Stat. 348, 603 (Mar. 23, 2018); *see also*

¹¹ Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2017 Annual Survey,” Henry J. Kaiser Family Foundation (Sept. 19, 2017), <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

¹² The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

Consolidated Appropriations Act, 2017, Div. C, section 808, Public Law 115–31 (May 5, 2017). The Departments consider it significant that Congress’s most recent statements on the prospect of Government-mandated contraceptive coverage specifically intend that a conscience clause be included to protect moral convictions.

The Departments also consider significant the many statutes listed above, in section I—Background footnote 1, that show Congress’s consistent protection of moral convictions alongside religious beliefs in the federal regulation of health care. These include laws such as the Church Amendments (dating back to 1973), which we discuss at length below, to the 2018 Consolidated Appropriations Act discussed above. Notably among those laws, and in addition to the Church Amendments, Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object “on moral or religious grounds” to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare + Choice (now Medicare Advantage) managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”). Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions.” Consolidated Appropriations Act, 2018, Public Law 115–141, Division E, section 726(c); *see also* Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.¹³

The Departments disagree with commenters that suggested we should not consider Congress’s history of protecting moral objections in certain health care contexts due to Congress’s failure to explicitly include exemptions in section 2713(a)(4) itself. The argument by these commenters proves too much, since Congress also did not

specifically require contraceptive coverage in section 2713 of the PHS Act. This argument would also negate not just these expanded exemptions, but the previous exemptions provided for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress’s long history of respecting moral convictions in the context of certain federal health care requirements.

a. The Church Amendments’ Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations because they had received federal funds. These sections of the U.S. Code are known as the Church Amendments, named after their primary sponsor, Senator Frank Church (D-Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions, not just religious beliefs. Among other things, the amendments protect the recipients of certain federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object “on the basis of religious beliefs or moral convictions,” and they prohibit recipients of certain federal health funds from discriminating against any personnel “because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions” (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to “any lawful health service,” or to “any part of a health service program.” (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute “any lawful health service” or a “part of a health service program.” As such, the

protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court’s decision in *Roe v. Wade*, 410 U.S. 113 (1973). Although the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens facilitate its exercise. Indeed, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared, “Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.” 410 U.S. at 144 & n.38 (1973). Likewise, in *Roe*’s companion case, *Doe v. Bolton*, the Court observed that, under state law, “a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.” 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions “obviously . . . afford appropriate protection.” *Id.* at 198. As an Arizona court later put it, “a woman’s right to an abortion or to contraception does not compel a private person or entity to facilitate either.” *Planned Parenthood Ariz., Inc. v. Am. Ass’n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe v. Wade*, but also an instance where a federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D-IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record records this discussion:

Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.

One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or

¹³ The Departments also note that, in protecting those individual and institutional health care entities that object to certain abortion-related services and activities regardless of the basis for such objection, the Coats-Snowe Amendment, PHS Act section 245 (42 U.S.C. 238n), and the Weldon Amendment, Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141, protect those whose objection is based on moral conviction.

participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.

As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?

Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words “or moral”?

Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words “or moral conviction” were added after “religious belief.” I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.

Mr. STEVENSON. The Senator’s suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18

As the debate proceeded, Senator Church went on to quote *Doe v. Bolton*’s reliance on a Georgia statute that stated “a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure.” 119 Congr. Rec. S5722 (quoting 410 U.S. at 197–98). Senator Church added, “I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations.” *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D-WI) asked whether, “if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, ‘We are not going to bother with this kind of procedure in this hospital,’ would the pending amendment permit that?” 119 Congr. Rec. S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C-NY), speaking in support of the amendment, added the following perspective:

Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the

recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic]¹⁴ to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words “moral conviction,” because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. S5723

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R-MA)¹⁵ likewise observed that “the right of conscience has long been recognized in the parallel situation in which the individual’s right to conscientious objector status in our selective service system has been protected” and “expanded by the Supreme Court to include moral conviction as well as formal religious belief.” 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, “We are concerned here only with the right of moral conscience, which has always been a part of our national tradition.” *Id.* at 4149.

These first sections of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions, as well as those who object

to such services on the basis of religious beliefs. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion. *See* 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141.

- Protections for entities and individuals that object to providing or covering contraceptives. *See id.* at Div. E, Sec. 808; *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act); *id.* at Div. K, Title III.

- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives. *See* 42 U.S.C. 290bb–36; 42 U.S.C. 1396a(w)(3); 42 U.S.C. 14406; 42 U.S.C. 18113 (adopted as part of the ACA).

The Departments believe that the intent behind Congress’s protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports the Departments’ decision in the Moral IFC and these final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

b. Court Precedents Relevant to These Expanded Exemptions

As reflected in the legislative history of the first Church Amendments, the Supreme Court has long afforded protection to moral convictions alongside religious beliefs. Indeed, Senator Church cited *Doe v. Bolton*, 410 U.S. 179, as a parallel instance of conscience protection and spoke of the Supreme Court generally giving “comparable treatment to deeply held moral convictions.” Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court’s protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh v. United States*, 398 U.S. 333 (1970), which the Supreme Court had decided just three years earlier.

Welsh involved what is perhaps the Government’s paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on “religious training and belief,” that protection would also extend to avowedly non-religious objections to war held with the same moral strength.

¹⁴ The Senator might have meant “[forced] . . . against his will.”

¹⁵ Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

Id. at 343. The Court declared, “[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual ‘a place parallel to that filled by . . . God’ in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a ‘religious’ conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions.”

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby*, Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan’s opinion in *Welsh*, 398 U.S. at 357–58, in support of her statement that “[s]eparating moral convictions from religious beliefs would be of questionable legitimacy.” 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious beliefs constitute an illegitimate “separat[ion]” of moral convictions, nor do the Departments assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress’s intent in the Church Amendments and in later federal statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

c. Conscience Protections in Other Federal and State Contexts

The tradition of protecting moral convictions in certain health contexts is not limited to laws passed by Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.¹⁶ Other federal

regulations have also applied the principle of respecting moral convictions alongside religious beliefs in particular circumstances. The Equal Employment Opportunity Commission has consistently protected “moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views” alongside religious views under the “standard [] developed in *United States v. Seeger*, 380 U.S. 163 (1965) and [*Welsh*].” 29 CFR 1605.1. The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so “is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics.” 28 CFR 26.5.¹⁷

Forty-five states have health care conscience protections covering objections to abortion; several of these also cover sterilization or contraception.¹⁸ Most of those state laws protect objections based on “moral,” “ethical,” or “conscientious” grounds in addition to “religious” grounds. Particularly in the case of abortion, some federal and state conscience laws do not require any specified motive for the objection. 42 U.S.C. 238n; Consolidated Appropriations, 2018, Public Law 115–141, Div. H, section 507(d).

These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts. The contraceptive Mandate implicates that governmental interest. Many persons and entities object to the Mandate in part because they consider some forms of FDA-approved contraceptives to be

moral or religious grounds”); 48 CFR 1609.7001 (“health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs.”); 48 CFR 352.270–9 (“Non-Discrimination for Conscience” clause for organizations receiving HIV or Malaria relief funds).

¹⁷ See also 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA’s request will depend in part on “[c]ultural, religious, or moral objections to the request”).

¹⁸ According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). “Refusing to Provide Health Services,” The Guttmacher Institute (June 1, 2017), <https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services>.

morally equivalent to abortion due to the possibility that such items may prevent the implantation of a human embryo after fertilization.¹⁹ The Supreme Court, in describing family business owners with religious objections, explained that “[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions.” *Hobby Lobby*, 134 S. Ct. at 2751. Based on pleadings in the litigation, all of the litigants challenging the Mandate and asserting purely non-religious objections share this view. And as Congress has implicitly recognized in providing health care conscience protections pertaining to sterilization, contraception, and other health care services and practices, individuals or entities may have additional moral objections to contraception.²⁰

d. Founding Principles

The Departments also look to guidance from, and draw support for the Moral IFC and these final rules from, the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. In supporting the protection of conscience based on non-religious moral convictions, Senator Buckley declared “[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.” Representative Heckler similarly stated that “the right of moral conscience . . . has always been a part of our national tradition.” This tradition is reflected, for example, in a letter President George Washington wrote saying that “[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of

¹⁹ FDA, “Birth Control,” U.S. Food and Drug Administration (Mar. 6, 2018), <https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm> (various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization, but “may also work . . . by preventing attachment (implantation) to the womb (uterus)” of a human embryo after fertilization).

²⁰ See *supra* note 1.

¹⁶ See, for example, 42 CFR 422.206 (declaring that the general Medicare Advantage rule “does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds.”); 42 CFR 438.102 (declaring that information requirements do not apply “if the MCO, PIHP, or PAHP objects to the service on

citizenship.”²¹ Thomas Jefferson similarly declared that “[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority.”²² Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience “the most sacred of all property,” and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that “the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed.”²³

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context, and the Departments do not suggest that the specific protections offered in the Moral IFC and these final rules would be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These final rules do not address in any way how the Government would balance its interests with respect to other health services not encompassed by the contraceptive Mandate.²⁴ Instead, the Departments highlight this tradition of respect for conscience from the Nation’s Founding Era to provide background support for the Departments’ decision to implement section 2713(a)(4), while protecting conscience in the exercise of moral convictions. The Departments believe that these final rules are consistent both with the American tradition of respect for conscience and with Congress’s history of providing conscience protections in the kinds of health care matters involved in this Mandate.

²¹ Letter from George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790) (available at <https://founders.archives.gov/documents/Washington/05-06-02-0135>).

²² Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809) (available at <https://founders.archives.gov/documents/Jefferson/99-01-02-9714>).

²³ James Madison, “Essay on Property” (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

²⁴ As the Supreme Court stated in *Hobby Lobby*, the Court’s decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer’s religious beliefs. Nor does the Court’s opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

e. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in these expanded exemptions and accommodation in these final rules, is consistent with recent executive orders. President Trump’s Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for “religious” beliefs, but for “conscience.” We interpret that term to include both religious beliefs and moral convictions. Moreover, President Trump’s first Executive Order, E.O. 13765, declared that “the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” The exemption and accommodation adopted in these final rules relieves a regulatory burden imposed on entities with moral convictions opposed to providing certain contraceptive coverage and is therefore consistent with both Executive Orders.

f. Litigation Concerning the Mandate

The Departments have further taken into consideration the litigation surrounding the Mandate in exercising their discretion to adopt the exemption in these final rules. Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. *See March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court affirmed a district court ruling that allows the previous regulations to be imposed in a way that affects the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives v. Sec’y, Dep’t of Health & Human Servs.*, 867 F.3d 338 (3d Cir. 2017). The Departments’ litigation of these cases has thus led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations,

issuers, third party administrators, and employees and beneficiaries. The organizations that have sued seeking a moral exemption have adopted longstanding moral tenets opposed to certain FDA-approved contraceptives, and hire only employees who share this view. As a result, it is reasonable to conclude that employees of these organizations would not benefit from the Mandate. Thus, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, as well as the legal requirement to comply with permanent injunctive relief currently imposed in *March for Life*, provide substantial reasons for the Departments to protect moral convictions through these final rules. Although, as discussed below, the Departments assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, the Departments know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, the Departments consider it appropriate to issue the protections set forth in these final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so the Departments, too, believe that “our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government” in this situation. *See* 119 Congr. Rec. S5717–18.

The litigation concerning the Mandate has also underscored how important it is for the Government to tread carefully when engaging in regulation concerning sensitive health care areas. As demonstrated by the litigation, as well as the public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that certain contraceptive items may cause early abortions. Providing conscience protections advances the ACA’s goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to

cover procedures that the owners “could not in good conscience” cover, such as abortion, “HHS would effectively exclude these people from full participation in the economic life of the Nation.” 134 S. Ct. at 2783. That sort of outcome is one the Departments wish to avoid. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) in a way that respects the moral convictions of Americans so that they are freer to engage in “full participation in the economic life of the Nation.” The exemptions in these final rules do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

3. Whether Moral Exemptions Should Exist, and Whom They Should Cover

As noted above, the Department received comments expressing diverse views as to whether exemptions based on moral convictions should exist and, if so, whom they should cover.

Some commenters supported the expanded exemptions and accommodation in the Moral IFC, and the choice of entities and individuals to which they applied. They stated the expanded exemptions and accommodation would be an appropriate exercise of discretion and would be consistent with moral exemptions Congress has provided in many similar contexts. Similarly, commenters stated that the accommodation would be an inadequate means to resolve moral objections and that the expanded exemptions are needed. They contended that the accommodation process was objectionable because it was another method of complying with the Mandate, its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and the coverage for contraceptive services “hijacked” or flowed in connection with the objecting organizations’ health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to moral objections that organizations would not have with an expanded exemption. Commenters also stated that, with respect to non-profit organizations that have moral objections and only hire persons who agree with those objections, the Mandate serves no legitimate government interest because the mandated coverage is neither wanted nor used and, therefore, would

yield no benefits—it would only suppress the existence of non-profit organizations holding those views.

Several other commenters stated that the exemptions were still too narrow. They asked that the exemptions set forth in these final rules be as broad as the exemptions set forth in the Religious IFC concerning sincerely held religious beliefs. Some of these commenters also asked that HHS withdraw its Mandate of contraceptive coverage from the Guidelines entirely. They contended that fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of a preventive health service; that contraceptives can pose medical risks for women; and that studies do not show that contraceptive programs reduce abortion rates or unintended pregnancies. Some commented that many women report that they sought an abortion because their contraception failed. Some other commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacient and, therefore, violate federal conscience protections such as the Weldon Amendment, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, § 507(d).

Other commenters contended that the exemptions in the Moral IFC were too broad. Some of these commenters expressed concern about the prospect of publicly traded for-profit entities also being afforded a moral exemption. One such commenter commented that allowing publicly traded for-profit entities a moral exemption could cause instability and confusion, as leadership changes at such a corporation may effectively change the corporation’s eligibility for a moral exemption. Still others stated that the Departments should not exempt various kinds of entities such as businesses, issuers, or nonprofit entities, arguing that only individuals, not entities, can possess moral convictions. Some commenters were concerned that providing moral exemptions would contribute to population growth and related societal woes. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318), which did not encompass moral convictions. Other commenters stated that the Departments should not provide exemptions, but merely an accommodation process, to resolve moral objections to the Mandate.

Some commenters objected to providing any exemption or accommodation for moral objections at all. Some of these commenters contended that even the previous regulations allowing an exemption and accommodation were too broad and that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible. Other commenters did not go that far, but rejected the idea of exemptions or an accommodation based on moral convictions, contending that such exemptions or accommodation would contribute to population growth and related social woes. Some of these commenters also contended that the exemption in the Moral IFC would constitute an exemption covering every business and non-profit organization.

After considering these comments, and although the previous Administration declined to afford any exemption based on moral convictions, the Departments have concluded that it is appropriate to provide moral exemptions and access to the accommodation, as set forth in these final rules. Congress did not mandate contraceptive coverage, nor provide any explicit guidance about incorporating conscience exemptions into the Guidelines. But as noted above, it is a long-standing Congressional practice to provide consistent exemptions for both religious beliefs and moral convictions in many federal statutes in the health care context, and specifically concerning issues such as abortion, sterilization, and contraception. It is not clear to the Departments that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar exemptions. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases. The exemptions finalized in these final rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. As noted above, the Departments consider the exemptions in these final rules consistent with the intent of Executive Order 13535. The Departments also wish to avoid the stark disparity that may result from respecting religious objections to providing contraceptive coverage among certain entities and individuals, but not respecting parallel objections for moral convictions possessed by any entities and

individuals at all because those objections are not specifically religious.

In addition, the Departments note that a significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.²⁵ Although the practice of states is by no means a limit on the discretion delegated to HRSA by the ACA, nor a statement about what the Federal Government may do consistent with other limitations in federal law, such state practices can inform the Departments' view that it is appropriate to provide conscience protections when exercising agency discretion.

The Departments decline to use these final rules to remove the contraceptive Mandate altogether, such as by declaring that HHS acting through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). HRSA's Guidelines were not issued, ratified, or updated through the regulations that preceded the Moral IFC and these final rules. Those Guidelines were issued in separate processes in 2011 and 2016, directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The regulations preceding these final rules attempted only to restate the statutory language of section 2713 in regulatory form, and delineate what exemptions and accommodations would apply if HRSA listed contraceptives in its Guidelines. We decline to use these final rules to direct the separate process that HRSA uses to determine what specific services are listed in the Guidelines generally. Some commenters stated that if contraceptives are not removed from the Guidelines entirely, entities or individuals with moral objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in these rules include a broad range of entities and individuals of whom we have notice may object based on moral convictions. The Departments are not aware of specific employers or individuals whose moral convictions would still be violated by compliance with the Mandate after the issuance of the Moral IFC and these final rules.

Some commenters stated that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions. Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These final rules focus on what moral exemptions and accommodation shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacient.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content and process of developing and updating the Guidelines, are welcome to communicate their views to HRSA, at wellwomancare@hrsa.gov.

The Departments also conclude that it would be inadequate to merely attempt to amend or expand the accommodation process to account for moral objectors, instead of providing the exemptions. In the past, the Departments stated in our regulations and court briefs that the previous accommodation required contraceptive coverage in a way that is "seamless" with the coverage provided by the objecting employer. As a result, in significant respects, the accommodation process did not actually accommodate the objections of many entities, as indicated by many entities with religious objections. The Departments have attempted to identify an accommodation that would eliminate the religious plaintiffs' objections, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but stated in January 2017 that we were unable to develop such an approach at that time.²⁶

²⁶ See Departments of Labor, Health and Human Services, and the Treasury, FAQs About Affordable Care Act Implementation Part 36, (Jan. 9, 2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36-1-9-17-Final.pdf> ("the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious

Just as the Departments continue to believe merely amending the accommodation process would not adequately address religious objections to compliance with the Mandate, we do not believe doing so would adequately address similar moral objections. Furthermore, the few litigants raising non-religious moral objections have been non-profit organizations that assert they only hire persons who share the employers' objection to contraceptive coverage. Consequently, the Departments conclude that the most appropriate approach to resolve these concerns is to provide the exemptions set forth in the Moral IFC and these final rules. These final rules also finalize the modifications to the accommodation process to make it available to entities with moral objections, without forcing such entities to choose between compliance with either the Mandate or the accommodation.

Some commenters expressed concern over the lack of a definition of "moral convictions" in the Moral IFC, arguing that, without a definition, any objection could be encompassed by the exemptions even if it is not based on moral convictions. The Departments did not adopt a regulatory definition of "moral convictions" in the Moral IFC, and have decided not to adopt such a definition in response to public comments at this time. Nevertheless, the Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in the Moral IFC and these final rules. Neither these final rules or the Moral IFC, nor the Church Amendments or other Federal health care conscience statutes, define "moral convictions" (nor do they define "religious beliefs"). But in issuing these final rules, we adopt the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions in parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the "individual deeply and sincerely holds"; (2) "that are purely ethical or moral in source and content"; (3) "but that nevertheless impose upon him a duty"; (4) and that "certainly occupy in the life of that individual a place parallel to that filled by . . . God' in traditionally religious persons," such

objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage").

²⁵ See "Insurance Coverage of Contraceptives," The Guttmacher Institute (June 11, 2018), <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

that one could say “his beliefs function as a religion in his life.” 398 U.S. at 339–40. As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises “capriciously.” Instead, along with the requirement that protected moral convictions must be “sincerely held,” this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

While moral convictions are the sort of principles that, in the life of an individual, occupy a place parallel to religion, sincerely held moral convictions can also be adopted by corporate bodies, not merely by individuals. Senators Church and Nelson, while discussing the fact that opposition to abortion or sterilization on the basis of “moral questions” does not include capricious opposition to abortion for no reason at all, were specifically talking about opposition to abortion by corporate entities: A “hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise.”²⁷ Corporate bodies operate by the decision-making actions of individuals. Thus, if individuals act in the governance of a corporate body so as to adopt a position for that body of adopting moral convictions against coverage of contraceptives, such an entity can be considered to have an objection to contraceptive coverage on the basis of sincerely held moral convictions.

4. The Departments’ Rebalancing of Government Interests

The Departments also received comments on their rebalancing of interests as expressed and referenced in the Moral IFC. Some public commenters agreed with the Departments’

conclusion that our interest in ensuring contraceptive coverage does not preclude the Departments from offering exemptions and an accommodation for entities, plans, and individuals with a qualifying objection to contraceptive coverage based on moral convictions. Some public commenters pointed out that protecting moral convictions serves to respect not only the interests of certain persons to access contraceptives, but also the interests of other persons to participate in a health coverage market consistent with their moral convictions. Other commenters disagreed with this rebalancing, and contended that the interest of women in receiving contraceptive coverage without cost-sharing is so great that it overrides private interests to the contrary, such that the government should or must force private entities to provide this coverage to other private citizens.

The Departments agree with the commenters who stated that the governmental interest in requiring contraceptive coverage does not override the interest in protecting moral convictions and does not make these expanded exemptions inappropriate. For additional discussion of the Government’s balance of interests as applicable to religious beliefs, see section II.C.2.b. of the companion final rules concerning religious exemptions published by the Departments contemporaneously with these final rules elsewhere in today’s **Federal Register**. There, and in the Religious and Moral IFCs, the Departments acknowledged the reasons why the Departments have changed the policies and interpretations previously adopted with respect to the Mandate and the governmental interests underlying it. For parallel reasons, the Departments believe the Government’s legitimate interests in providing for contraceptive coverage do not require the Departments to violate sincerely held moral convictions while implementing the Guidelines. The Departments likewise believe Congress did not set forth interests that require us to violate sincerely held moral convictions if we otherwise require contraceptive coverage in our discretionary implementation of the women’s preventive services Guidelines under section 2713(a)(4).

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4), added to the PHS Act in 2010. The

Departments’ expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after considering public comments on various sides of the issue, and reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant federal law, the Departments have determined that affording the exemptions to protect moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to invoke these exemptions and accommodation may be small, the Departments believe that it is important to provide such protection, given the long-standing recognition of such protections in law and regulation in the health care and health insurance contexts. The Moral IFC and these final rules leave unchanged HRSA’s authority to decide whether to include contraceptives in the women’s preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, including through such programs as Medicaid and Title X. The Departments also note that the exemptions created here, like the exemptions created by the previous Administration, do not burden third parties to a degree that counsels against providing the exemptions, as discussed below.

5. Burdens on Third Parties

The Department received a variety of comments about the effect that the exemptions and accommodation based on moral convictions would have on third parties. Some commenters stated that the exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might otherwise receive contraceptive coverage with no cost sharing. Other commenters disagreed, asserting that the exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more

²⁷ Nor was this recognition of the need to protect organizations that object to performance of certain health care procedures on the basis of moral conviction limited to the Church Amendments’ legislative history. The first of the Church Amendments provides, in part, that the receipt of certain federal funds “by any individual or entity does not authorize any court or any public official or other public authority to require— . . . (2) such entity to—(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.” 42 U.S.C. 300a–7(b).

unintended pregnancies,²⁸ births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as prioritizing conscientious objection of exempted entities over the conscience, choices, or religious liberty of women who would not receive contraceptive coverage where an exemption is used. Some commenters disagreed and said the exemptions do not violate laws and constitutional protections, nor do they inappropriately prioritize the conscience of exempted entities over those of third parties.

The Departments note that the exemptions in the Moral IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. Agency discretion was exercised to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties whom the government chooses not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: That the government has an obligation to force private parties to benefit those third parties, and that the third parties have a right to those benefits. Congress did not create a right to receive contraceptive coverage from other private citizens through section 2713 of the PHS Act, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative

discretion to require private parties to provide coverage to which they morally object, to benefit other private parties, does not prevent the government from relieving some or all of the burden of that Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Moral IFC and these final rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through the grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris v. McRae*, 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the government refrain from requiring private citizens, in violation of their moral convictions, to cover contraception for other citizens. *Cf. Rust v. Sullivan*, 500 U.S. 173, 192–93 (1991) (“A refusal to fund protected activity, without more, cannot be equated with the imposition of a ‘penalty’ on that activity.”). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting moral objections to such governmental mandates, especially where, as here, the Mandate is not an explicit statutory requirement.²⁹ The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these rules.

Some commenters objected that the exemptions would violate the Establishment Clause of the First Amendment. The Moral IFC and these final rules create exemptions for moral convictions, not religious beliefs, and they do so for the same neutral purposes

for which Congress has created similar exemptions for over four decades. Not only do these final rules not violate the Establishment Clause, but the Departments’ decision to provide the exemptions and accommodation for moral convictions, instead of limiting the exemptions to identical objections based on religious beliefs, further demonstrates that neither the purpose nor the effect of these exemptions is to establish religion. The Establishment Clause does not force the Department to impose a contraceptive Mandate in violation of the moral convictions of entities and individuals protected by these rules.

American governmental bodies have, in many instances, refrained from requiring certain private parties to cover contraceptive services for other private parties. From 1789 through 2012 (when HRSA’s Guidelines went into effect), there was no federal women’s preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA’s Guidelines, and it did not require any preventive services required under section 2713 of the PHS Act to be covered by grandfathered plans. Many states do not impose contraceptive coverage mandates, or they offer religious, and in some cases moral, exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or state courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. The Departments are not aware of federal courts declaring that the exemptions, safe harbor, or accommodations gave rise to third party burdens that required the government to mandate contraceptive coverage by entities eligible for an exemption or accommodation. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including

²⁸ Some commenters attempted to quantify the costs of unintended pregnancy, but were unable to provide estimates with regard to the number of women that this exemption may affect.

²⁹ See, for example, *Planned Parenthood Ariz., Inc. v. Am. Ass’n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (“[A] woman’s right to an abortion or to contraception does not compel a private person or entity to facilitate either.”).

under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters stated that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others commenters stated that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. Until 2012, there was no federal mandate of contraceptive coverage across health insurance and health plans nationwide. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to state or local governments. The various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage, have not been deemed to cause a cognizable injury to state or local governments. The Departments find no legal prohibition on finalizing these final rules based on the allegation of an impact on state or local governments, and disagree with the suggestion that once having exercised our discretion to deny exemptions—no matter how recently or incompletely—the Departments cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, the exemptions at issue here are available only to a tiny fraction of entities to which the Mandate would otherwise apply—those with qualifying moral objections. Public comments did not provide reliable data on how many entities would use these expanded moral exemptions, in which states women in those plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would potentially have to cover. As noted below, at least one

study³⁰ has concluded the Mandate caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates. In addition, the only entities that have brought suit based on their moral objections to the Mandate are non-profit entities that have said they only hire persons who share their objections and do not use the contraceptives to which their employers object, so it is unlikely that exemptions for those entities would have any impact on safety net programs. Below, we predict that a small number of additional nonprofit and closely held for-profit entities will use the exemptions based on moral convictions. In light of the limited evidence of third party or state and local government impact of these final rules, the Departments consider it an appropriate policy option to provide the exemptions.

Some commenters contended that the exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socioeconomic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead, they allow entities that have sincerely held moral objections to providing some

or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

Those commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these final rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not in its capacity as an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII “does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women”). Second, these rules create no disparate impact. The women's preventive service mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inure to the specific benefit of women—men are denied any benefit from section 2713(a)(4). Both before and after these rules are in effect, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions encompass moral objections. The previous rules, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship and integrated auxiliaries, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby's* holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women

³⁰M.L. Kavanaugh et al., “Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,” 97 *Contraception* 14, 14–21 (2018), available at [http://www.contraceptionjournal.org/article/S0010-7824\(17\)30478-X/pdf](http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf).

because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters stated that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some commenters objected that the Moral IFC's estimate of a \$584 yearly cost of contraceptives for women was too low. But some of those same commenters provided similar estimates, citing sources claiming that birth control pills can cost up to \$600 per year, and stated that IUDs, which can last 3 to 6 years or more,³¹ can cost \$1,100 (that is, less than \$50 per month over the duration of use). Some commenters stated that, for lower income women, contraceptives and related education and counseling can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately covered individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member, and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, emphasizing that income and eligibility thresholds could prevent some women from receiving contraceptives through certain government programs if they were no longer covered in their group health plans or health insurance plans.

The Departments do not believe that such differences make it inappropriate to issue the expanded exemptions set forth in these rules. As explained more fully below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. Moreover, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has

recently issued a proposed rule to amend the regulations governing its Title X family planning program. The proposed rule would amend the definition of "low income family"—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions. (83 FR 25502). If that rule is finalized as proposed, it would further reduce any potential effect of these final rules on women's access to contraceptives.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS "shall not promulgate any regulation" that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impedes timely access to health care services," "interferes with communications regarding a full range of treatment options between the patient and the provider," "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," "violates the principles of informed consent and the ethical standards of health care professionals," or "limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. 18114. Such commenters urged, for example, that the Moral IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554 of the ACA. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections; multiple courts considered those regulations; and while many ruled that entities did not need to provide contraceptive coverage, none ruled that the exemptions or accommodations in the regulations violated section 1554 of the ACA. Moreover, the decision not to impose a governmental mandate is not the creation of a "barrier," especially when that mandate requires private citizens to provide services to other private citizens. This would turn the assumptions of the United States' system of government on its head. *See, for example*, U.S. Constitution, Ninth Amendment. Section 1554 of the ACA

likewise does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 of the ACA prohibit the Departments from providing exemptions to relieve burdens on moral convictions, or as is the case here, from refraining to impose the Mandate in cases where moral convictions would be burdened by the Mandate. Moral exemptions from federal mandates in certain health contexts, including sterilization, contraception, or items believed to be abortifacient, have existed in federal laws for decades. Some of those laws were referenced by President Obama in signing Executive Order 13535. In light of that Executive Order and Congress's long history of providing exemptions for moral convictions in the health context, providing moral exemptions is a reasonable administrative response to this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts.

In short, we do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered, or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

In summary, members of the public have widely divergent views on whether the exemptions in the Moral IFC and these final rules are good public policy. Some commenters stated that the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind the exemption, and arguing that the exemption would not interfere with the physician-patient relationship. The Departments have determined that these final rules are an appropriate exercise of public policy discretion. Because of the importance of the moral convictions being accommodated, the limited impact of these final rules, and uncertainty about

³¹ *See, for example*, "IUD," Planned Parenthood, <https://www.plannedparenthood.org/learn/birth-control/iud>.

the impact of the Mandate overall according to some studies, the Departments do not believe these final rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

6. Interim Final Rulemaking

The Departments received several comments about the decision to issue the Moral IFC as interim final rules with request for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Moral IFC in that way, agreeing with the Departments that there was explicit statutory authority to do so, good cause under the APA, or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe authority existed to issue the Moral IFC as interim final rules. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of that Act, and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Moral IFC, the Departments issued three interim final regulations implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Moral IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Moral IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules were issued after receiving and thoroughly considering public comments as requested in the Moral IFC. These final rules therefore comply with the APA's notice and comment requirements.

7. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause, or are associated with, an increased risk of depression,³² venous thromboembolic disease,³³ fatal pulmonary embolism,³⁴ thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are

older),³⁵ hypertension,³⁶ HIV-1 acquisition and transmission,³⁷ and breast, cervical, and liver cancers.³⁸ Some commenters also stated that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that it is not the case that contraceptive access reduces unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated

³² Commenters cited Charlotte Wessel Skovlund, et al., "Association of Hormonal Contraception with Depression," *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) ("Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use.").

³³ Commenters cited the Practice Committee of the American Society for Reproductive Medicine, "Hormonal Contraception: Recent Advances and Controversies," 82 *Fertility and Sterility* S26, S30 (2004); V.A. Van Hylckama et al., "The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study," 339 *Brit. Med. J.* b2921 (2009); Y. Vinogradova et al., "Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases," 350 *Brit. Med. J.* h2135 (2015) ("Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year."); Ø. Lidegaard et al., "Hormonal contraception and risk of venous thromboembolism: national follow-up study," 339 *Brit. Med. J.* b2890 (2009); M. de Bastos et al., "Combined oral contraceptives: venous thrombosis," *Cochrane Database Syst. Rev.*, Mar. 3, 2014. doi: 10.1002/14651858.CD010813.pub2, available at <https://www.ncbi.nlm.nih.gov/pubmed?term=24590565>; L.J. Havrilesky et al., "Oral Contraceptive User for the Primary Prevention of Ovarian Cancer," Agency for Healthcare Research and Quality, Report No. 13-E002-EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html>; and Robert A. Hatcher et al., *Contraceptive Technology*, 405-07 (Arden Media 18th rev. ed. 2004).

³⁴ Commenters cited N.R. Poulter, "Risk of Fatal Pulmonary Embolism with Oral Contraceptives," 355 *Lancet* 2088 (2000).

³⁵ Commenters cited Ø. Lidegaard et al., "Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception, 366 *N. Engl. J. Med.* 2257, 2257 (2012) (risks "increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 µg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 µg"); Practice Committee of the American Society for Reproductive Medicine, "Hormonal Contraception"; M. Vessey et al., "Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking," 362 *Lancet* 185, 185-91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, "Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study," 349 *Lancet* 1202, 1202-09 (1997); K.M. Curtis et al., "Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review," 73 *Contraception* 179, 179-188 (2006); L.A. Gillum et al., "Ischemic stroke risk with oral contraceptives: A meta analysis," 284 *JAMA* 72, 72-78 (2000), available at <https://www.ncbi.nlm.nih.gov/pubmed/10872016>; and Robert A. Hatcher et al., *Contraceptive Technology*, 404-05, 445 (Arden Media 18th rev. ed. 2004).

³⁶ Commenters cited Robert A. Hatcher et al., *Contraceptive Technology*, 407, 445 (Arden Media 18th rev. ed. 2004).

³⁷ Commenters cited Renee Heffron et al., "Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study," 12 *Lancet Infectious Diseases* 19, 24 (2012) ("Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV-1 acquisition by women and HIV-1 transmission from women to men."); and "Hormonal Contraception Doubles HIV Risk, Study Suggests," *Science Daily* (Oct. 4, 2011), <https://www.sciencedaily.com/releases/2011/10/111003195253.htm>.

³⁸ Commenters cited "Oral Contraceptives and Cancer Risk," National Cancer Institute (Mar. 21, 2012), <https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet>; L.J. Havrilesky et al., "Oral Contraceptive User for the Primary Prevention of Ovarian Cancer," Agency for Healthcare Research and Quality, Report No. 13-E002-EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html>; S. N. Bhupathiraju et al., "Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study," 106 *Am. J. Pub. Health* 1631, 1631-37 (2016); The World Health Organization Department of Reproductive Health and Research, "Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment," (Sept. 2005), available at http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf; and the American Cancer Society, "Known and Probably Human Carcinogens," American Cancer Society (rev. Nov. 3, 2016), <https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html>.

with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 Report of the Institute of Medicine (IOM), “Clinical Preventive Services for Women: Closing the Gaps,” in its discussion of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality. Commenters also stated that studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer, and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.³⁹ Some commenters stated that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters stated that, in the Moral IFC, the Departments relied on incorrect statements concerning scientific studies. For example, some commenters stated that there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Departments for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR 47804, the 2013 Agency for Healthcare Research and Quality study, and other sources, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to consider these studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did

not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,⁴⁰ the purpose for the Departments’ reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some commenters agreed with the quotation, in the Moral IFC, of FDA materials⁴¹ that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Moral IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Moral IFC that some persons believe those possible effects are “abortifacient.”

This objection on this issue appears to be partially one of semantics. People disagree about whether to define “conception” or “pregnancy” to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items “abortifacient”—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization

embryo inside the mother’s body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby*, 134 U.S. at 2765 (“The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.”).

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere moral objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of an objection based on sincerely held religious belief under RFRA.⁴² Several litigants have separately raised non-religious moral objections to contraceptive coverage based on the same basic rationale. Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA’s statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer moral exemptions with respect to this Mandate.

The Departments also received comments about their discussion, located in the Religious IFC but partly relied upon in the Moral IFC, concerning uncertainty about the effects the Mandate’s expanded exemptions might have on teen sexual activity. In this respect, the Departments stated, “With respect to teens, the Santelli and Melnikas study cited by IOM 2011

⁴² “Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. *See* Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.” *Hobby Lobby*, 134 S. Ct. at 2762–63. “The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.” *Id.* at 2765–66.

³⁹ To the extent that contraceptives are prescribed to treat health conditions, and not for preventive purposes, the Mandate would not be applicable.

⁴⁰ 82 FR at 47803–04.

⁴¹ FDA’s guide “Birth Control” specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and “may also work . . . by preventing attachment (implantation) to the womb (uterus)” of a human embryo after fertilization. Available at <https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm>.

observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that “[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.”⁴³ Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that limiting the exemptions to the Mandate to those that existed prior to the Religious and Moral IFCs is not tailored towards advancing the Government’s interests in reducing teen pregnancy. Instead they suggested there are means of reducing teen pregnancy that are less burdensome on conscientious objections.⁴⁴ Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.⁴⁵

Many commenters opposing the moral exemptions misunderstood the Departments’ discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The

Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, the Departments note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general make it difficult to establish causation between exemptions to the contraceptive Mandate, and an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including, but not limited to, reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline). It concluded that “that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.”⁴⁶ One study found that, during the teen pregnancy decline between 2007 through 2012, teen sexual activity was also decreasing.⁴⁷ One study concluded that falling unemployment rates in the 1990s accounted for 85 percent of the decrease in rates of first births among 18 to 19 year-old African Americans.⁴⁸ Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.⁴⁹ One study concluded that an “increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.”⁵⁰ Similarly,

one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.⁵¹ Some commenters also cited studies—which are not limited to the issue of teen pregnancy—that have found that many women who have abortions report that they were using contraceptives when they became pregnant.⁵²

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women’s preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of public comments has reinforced the Departments’ view that the uncertainty surrounding these weighty and important issues makes it appropriate to provide the moral exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing moral exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments to implement the ACA.

8. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promoted the health and equality of women, especially low income women, and promoted female participation and

available at <https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf> (“[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women”).

⁵¹ See D. Paton & L. Wright, “The effect of spending cuts on teen pregnancy,” 54 *J. Health Econ.* 135, 135–46 (2017), available at <https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551> (“Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates”).

⁵² Commenters cited, for example, Guttmacher Institute, “Fact Sheet: Induced Abortion in the United States” (Jan. 2018) (“Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant”), available at https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.

⁴³ Citing J.S. Santelli & A.J. Melnikas, “Teen fertility in transition: recent and historic trends in the United States,” 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at <http://public.econ.duke.edu/~psarcidi/addicted13.pdf>. See also K. Buckles & D. Hungerman, “The Incidental Fertility Effects of School Condom Distribution Programs,” *Nat’l Bureau of Econ. Research Working Paper No. 22322* (June 2016), available at <http://www.nber.org/papers/w22322> (“access to condoms in schools increases teen fertility by about 10 percent” and increased sexually transmitted infections).

⁴⁴ See Helen Alvaré, “No Compelling Interest: The ‘Birth Control’ Mandate and Religious Freedom,” 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

⁴⁵ See, e.g., Lindberg L., Santelli J., “Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,” 59 *J. Adolescent Health* 577–83 (Nov. 2016), <https://doi.org/10.1016/j.jadohealth.2016.06.024>; see also Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, www.regulations.gov (discussing teen pregnancy data from Colorado).

⁴⁶ Kearney MS and Levine PB, “Investigating recent trends in the U.S. birth rate,” 41 *J. Health Econ.* 15–29 (2015), available at <https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041>.

⁴⁷ See, e.g., K. Ethier et al., “Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,” 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at <http://dx.doi.org/10.15585/mmwr.mm665152a1> (“Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall . . .”).

⁴⁸ Colen CG, Geronimus AT, and Phipps MG, “Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,” 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at <https://www.sciencedirect.com/science/article/pii/S027795360600205X>.

⁴⁹ Atkins DN and Wilkins VM, “Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,” 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at <https://academic.oup.com/jpart/article-abstract/23/4/771/963674>.

⁵⁰ E. Collins & B. Herchheim, “The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,” *U. Mich. Pop. Studies Ctr. Report* 11–737 (May 2011),

equality in the workforce. Other commenters contended there was insufficient evidence showing that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence to show that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed a study published and revised by the Guttmacher Institute in October 2017, concluding that “[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy.”⁵³ This timeframe includes the first two years of the contraceptive Mandate’s implementation. Despite some changes in the use of various methods of contraceptives, the study concluded that, “[f]or the most part, women are changing method type within the group of most or moderately effective methods and not shifting from less effective to more effective methods.” Regarding the effect of this Mandate in particular, the authors concluded that “[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.” The authors observed that other “[s]tudies have produced mixed evidence regarding the relationship between the implementation of the ACA and contraceptive use patterns.” In explaining some possible reasons or no clear effect on contraceptive use, the authors suggested that “existence of these safety net programs [publicly funded family planning centers and Medicaid] may have dampened any impact that the ACA could have had on contraceptive use,” “cost is not the only barrier to accessing a full range of method options,” and “access to affordable and/or free contraception made possible through programs such as Title X” may have led to income not being associated with the use of most

contraceptive methods.⁵⁴ In addition, commenters noted that in the 29 states where contraceptive coverage mandates have been imposed statewide,⁵⁵ those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.⁵⁶

Other commenters, however, disputed the significance of these state statistics, noting that, of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the exemption in these rules might have on the Mandate more broadly. The state mandates of contraceptive coverage still apply to a very large number of plans and plan participants notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups were already exempt from the federal Mandate prior to the 2017 Religious and Moral IFCs. The exemptions as set forth in the Moral IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might result from the contraceptive Mandate here.

Some commenters took a view that appears to disagree with the assertion in

the 2017 Guttmacher study, that “[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.” These commenters instead observed that, under the Mandate, more women have coverage of contraceptives and contraception counseling and that more contraceptives are provided without co-pays than before. Still others argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA⁵⁷ and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also stated that studies show that decreases in unintended pregnancies are due to broader access to contraceptives. Finally, some commenters also stated that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on that review, it is not clear that merely offering the exemption in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from contraceptive access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women’s preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, the Departments

⁵⁴ Id.

⁵⁵ See Guttmacher Institute, “Insurance Coverage of Contraceptives” (June 11, 2018); “State Requirements for Insurance Coverage of Contraceptives,” Henry J. Kaiser Family Foundation (Jan. 1, 2018), <https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

⁵⁶ See Michael J. New, “Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,” 13 *Ave Maria L. Rev.* 345 (2015), available at <http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf>.

⁵⁷ Citing, for example, Adelle Simmons et al., “The Affordable Care Act: Promoting Better Health for Women,” Table 1, ASPE (June 14, 2016), <https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf>.

⁵³ M.L. Kavanaugh et al., “Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,” 97 *Contraception* 14, 14–21 (2018), available at [http://www.contraceptionjournal.org/article/S0010-7824\(17\)30478-X/pdf](http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf).

conclude that the Moral IFC and these final rules—which merely withdraw the Mandate’s requirement from what appears to be a small number of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. The Departments also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, an appropriate exercise of the Departments’ discretion.

Moreover, the Departments conclude that the best way to balance the various policy interests at stake in the Moral IFC and these final rules is to provide the exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules provide tangible conscience protections for moral convictions, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a burden on their moral convictions. The Departments view the provision of those protections to preserve conscience in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for moral convictions set forth in the Moral IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

9. Other General Comments

Some commenters expressed the view that the exemptions afforded in the Moral IFC and herein violate the RFRA rights of women who might not receive contraceptive coverage as the result of these final rules, by allowing their employers to impose their moral convictions on them by removing contraceptive coverage through use of the exemption. Still other commenters stated that employer payment of insurance premiums is part of any employee’s compensation package, the benefits of which employers should not be able to limit. In the Departments’ view, the expanded exemptions in these final rules do not prohibit employers from providing contraceptive coverage. Instead, they lift a government burden that was imposed on some employers to provide contraceptive coverage to their employees in violation of those employers’ moral convictions. The

Departments do not believe RFRA requires, or has ever required, the federal government to force employers to provide contraceptive coverage. The federal government’s decision to exempt some entities from a requirement to provide no-cost-sharing services to private citizens does not constitute a federal government-imposed burden on the latter under RFRA.

Some commenters asked the Departments to discuss the interaction between these rules and state laws that either require contraceptive coverage or provide exemptions from those and other requirements. Some commenters argue that providing the exemptions in these rules would negate state contraceptive requirements or narrower state exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage.

The Departments agree that these rules only concern the applicability of the federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state exemptions. If a plan is exempt under the Moral IFC and these final rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the moral exemption rules to declare whether the federal contraceptive Mandate would still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.⁵⁸

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive

coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1).

These final rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with moral objections to cover contraceptives.

Finally, some commenters expressed concern that providing moral exemptions to the mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, section 2713(a)(2) of the PHS Act requires coverage of “immunizations,” and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting moral convictions from certain health care mandates concerning issues such as sterilization, abortion and birth control.

B. Text of the Final Rules

In this section, the Departments describe the regulations from the Moral IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments’ response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. We also note the regulatory text as it existed prior to the Religious and Moral IFCs, as appropriate. The Departments consider the exemptions finalized here to be an appropriate and permissible policy

⁵⁸ Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. In the preamble to the companion final rules concerning religious exemptions published elsewhere in today’s *Federal Register*, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these exemptions.

As noted above, various members of the public provided comments that were supportive, or critical, of the regulations overall, or of significant policies pertaining to the regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

1. Restatement of Statutory Requirements of Section 2713(a) and (a)(4) of the PHS Act (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) and (a)(4) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified those restatements to more closely align them with the text of section 2713(a) and (a)(4) of the PHS Act. Those sections cross-reference the other sections of the Departments' rules that provide exemptions to the contraceptive Mandate. After the Religious IFC changed those sections, the Moral IFC inserted, within those cross-references, references to the new § 147.133, which contains the text of the moral exemptions. The insertions correspond to the cross-references to the religious exemptions added by the Religious IFC. The Departments finalize these parts of the Moral IFC without change.

2. Exemption for Objecting Entities Based on Moral Convictions (45 CFR 147.133(a))

The previous regulations contained no exemption concerning moral convictions, as distinct from religious beliefs. Instead, at 45 CFR 147.131(a), they offered an exemption for houses of worship and integrated auxiliaries. In the remaining part of § 147.131, the previous regulations described the accommodation process for organizations with religious objections. The Religious IFC moved the religious exemption to a new section 45 CFR 147.132, and expanded its scope. The Moral IFC created a new section 45 CFR 147.133, providing exemptions for moral convictions similar to, but not exactly the same as, the exemptions for religious beliefs set forth in § 147.132.

The prefatory language of § 147.133(a) not only specifies that certain entities are “exempt,” but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women's preventive services coverage only “as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.” To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are “exempt” by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as “exempt,” and in referring to the “exemption” encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.133(a) applies to several distinct entities involved in the provision of coverage to an objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When § 147.133(a)(1) and (a)(1)(i) specify that “[a] group health plan,” “health insurance coverage provided in connection with a group health plan,” and “health insurance coverage offered or arranged by an objecting organization” are exempt “to the extent” of the objections “as specified in paragraph (a)(2),” that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815 through 2713(a)(1)(iv) and 29 CFR 2590.715 through 2713(a)(1)(v)), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while a plan sponsor's or arranger's objection removes penalties from that group health plan's issuer, it only does so with respect to that group health plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information

on the effects of the objection of a health insurance issuer in § 147.133(a)(1)(iii) is included below.

The exemptions in § 147.133(a)(1) apply “to the extent” of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters stated it was unclear whether the plans of entities or individuals that morally object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite moral objection to some, but not all, contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules the Departments finalize the prefatory language of § 147.133(a) so that the first sentence of that paragraph states that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, “to the extent of the objections specified below.” The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying “to the extent” of the objection(s).

The exemptions contained in previous regulations, at § 147.131(a), did not require an exempt entity to submit any particular self-certification or notice, either to the government or to the entity's issuer or third party administrator, in order to obtain or qualify for their exemption. Similarly, under the expanded exemptions in § 147.133, the Moral IFC did not require exempt entities to comply with a self-certification process. We finalize that approach without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan

document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.⁵⁹ Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported this approach, while others did not. Those in favor suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use their exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process.

After considering the comments, the Departments continue to believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption, although there may have been thousands of houses of worship and integrated auxiliaries covered by the previous exemption and the Departments think it likely that only a small number of entities will use the moral exemption. Adding a self-certification or notice to the exemption would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional

public costs if those certifications or notices are to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement and accountability under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries will know whether their health plan claims a contraceptive Mandate exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these final rules to continue to not require notices or self-certifications for using the exemption.

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these final rules. The exemptions in these final rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. Final rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (In the companion rules concerning religious beliefs published elsewhere in today's **Federal Register**, the Departments discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do

so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed in the companion religious final rule published elsewhere in today's **Federal Register**, the Departments have added language from the previous regulations, in § 147.131(f), to protect issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in, and derived from, the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators. The Departments do not believe it necessary to do so in these final rules.

Commenters disagreed about the likely effects of the moral exemptions on the health coverage market. Some commenters stated that expanding the exemptions to encompass moral convictions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans, or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or only some contraceptives—to houses of worship and integrated auxiliaries, and some commenters and litigants said that issuers were doing so. These cases

⁵⁹ See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102-2, 2520.102-3, & 2520.104b-3(d), and 29 CFR 2590.715-2715. See also 45 CFR 147.200 (requiring disclosure of the “exceptions, reductions, and limitations of the coverage,” including group health plans and group & individual issuers).

where plans did not need to comply with the Mandate, and the Departments' previous accommodation process which had the effect of allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.⁶⁰

Concerning the prospect raised by some commenters of different risk pools between men and women, section 2713(a) of the PHS Act itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage will be required. The Moral IFC and these final rules do not require issuers to offer health insurance products that satisfy morally objecting entities, they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to objecting entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

3. Exemption for Certain Plan Sponsors (45 CFR 147.133(a)(1)(i))

The exemption in § 147.133(a)(1)(i) of the Moral IFC covers a group health plan and health insurance coverage for non-governmental plan sponsors that object as specified in paragraph (a)(2), and that are either nonprofit organizations, or are for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The Departments finalize this paragraph without change, and discuss each part of the paragraph in turn.

a. Plan Sponsors in General (45 CFR 147.133(a)(1)(i) Prefatory Text)

Under the plan sponsor exemption in § 147.132(a)(1)(i), the prefatory text in that paragraph specifies that it encompasses group health plans, and health insurance coverage provided in connection with such group health plans, that are sponsored by certain kinds of entities, namely, nonprofit organizations or for-profit entities that have no publicly traded ownership interests.

Such plan sponsors, if they are otherwise nonprofit organizations or for-profit entities that have no publicly traded ownership interests, can include entities that are not employers (for example, a union, or a sponsor of a multiemployer plan), where the plan sponsor objects based on sincerely held moral convictions to coverage of contraceptives or sterilization. Plan sponsors encompassed by the exemption can also include employers, and consistent with the definition of "employer" in 29 CFR 2510.3–5, can include association health plans, where the plan sponsor is a nonprofit organization or a for-profit entity that has no publicly traded ownership interests.

Some commenters objected to extending the exemption to plan sponsors that are not single employers, arguing that they could not have the same kind of moral objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite moral objection. The Departments conclude that it is appropriate, where a plan sponsor of a multiemployer plan or multiple employer plan adopts a moral objection using the same procedures that such a plan sponsor might use to make other decisions, to respect that decision by providing an exemption from the Mandate.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.133(a)(1)(i), which instead limits the moral exemptions to "non-governmental plan sponsors." As noted above, the Departments sought public comment on whether to extend the exemptions to non-federal governmental plan sponsors. Some commenters suggested that the moral exemptions should include government entities because other conscience laws can include government entities, such as when they oppose offering abortions. Others disagreed, contending that governmental entities should not or cannot object based on moral convictions, or that it would be unlawful for them to do so.

The Departments are sympathetic to the arguments of commenters that favor including government entities in the exemption for moral convictions. The protections outlined in the first paragraph of the Church Amendments for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Both the Weldon and Coats-Snowe Amendments also protect state and local government entities from providing, promoting, or paying for abortions in particular ways.⁶¹ Congress has generally not limited protections for conscience based on the nature of an entity—even in the case of governmental entities.

At the same time, the Departments do not at this time have information suggesting that an exemption for governmental entities is needed or desired. The Departments have not been sued by any governmental entities raising objections to the Mandate based on non-religious moral convictions. Although the Departments sought public comment on the issue, the Departments received no public comments identifying governmental entities that need or desire such an exemption. Rather, the Departments are aware of governmental entities that, despite not possessing their own objections to contraceptive coverage, have acted to protect their employees who have conscientious objections to receiving contraceptive coverage in their employer-provided health insurance plans. *See Wieland v. U.S. Dep't of Health & Human Servs.*, 196 F. Supp. 1010, 1015–16 (E.D. Mo. 2016) (quoting Mo. Rev. Stat. 191.724). The individual exemption adopted in these rules will ensure the Mandate is not an obstacle to those efforts.

Thus, in light of the balance of public comments, the Departments decline to extend the moral convictions exemption to governmental entities. As is the case with the Departments' decision not to extend the moral exemption to publicly traded for-profit entities, this decision does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions

⁶⁰ See also *Real Alternatives*, 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) ("Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny." (citation and internal quotation marks omitted)).

⁶¹ Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), 132 Stat. at 764 (protecting any "hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion); 42 U.S.C. 238n (protecting entities that object to abortion, including, but not limited to, any "postgraduate physician training program").

without categorically excluding governmental entities. The Departments remain open to the possibility of future rulemaking on this issue if the Departments become aware of a governmental entity seeking to be exempt from the contraceptive Mandate.

b. Nonprofit Organizations (45 CFR 147.133(a)(1)(i)(A))

As discussed above, some commenters opposed offering exemptions based on moral convictions to any plan sponsors, and/or objected to doing so for nonprofit organizations, on various grounds, including but not limited to arguments that the benefits of contraception access should override moral objections, entities cannot assert moral objections, and moral objections burden third parties. Other commenters supported the exemptions, generally defending the interest of nonprofit organizations not to be forced to violate their moral convictions, supporting the history of government protection of moral convictions in similar contexts, and disputing the claims of opponents of the exemptions.

The Departments are aware, through litigation, of only two non-religious nonprofit organizations with moral objections to the contraceptive Mandate. Many more nonprofit religious organizations have sued suggesting—as discussed below—that the effect of this exemption for non-religious nonprofit objections to the Mandate will be far less significant than commenters who oppose the exemption believe it will. The two non-religious nonprofit organizations that challenged the Mandate in court provide a good illustration of the reasons why the Department has decided to provide this exemption to nonprofit organizations. Both organizations have said in court they oppose certain contraceptives on non-religious moral grounds as being abortifacient and state that they only hire employees who share that view. Public comments and litigation reflect that many nonprofit organizations publicly describe their beliefs and convictions. Government records and many of those groups' websites also often reflect those groups' religious or moral character, as the case may be. If a person who desires contraceptive coverage works at a nonprofit organization, the Departments view it as sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit organization that opposes contraceptive coverage to hire a person who disagrees with the organization's

view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.⁶²

The Departments agree with commenters who support offering the exemption to nonprofit organizations and believe that doing so is an appropriate protection and is not likely to have a significant impact on women who want contraceptive coverage.

c. For-Profit Entities (45 CFR 147.133(a)(1)(i)(B))

With respect to for-profit organizations addressed in § 147.133(a)(1)(i)(B), in the Moral IFC, the Departments did not limit the exemption to nonprofit organizations, but also included some for-profit entities. Some commenters supported including for-profit entities in the exemption, saying owners of such entities exercise their moral convictions through their businesses, and that such owners should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise moral convictions or should not have their moral opposition to contraceptive coverage protected by the exemption. Some commenters stated that the entities should not be able to impose their beliefs about contraceptive coverage on their employees and that doing so constitutes discrimination.

The Departments agree with commenters who support including some for-profit entities in the exemption. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities, without regard to whether they operate as nonprofit organizations or for-profit entities. In addition, nearly half of the states either impose no contraceptive coverage requirement or offer “an almost unlimited” exemption encompassing both “religious and secular organizations.”⁶³ States also generally protect moral convictions in other

health care conscience laws whether or not an entity operates as a nonprofit.⁶⁴

Extending the exemption to certain for-profit entities is also consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization and rejected the Departments' argument to the contrary. 134 S. Ct. at 2768–75. The mechanisms by which a for-profit company makes decisions of conscience, or resolves disputes on those issues among their owners, are problems that “state corporate law provides a ready means” of solving. *Id.* at 2774–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.⁶⁵ Because all of those appear to be informed by religious beliefs, extending the exemption to entities with non-religious moral convictions would seem to have an even smaller impact on access to contraceptive coverage.

The Moral IFC only extended the exemption covering for-profit entities to those that are closely held, not to for-profit entities that are publicly traded, but asked for comment on whether publicly traded entities should be included in the moral exemption. In this way the Moral IFC differed from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in the Religious IFC, at § 147.132(a)(1), finalized in companion rules published elsewhere in today's **Federal Register**.

Some commenters supported including publicly traded entities in the moral exemption, contending that publicly traded entities have historically taken various positions on important public concerns beyond merely seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to establish and exercise moral convictions against contraceptive coverage. They observed that large publicly traded entities are exempt from the contraceptive Mandate by means of the grandfathering provision of the ACA, so

⁶² Notably, “the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be ‘expressive association.’” *Boy Scouts of America v. Dale*, 530 U.S. 640, 655 (2000).

⁶³ “Insurance Coverage of Contraceptives,” The Guttmacher Institute (June 11, 2018), <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

⁶⁴ See, e.g., “Refusing to Provide Health Services,” The Guttmacher Institute (June 1, 2018), <https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services>.

⁶⁵ See Jennifer Haberkorn, “Two years later, few Hobby Lobby copycats emerge,” *Politico* (Oct. 11, 2016), <http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627>.

that it is inappropriate to refuse to exempt publicly traded entities that actually have sincerely held moral convictions against compliance with the Mandate. They further argued that in some instances there are closely held companies that are as large as publicly traded companies of significant size. They also stated that other protections for moral convictions in certain federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines “persons” to include all forms of corporations, not just closely held corporations, at 1 U.S.C. 1. Additionally, some commenters were concerned that not providing a moral exemption for publicly traded for-profit entities but allowing a religious exemption for publicly traded for-profit entities (as was allowed in the Religious IFC, and as is allowed in the companion religious final rules published elsewhere in today’s **Federal Register**), may raise Establishment Clause questions, may cause confusion to the public, and may make the exemptions more difficult for the Departments and enforcing agencies to administer. They stated that it is incongruous to include publicly traded entities in the exemption for religious beliefs, but exclude them from the exemption for moral convictions.

Other commenters opposed including publicly traded companies in these moral exemptions. Some stated that such companies could not exercise moral convictions and opposed the effects on women if they would. They also objected that including such companies, along with closely held businesses, would extend the exemptions to all or virtually all companies. Some commenters stated that many publicly traded companies would use a moral exemption if available to them, because many closely held for-profit businesses expressed religious objections to the Mandate, or availed themselves of the religious accommodation.

As is the case for non-federal governmental employers, the Departments are sympathetic to the arguments of commenters that favor including publicly traded entities in the exemption for moral convictions. In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities’ moral objections without regard to their ownership status. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their

facilities or personnel available to assist in the performance of abortions or sterilizations; the protections of the Church Amendments do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. Other federal conscience protections in the health sector apply in the same manner:

- The Coats-Snowe Amendment (42 U.S.C. 238n) provides certain protections for health care entities and postgraduate physician training programs that, among other things, choose not to perform, refer for, or provide training for, abortions.

- The Weldon Amendment⁶⁶ provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions.

- The ACA provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing. (42 U.S.C. 18113).⁶⁷

- Social Security Act sections 1852(j)(3)(B) (Medicare) and 1932(b)(3)(B) (Medicaid), 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B), provide protections so that the statutes cannot be construed to require organizations that offer Medicare Advantage and Medicaid managed care plans in certain contexts to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds.

- Congress’s most recent statement on contraceptive coverage specified that, if the District of Columbia requires “the

provision of contraceptive coverage by health insurance plans,” “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.” Consolidated Appropriations Act, 2018, Public Law 115–141, Div. E, Sec. 808.

In all of these instances, Congress did not limit the protection for conscience based on the nature of the entity—and did not exclude publicly traded entities from protection.

At the same time, as stated in the Moral IFC, the Departments continue to lack significant information about whether there is a need to extend the expanded exemption to publicly traded entities. The Departments have been sued by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, as well as by closely held for-profit entities expressing religious objections, but not by any publicly traded entities. In addition, the Departments sought public comments on whether publicly traded entities might benefit from extending the moral exemption to them. No such entities were brought to the attention of the Department through the comment process. The Supreme Court concluded it is improbable that publicly traded companies with numerous “unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs.” *Hobby Lobby*, 134 S. Ct. at 2774. It would appear to be even less probable that publicly traded entities would adopt that view based on non-religious moral convictions.

In light of the balance of public comments, the Departments decline to extend the moral convictions exemption to publicly traded entities. Because the Departments are aware of so many closely-held for-profit entities with religious objections to contraceptive coverage, and of some nonprofit entities with non-religious moral objections to contraceptive coverage, the Departments believe it is reasonably possible that closely held for-profit entities with non-religious moral objections to contraceptive coverage might exist or come into being. The Departments have also concluded that it is reasonably possible, even if improbable, that publicly traded entities with religious objections to contraceptive coverage might exist or come into being. But the Departments conclude there is not a similar probability that publicly traded for-profit entities with non-religious moral objections to contraceptive

⁶⁶ See Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d) (Mar. 2018).

⁶⁷ The lack of the limitation in this provision may be particularly relevant since it was enacted in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—were promulgated.

coverage may exist and need to be included in these expanded exemptions. The decision to not extend the moral exemption to publicly traded for-profit entities in these rules does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions without categorically excluding publicly traded entities. The Departments remain open to the possibility of future rulemaking on this issue, if we become aware of the need to expand the exemptions to publicly traded corporations with non-religious moral objections to all (or a subset of) contraceptives.

In contrast, the Departments finalize, without change, the Moral IFC's extension of the exemptions in these rules to closely held for-profit entities with moral convictions opposed to offering coverage of some or all contraceptives. The Departments conclude that it is sufficiently likely that closely held for-profit entities exist or may come into being and may maintain moral objections to certain contraceptives, so as to support including them in these expanded exemptions. The Departments seek to remove an obstacle that might prevent individuals with moral objections from forming or maintaining such small or closely held businesses and providing health coverage to their employees in accordance with their moral convictions.

In defining what constitutes a closely held for-profit entity to which these exemptions extend, the Moral IFC used language derived from the July 2015 final regulations. Those regulations, in offering the accommodation (not an exemption) to religious (not moral) closely held for-profit entities, did so by attempting to positively define what constitutes a closely held entity, formulating a multi-factor, and partially open-ended, definition for that purpose. (80 FR 41313). Any such positive definition runs up against the myriad state differences in defining such entities and potentially intrudes into a traditional area of state regulation of business organizations. Instead of attempting to positively define closely held businesses in the Moral IFC, however, the Departments considered it much clearer, effective, and preferable to define the category negatively, by reference to one element of the previous definition: that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

4. Institutions of Higher Education (45 CFR 147.133(a)(1)(ii))

The previous regulations did not exempt plans arranged by institutions of higher education, although they did include, in the accommodation, plans arranged by institutions of higher education similarly to the way in which the regulations provided the accommodation to plans of nonprofit religious employers. (See 80 FR 41347). The Moral IFC provided an exemption, in § 147.133(a)(1)(ii), encompassing institutions of higher education that arrange student health insurance coverage, and stating the exemption would operate in a manner comparable to the exemption for employers with respect to plans they sponsor. In these final rules, the Departments finalize § 147.133(a)(1)(ii) with one change.

These rules treat the health plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. The rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held moral convictions, to their arrangement of student health insurance coverage, in a manner comparable to the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

Some commenters supported including, in the exemptions, institutions of higher education that provide health coverage for students through student health plans but have moral objections to providing certain contraceptive coverage. They stated that moral exemptions allow freedom for certain institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemption would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result.

In the Departments' view, the reasons for extending the exemption to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. The Departments are not aware of any institutions of higher education that arrange student health insurance coverage and object to the Mandate based on non-religious moral convictions. But because the Departments have been sued by several institutions of higher education that arrange student health insurance coverage and object to the Mandate based on religious beliefs and by several nonprofit organizations with moral objections, the Departments believe the existence of institutions of higher education with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible to justify including protections for such entities in these final rules.

The Departments conclude that this aspect of the exemption is likely to have a minimal impact on contraceptive coverage for women at institutions of higher education. As noted above, the Departments are not aware of any institutions of higher education that would currently qualify for the objection. In addition, only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities, as opposed to from other sources, and an even smaller number receive such coverage from schools objecting to contraceptive coverage. Exempting institutions of higher education that object to contraceptive coverage based on moral convictions does not affect student health insurance contraceptive coverage at the vast majority of institutions of higher education. The exemption simply makes it legal under federal law for institutions to adhere to moral convictions that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, because it makes it easier for students to attend institutions of higher education that hold those views, if the institutions exist or come into being and students choose to attend them. Moreover, because institutions of higher education have no legal obligation to sponsor student health insurance coverage, providing this moral exemption removes an obstacle to such institutions sponsoring student health insurance coverage, thus possibly encouraging

more widespread health insurance coverage.

As noted above, after seeking public comment on whether the final moral exemptions rules should be extended to include non-federal governmental entities, the Departments have concluded they should only include non-governmental entities. For the same reasons, the Departments are inserting a reference into § 147.133(a)(1)(ii) specifying that it includes an institution of higher education “which is non-governmental.” This language is parallel to the same limiting phrase used in the religious exemptions rule governing institutions of higher education, at § 147.132(a)(1)(ii). Thus, the first sentence of § 147.133(a)(1)(ii) is finalized to read: “An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section.” The remaining text of § 147.133(a)(1)(ii) is finalized without change.

5. Health Insurance Issuers (45 CFR 147.133(a)(1)(iii))

The Moral IFC extended the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services. The issuer exemption only applied to the group health plan if the plan itself was also exempt under an exemption for the plan sponsor or individuals. In these final rules, the Departments finalize § 147.133(a)(1)(iii) without change.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing contraceptive coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on that objection. An exempt issuer can then offer an exempt product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities

and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer under this paragraph (a)(1)(iii) that does not include some or all contraceptive services, are plan sponsors or individuals who themselves object and are exempt.

Under these rules, issuers that hold their own objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their moral convictions, or if they are exempt based on their religious beliefs under the companion final rules published elsewhere in today’s **Federal Register**. Likewise, issuers with sincerely held religious beliefs, that are exempt under those companion final rules, could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Some commenters supported including this exemption for issuers in these rules, both to protect the moral convictions of issuers, and so that, in the future, issuers would be free to organize that may wish to specifically serve plan sponsors and individuals that object to contraception based on religious or moral reasons. Other commenters objected to including an exemption for issuers. Some commenters stated that issuers cannot exercise moral convictions, while others stated that exempting issuers would threaten contraceptive coverage for women. Some commenters stated that it was arbitrary and capricious for the Departments to provide an exemption for issuers if they do not know that issuers with qualifying moral objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will

it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage.

The issuer exemption serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors, plans, and individuals that independently qualify for an exemption, will remove a possible obstacle to issuers with moral convictions being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held moral convictions will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers both from being required to issue policies that cover contraception in violation of the issuers’ sincerely held moral convictions and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise moral convictions. Many federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicare Advantage or Medicaid. The Weldon Amendment specifically protects, among other entities, HMOs, health insurance plans, and “any other kind of health care facility[ies], organization[s] or plan[s]” as a “health care entity” from being required to provide coverage of, or pay for, abortions. See, for example, Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d).⁶⁸ The most recently enacted Consolidated Appropriations Act declares that Congress supports a

⁶⁸ ACA section 1553 protects an identically defined group of “health care entities,” including provider-sponsored organizations, HMOs, health insurance plans, and “any other kind of . . . plan,” from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

“conscience clause” to protect moral convictions concerning “the provision of contraceptive coverage by health insurance plans.” See *id.* at Div. E, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion Religious IFC and final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today’s **Federal Register**.⁶⁹

6. Description of the Moral Objection (45 CFR 147.133(a)(2))

The Moral IFC set forth the scope of the moral objection of objecting entities in § 147.133(a)(2), so that it applies to the extent an entity described in paragraph (a)(1), based on sincerely held moral convictions, objects to “establishing, maintaining, providing, offering, or arranging” either “coverage or payments” for contraceptives, or “for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.” The Departments are finalizing this exemption with structural changes separating the second half of the sentence into separate subparagraphs, so as to more clearly specify, as set forth in the Moral IFC text, that the objection may pertain either to coverage or payments for contraceptives, or to a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

Some commenters observed that, by allowing exempt plan sponsors to object to “some or all” contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators.

The Departments have concluded, however, that just as the previous exemption rules allowed certain religious plan sponsors to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. These rules do not require any issuer or

third party administrator to contract with an exempt entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual plan variation. These rules simply remove the federal Mandate, in some cases, where it could have led to penalties on an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying moral objection. That approach is consistent with the approach under the previous regulations, which did not require issuers and third party administrators to contract with exempt plans of houses of worship or integrated auxiliaries if they did not wish to do so.

The definition does not specify that the moral convictions that can support an exemption need to be non-religious moral convictions. We find it unnecessary to limit the definition in that way. Even though moral convictions need not be based on religious beliefs, religious beliefs can have a moral component. It is not always clear whether a moral conviction is based on religious tenets. As noted in *Welsh*, a moral conviction can be “purely ethical or moral in source and content but that nevertheless . . . occupy in the life of that individual a place parallel to that filled by God [and] function as a religion in his life.” 398 U.S. at 340. One reason for providing exemptions for moral convictions is so that the government need not engage in the potentially difficult task of parsing which convictions are religious and which are not. If sincerely held moral convictions supporting an exemption are religious, they will be encompassed by the exemption for sincerely held religious beliefs. If the moral convictions are not also religious, or if their religious quality is unclear but they are ethical or moral, they can qualify as sincerely held moral convictions under these rules if the other requirements of these rules are met.

The Departments are not aware of any entities that qualify for an exemption under the religious exemptions finalized elsewhere in today’s **Federal Register**, but not under the moral exemptions finalized here, such as publicly traded entities. If publicly traded entities object to the Mandate, it seems unlikely their objection is based on moral convictions and not religious beliefs, given that many more objections to the Mandate have been based on religious beliefs. Thus, the Departments find it unlikely that they would be faced with a

situation where a publicly traded entity, for example, has an objection to the contraceptive Mandate, but it is not clear whether that objection is based on sincerely held religious beliefs or merely based on sincerely held moral convictions.

7. Individuals (45 CFR 147.133(b))

The previous regulations did not provide an exemption for objecting individuals. The Moral IFC provided such an exemption for objecting individuals (referred to here as the “individual exemption”), using the following language at § 147.133(b): “Objecting individuals”. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.”

The Departments finalize this language, with changes in response to public comments in some of the text and in a new sentence at the end of the paragraph that clarify how the exemption applies.

Section 147.133(b) sets forth a special rule pertaining to individuals (referred to here as the “individual exemption”). This rule exempts plans of certain individuals with moral objections to contraceptive coverage where the plan sponsor and, as applicable, issuer is willing to provide a plan compliant with the individuals’ objections to such plan sponsors or individuals, as applicable.

Some commenters supported this exemption as providing appropriate protections for the moral convictions of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to coverage of contraceptives but is willing (and, as applicable, the issuer is also willing) to provide coverage consistent with an individual’s moral objections. They commented that this exemption

⁶⁹ The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for employers. Because the issuer exemption operates more narrowly than the exemption for plan sponsors operates, in the ways described here (*i.e.*, the issuer exemption does not operate unless the plan sponsor or individual, as applicable, is also exempt), and exists in part to help preserve market options for objecting plan sponsors and individuals, the Departments consider it appropriate to not draw such a distinction among issuers.

would free individuals from having their moral convictions placed in tension with their desire for health coverage. They also contended that the individual exemption would not undermine any government interests behind the contraceptive Mandate, since the individuals would be choosing not to have the coverage. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage.

Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. The Departments note that this individual exemption only operates in the case where the issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases. But the Departments do not wish to pose an obstacle to the offering of such coverage.

The Departments note that their decision is consistent with the decision by Congress to provide protections in certain contexts for individuals who object to prescribing or providing contraceptives contrary to their moral convictions. *See, for example*, Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Mar. 23, 2018). While some commenters argued that such express protections are narrow, Congress likewise provided that, if the

District of Columbia requires “the provision of contraceptive coverage by health insurance plans,” “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions”. *Id.* at Div. E, Sec. 808. A moral exemption for individuals would not be effective if the government did not, at the same time, permit issuers and group health plans to provide individuals with policies that comply with their moral convictions.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan’s or issuer’s obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers. Thus, this individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations “does not undermine the governmental interests furthered by the contraceptive coverage requirement.” (78 FR 39874). For parallel reasons, as the Departments stated in the Moral IFC (83 FR at 47853 through 47854), this individual exemption does not undermine the governmental interests furthered by the contraceptive coverage requirement, because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the state is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees’ religious beliefs “or moral convictions,” or against the individual employees who accept such offers. *See Wieland*,

196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption in these rules, employers sponsoring governmental plans would be free to honor the moral objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

In the separate companion IFC to the Moral IFC—the Religious IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Moral IFC said a willing issuer and plan sponsor may offer “a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects” under the individual exemption, the Religious IFC described what may be offered to objecting individuals as “a separate benefit package option, or a separate policy, certificate or contract of insurance.” Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of “a separate group health plan,” because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee’s objection. Consequently, these rules finalize the individual exemption by making a technical change to the language to adopt the formulation, “a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects.”

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or

sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these rules do not affect such other laws or terms.

The Departments received numerous comments about the administrative burden from the potential variations in moral convictions held by individuals. Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives, while others expressed concern that the variations in the kinds of contraceptive coverage to which individuals object might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the moral convictions of an exempt individual.

If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Moral IFC implied this conclusion by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, that language differed from the language applicable to the exemptions under § 147.133(a), which specifies that those exemptions apply “to the extent” of the moral objections, so that, as discussed above, they include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b), with the following change, by adding the following sentence at the end of the paragraph: “Under this

exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.”

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held moral convictions objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to the employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under her policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to do so. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with changes, to read as follows: “(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to

prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.”

8. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations did not offer the accommodation process to entities with moral non-religious objections. The Religious IFC amended the accommodation regulations to offer it to all entities that are exempt on the basis of religious beliefs under § 147.132, as an optional process in which such entities could participate voluntarily. The Moral IFC did not change that accommodation process, but inserted references in it to the new section § 147.133, alongside the references to section § 147.132. These changes made entities eligible for the voluntary accommodation process if they are exempt on the basis of moral convictions. The references were inserted in 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A.

In these rules, the Departments finalize, without change, the Moral IFC's revisions of 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. The operation of the accommodation process, changes made in the Religious IFC, and public comments concerning the accommodation, are more fully described in the Religious IFC, and in the companion final rules concerning the religious exemptions and accommodation, published elsewhere in today's **Federal Register**. Those descriptions are incorporated here by reference to the extent they apply to these rules.

Many commenters supported extending the accommodation process to entities with objections based on moral convictions. Others objected to doing so, raising arguments parallel to their objections to creating exemptions for group health plan sponsors with moral convictions. For much the same reasons discussed above concerning why the Departments find it appropriate to exempt entities with moral objections to contraceptive coverage, the Departments find it appropriate to extend the optional accommodation process to these entities. The Departments observe that, to the extent such entities wish to use the process, it will not be an obstacle to contraceptive coverage, but will instead help deliver contraceptive coverage to women who receive health coverage from such entities while respecting the moral convictions of the entities. The Departments are not aware of entities with non-religious moral convictions against contraceptive coverage that also consider the accommodation acceptable and would opt into it, but we are aware of a small number of entities with non-religious moral objections to the Mandate. The Departments, therefore, continue to consider it appropriate to extend the optional accommodation to such entities in case any wish to use it. Below, albeit based on very limited data, the Departments estimate that a small number of entities with non-religious moral objections may use the accommodation process.

9. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under “Contraceptive methods and counseling,” “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” The previous regulations concerning the exemption and the accommodation used the terms “contraceptive services” and “contraceptive coverage” as catch-all terms to encompass all of those Guidelines requirements. The 2016 update to the Guidelines are similarly worded. Under “Contraception,” they include the “full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,” “instruction in fertility awareness-based methods,” and “[c]ontraceptive care” to “include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or

discontinuation of the contraceptive method).”⁷⁰

To more explicitly state that the expanded exemptions encompass any of the contraceptive or sterilization services, items, procedures, or related patient education or information that have been required under the Guidelines, the Moral IFC included a definition of contraceptive services, benefits or coverage, at 45 CFR 147.133(c). These rules finalize that definition without change.

10. Severability

The Departments finalize, without change, the severability clause set forth at § 147.133(d).

C. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that moral objections to the Mandate should not be permitted in cases where contraceptive methods are used to treat such existing medical conditions and not for preventive purposes, even if those contraceptive methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to “preventive” care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to “preventive” services or care.⁷¹ The requirement in the Guidelines concerning “contraception” specifies several times that it encompasses “contraceptives,” that is, medical products, methods, and services applied for “contraceptive” uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products,

methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines’ inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.⁷² The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans’ decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so that plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use. Section 2713(a)(4), however, draws a distinction between preventive and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of care unless it is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are

⁷² The Departments previously cited the IOM’s listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that “there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.” 77 FR 8727 & n.7. This was not, however, an assertion that section 2713(a)(4) or the Guidelines require coverage of “contraceptive” methods when prescribed for an exclusively non-contraceptive, non-preventive use. Instead, it was an observation that such drugs—generally referred to as “contraceptives”—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

⁷⁰ “Women’s Preventive Services Guidelines,” HRSA (last reviewed Oct. 2017), <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

⁷¹ *Id.*

prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply if the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that, under section 2713(a)(4), exempt organizations must provide coverage for drugs or items prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Moral IFC that the moral exemptions are likely to affect only a very small number of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the exemptions could take contraceptive coverage away from many or most women. Still others opposed establishing the exemptions, but contended that accurately determining the number of women affected by the exemptions is not possible. Public comments included various statements that these exemptions would impact coverage for a large number of women, while others stated they would affect only a very small number. But few, if any, public commenters provided data predicting a precise number of entities that would make use of the exemptions for moral convictions nor a precise number of employees that would potentially be affected.

After reviewing the public comments, the Departments do not find the suggestions of commenters who predicted a very large impact any more reliable than the estimates set forth in the Religious and Moral IFCs. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious and Moral IFCs are still the best estimates available. The Departments' estimates are discussed in more detail in the following section.

III. Economic Impact and Paperwork Burden

The Departments have examined the impacts of these final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section 1102(b) of the Social Security

Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and an “economically significant” regulatory action is subject to review by OMB. As discussed below regarding their anticipated effects, the these final rules are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules and the Departments have

provided the following assessment of their impact.

1. Need for Regulatory Action

The Religious IFC amended the Departments' July 2015 final regulations. The Moral IFC amended those regulations further, and added an additional rule at 45 CFR part 147.133. These final rules adopt as final, and further amend, the amendments made by the Moral IFC. The Departments do so in conjunction with the amendments made in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. These rules provide an exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4), section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, for certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process by making the accommodation applicable to organizations with such convictions as an option. The exemption applies to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action has been taken to provide for participation in the health insurance market by certain entities or individuals in a manner free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to ensure the preventive services coverage requirement is implemented in a way consistent with longstanding federal conscience statutes, to prevent lawsuits of the kind that were filed against the Departments when the expanded exemption in these final rules was not offered, and for the other reasons discussed above.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these final rules, we believe it to be small.

With respect to the exemption for nonprofit organizations with objections based on moral convictions, as noted

above, the Departments are aware of two small nonprofit organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the nature of certain contraceptives subject to coverage under the Mandate.⁷³ One of them has obtained a permanent injunction against any regulations implementing the contraceptive Mandate, and so will not be affected by these final rules. Based on comments submitted in response to rulemakings prior to the Moral and Religious IFCs, the Departments believe that at least one other similar entity exists.⁷⁴ However, the Departments do not know how many similar entities exist and are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities.

The Departments also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with the conclusion in previous regulations that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (See 76 FR 46625 and 78 FR 39889). The Departments reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception and without requiring that such entities actually oppose contraception in order to be exempt (in contrast, the exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to contraceptive coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, the

Departments relied on the assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is appropriate with respect to the expanded exemption for nonprofit organizations with objections based on moral convictions. To the knowledge of the Departments, the vast majority of organizations objecting to the Mandate assert objections based on religious beliefs. The only nonprofit organizations of which they are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under the Departments' previous regulations that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.⁷⁵ Although the Departments are unable to find sufficient data on this issue, we believe that there are far fewer nonprofit organizations opposed to contraceptive coverage on the basis of moral convictions than there are houses of worship or integrated auxiliaries with religious objections to such coverage. Based on the limited data available, the Departments believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose certain contraceptive coverage. Therefore, the Departments expect that the moral exemption for nonprofit entities will have a minimal effect of reducing contraceptive coverage with respect to employees who want such coverage.

These rules extend the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and make exempt entities with moral objections eligible to avail themselves of the accommodation. The Departments are not aware of any institutions of higher education with this kind of non-religious moral

convictions. Moreover, the Departments believe the overall number of entities that would object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education. Public comments did not reveal the existence of any institutions of higher education with such moral convictions. Therefore, for the purposes of estimating the anticipated effect of these final rules on contraceptive coverage of women who wish to receive such coverage, the Departments assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no other entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on reasons similar to those given above for why the exemptions and accommodations are extended to other entities.

The Departments believe that the exemption for issuers with objections based on moral convictions will not result in a distinct effect on contraceptive coverage for women who wish to receive it, because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein, or in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. The exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The moral exemption will also cover for-profit entities that do not have publicly traded ownership interests and that have non-religious moral objections to the Mandate, if such entities exist. Some commenters agreed that the impact of these final rules would be no more than the Departments estimated in the Moral IFC, and some commenters stated the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended

⁷³ Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

⁷⁴ See, for example, Americans United for Life ("AUL") Comment on CMA-9992-IFC2 at 10 (Nov. 1, 2011), available at <http://www.regulations.gov/#/documentDetail;D=HHS-OS-2011-0023-59496>, and AUL Comment on CMS-9968-P at 5 (Apr. 8, 2013), available at <http://www.regulations.gov/#/documentDetail;D=CMS-2012-0031-79115>.

⁷⁵ Cf., for example, Frank Newport, "Americans, Including Catholics, Say Birth Control Is Morally OK," Gallup, (May 22, 2012), <http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx> ("Eighty-two percent of U.S. Catholics say birth control is morally acceptable").

pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women. These general comments did not, however, substantially assist the Departments in estimating the number of women that would potentially be affected by these exemptions for moral convictions specifically, or among them, how many unintended pregnancies would result, how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the estimated transfer costs, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives.

Some of the comments opposing these exemptions assert that they will lead to a large number of entities dropping contraceptive coverage. The Departments disagree; they are aware of only two entities that hold non-religious moral convictions against contraceptive coverage. Both only hire employees that share their beliefs, and one will not be affected by these final rules because it is protected by an injunction from any regulations implementing the contraceptive Mandate. Commenters cited no other specific entities that might assert these moral convictions, and did not provide better data to estimate how many entities might exist. Likewise, the Departments find it unlikely that any of the vast majority of entities that covered contraceptives before this Mandate was announced in 2011 would terminate such coverage because of these exemptions based on moral convictions. The Departments also find it unlikely that a significant number of for-profit entities, whose plans include a significant number of women, omitted contraceptive coverage before the ACA on the basis of objections grounded in non-religious moral convictions, and would claim an exemption under these final rules. No such entities, or data concerning such entities, were identified by public commenters, nor are the Departments aware of any involved in litigation over the Mandate.

Numerous for-profit entities claiming religious objections have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—and both were nonprofit organizations. Among the general public, polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they

believe in God.⁷⁶ Among non-religious persons, only a very small percentage of the population appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.⁷⁷ Combined, this suggests that 0.2 percent of Americans at most⁷⁸ might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. The Departments have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral convictions set forth in these final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, the Departments assume that some similar for-profit entities with non-religious moral objections exist. But the Departments expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities without publicly traded ownership interests and with sincere moral objections to the Mandate, the Departments expect that fewer than 10 entities, if any, will do so—so the Departments assume nine for-profit entities will use the exemption in these final rules.

The moral exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS-IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.⁷⁹ The average number of

policyholders (9) in plans with under 100 employees was obtained. It is not known how many employees would be employed by the for-profit employers that might claim this exemption, but as discussed above these final rules do not include publicly traded companies, and both of the two nonprofit entities that challenged the Mandate based on moral objections included fewer than five policyholders in their group plans. Therefore, the Departments assume that the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For 9 entities, the total number of policyholders would be approximately 81. DOL estimates that for each policyholder, there is approximately one dependent.⁸⁰ This amounts to approximately 162 covered persons. Census data indicate that women of childbearing age, *i.e.*, women aged 15 to 44, comprise 20.2 percent of the general population.⁸¹ This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.⁸² Thus, the Departments estimate that approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules.⁸³ In the companion final

Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>. Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance.

⁸⁰ "Health Insurance Coverage Bulletin" Dept. of Labor" (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

⁸¹ U.S. Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at <https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf>. The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." Women's Preventive Services Guidelines, HRSA (last reviewed Oct. 2017), <https://www.hrsa.gov/womensguidelines/>; see also 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, e.g., "Contraceptive Use in the United States," The Guttmacher Institute (Sept. 2016), <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁸² See "Contraceptive Use in the United States," The Guttmacher Institute (Sept. 2016), <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁸³ The Departments note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be

⁷⁶ Frank Newport, "Most Americans Still Believe in God," Gallup (June 29, 2016), <http://www.gallup.com/poll/193271/americans-believe-god.aspx>.

⁷⁷ Pew Research Center, "Where the Public Stands on Religious Liberty vs. Nondiscrimination," Pew Research Center, 26 (Sept. 28, 2016), <http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf>.

⁷⁸ The study defined religiously "unaffiliated" as agnostic, atheist or "nothing in particular", *id.* at 8, as distinct from several versions of Protestants, or Catholics. "Nothing in particular" might have included some theists.

⁷⁹ "Health Insurance Coverage Bulletin," Dept. of Labor (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic

Continued

rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, in health plans that cover contraception, is \$584. Consequently, the Departments estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded moral exemption in these final rules is approximately \$8,760.

The Departments estimate that these final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will avail themselves of the accommodation, although the Departments wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. While these final rules make it legal for issuers to offer insurance coverage that omits contraceptives to/for exempt entities and individuals, these final rules do not require issuers to do so. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, the Departments do not anticipate that these final rules will result in any burden from such entities acting to revoke their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the exemptions finalized in these final rules. The Departments acknowledge uncertainty in the estimate and, therefore, conducted a second analysis using an alternative framework, which is set forth in the companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, with reference to the analysis conducted in the Religious IFC. Under either estimate, these final rules are not deemed to be economically significant.

covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion—and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

The Departments reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) imposes certain requirements with respect to federal regulations that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The Moral IFC was a set of interim final rules with comment, and in these final rules, the Departments finalize the Moral IFC with certain changes based on public comments. The Moral IFC was exempt from the notice and comment requirements of the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA did not apply to the Moral IFC. These final rules are, however, issued after a notice and comment period.

The Departments carefully considered the likely impact of the rules on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to

some or all contraceptives and/or sterilization—businesses and organizations which would otherwise be faced with the dilemma of complying with the Mandate (and violating their moral convictions), or of following their moral convictions and incurring potentially significant financial penalties for noncompliance—the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

The Departments estimate that these final rules will not result in additional burdens not accounted for as set forth in companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**. As discussed there, rules covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(e)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burden related to these information collection requirements (ICRs) received emergency review and approval under OMB Control Number 0938–1344. They have been resubmitted to OMB in conjunction with this final rule and are pending re-approval.

As discussed above, however, the Departments assume that no entities with non-religious moral objections to the Mandate will use the accommodation. The Departments know that no such entities were eligible for it until now, so that no entity possesses an accommodated status that would need to be revoked. Therefore, the Departments believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1344, as described in the final rules concerning religious beliefs issued contemporaneously with these final rules.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. In an effort to consolidate the number of information collections the Department is combining OMB control numbers 1210–0150 and 1210–0152 under OMB control number 1210–0150 and discontinuing OMB control number 1210–0152.

A copy of the ICR may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these final rules make entities with certain moral convictions eligible for the accommodation, the Department assumes (1) that no entities will use the accommodation rather than the exemption, and (2) entities using the moral exemption would not have to revoke an accommodation, because they previously were not eligible for it. Therefore, the Department believes these final rules do not involve additional burden not accounted for under OMB control number 1210–0150, which is published elsewhere in today's issue of the **Federal Register** in connection with the companion Religious Exemption and Accommodation Preventive Health Service final rule. The Department will

publish a notice informing the public of OMB's action with respect to the Department's submission of the ICRs under OMB control number 1210–0150.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, “[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [Affordable Care] Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” In addition, agencies are directed to “take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.” The Moral IFC and these final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.⁸⁴ However, in order to avoid

⁸⁴ Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (<https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation>) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention

double-counting with the Moral IFC, which has already been tallied as an E.O. 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) (Pub. L. 104–4)), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year.” In 2018, that threshold is approximately \$150 million. For purposes of the Unfunded Mandates Reform Act, the Moral IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of \$150 million or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

IV. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

leads to these final rules' medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October, 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713 [Amended]

■ 2. Section 54.9815–2713, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraph (a)(1)(iv) by removing the reference “147.131 and 147.132” and adding in its place the reference “147.131, 147.132, and 147.133”.

§ 54.9815–2713A [Amended]

■ 3. Section 54.9815–2713A, as amended elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (a)(1) by removing “or (ii)” and adding in its place “or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)”;

■ b. In paragraph (a)(2) by removing the reference “147.132(a)” and adding in its place the reference “147.132(a) or 147.133(a)”;

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ d. In paragraph (b)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

■ f. In paragraph (c)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”; and

■ g. In paragraph (c)(2) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ For the reasons set forth in the preamble, the Department of Labor adopts, as final, the interim final rules amending 29 CFR part 2590, published October 13, 2017 (82 FR 47838), without change.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47838) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 147, as revised elsewhere in this issue of the **Federal Register**, continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 5. Section 147.133 is amended by revising paragraph (a)(1) introductory text, (a)(1)(ii), (a)(2), and (b) to read as follow:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines’ requirements that relate to the provision of contraceptive services:

* * * * *

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health

insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and

* * * * *

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to

any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24514 Filed 11–7–18; 4:15 pm]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

Presidential Documents

Executive Order 13798 of May 4, 2017

Promoting Free Speech and Religious Liberty

By the authority vested in me as President by the Constitution and the laws of the United States of America, in order to guide the executive branch in formulating and implementing policies with implications for the religious liberty of persons and organizations in America, and to further compliance with the Constitution and with applicable statutes and Presidential Directives, it is hereby ordered as follows:

Section 1. *Policy.* It shall be the policy of the executive branch to vigorously enforce Federal law's robust protections for religious freedom. The Founders envisioned a Nation in which religious voices and views were integral to a vibrant public square, and in which religious people and institutions were free to practice their faith without fear of discrimination or retaliation by the Federal Government. For that reason, the United States Constitution enshrines and protects the fundamental right to religious liberty as Americans' first freedom. Federal law protects the freedom of Americans and their organizations to exercise religion and participate fully in civic life without undue interference by the Federal Government. The executive branch will honor and enforce those protections.

Sec. 2. *Respecting Religious and Political Speech.* All executive departments and agencies (agencies) shall, to the greatest extent practicable and to the extent permitted by law, respect and protect the freedom of persons and organizations to engage in religious and political speech. In particular, the Secretary of the Treasury shall ensure, to the extent permitted by law, that the Department of the Treasury does not take any adverse action against any individual, house of worship, or other religious organization on the basis that such individual or organization speaks or has spoken about moral or political issues from a religious perspective, where speech of similar character has, consistent with law, not ordinarily been treated as participation or intervention in a political campaign on behalf of (or in opposition to) a candidate for public office by the Department of the Treasury. As used in this section, the term "adverse action" means the imposition of any tax or tax penalty; the delay or denial of tax-exempt status; the disallowance of tax deductions for contributions made to entities exempted from taxation under section 501(c)(3) of title 26, United States Code; or any other action that makes unavailable or denies any tax deduction, exemption, credit, or benefit.

Sec. 3. *Conscience Protections with Respect to Preventive-Care Mandate.* The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code.

Sec. 4. *Religious Liberty Guidance.* In order to guide all agencies in complying with relevant Federal law, the Attorney General shall, as appropriate, issue guidance interpreting religious liberty protections in Federal law.

Sec. 5. *Severability.* If any provision of this order, or the application of any provision to any individual or circumstance, is held to be invalid, the remainder of this order and the application of its other provisions to any other individuals or circumstances shall not be affected thereby.

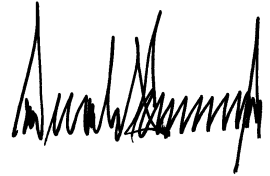
Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", located on the right side of the page.

THE WHITE HOUSE,
May 4, 2017.



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Women's Preventive Services Guidelines

Guideline Development

The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the [Institute of Medicine](#) (IOM), now known as the National Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. To address these, the Health Resources and Services Administration (HRSA) awarded a five-year cooperative agreement in March 2016 to convene a coalition of clinician, academic, and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the NAM *Clinical Practice Guidelines We Can Trust*. The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

The purpose of the Women's Preventive Services Guidelines is to improve women's health across the lifespan by identifying preventive services and screenings to be used in clinical practice. The Women's Preventive Services Initiative will review the recommendations biennially, or upon the availability of new evidence. Topics for future consideration can also be submitted on a rolling basis at the [Women's Preventive Services Initiative website](#).

Under section 2713 of the Public Health Services Act, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose.

Updated HRSA-Supported Women's Preventive Services Guidelines

HRSA is supporting the Women's Preventive Services Initiative clinical recommendations listed below for preventive services that address health needs specific to women and fill gaps in existing guidelines.*

Breast Cancer Screening for Average-Risk Women

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Breastfeeding Services and Supplies

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during

Learn More

- [Women's Preventive Services Initiative report](#)
- [2011 IOM Report *Clinical Preventive Services for Women: Closing the Gaps*](#)
- [US Preventive Services Task Force](#)
- [Bright Futures](#)
- [Advisory Committee on Immunization Practices](#)
- [Previous Preventive Services Guidelines](#) (August 2011)

For Further Information

Contact
wellwomancare@hrsa.gov

the antenatal, perinatal, and the postpartum period to ensure the successful initiation and maintenance of breastfeeding.

Screening for Cervical Cancer

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Contraception**

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), (8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Screening for Gestational Diabetes Mellitus

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women's Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Screening for Human Immunodeficiency Virus Infection

The Women's Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Screening for Interpersonal and Domestic Violence

The Women's Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive

coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Counseling for Sexually Transmitted Infections

The Women's Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women's Preventive Services Initiative recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Well-Woman Preventive Visits

The Women's Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services, including preconception, and many services necessary for prenatal and interconception care are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

Implementation Considerations

While not included as part of the HRSA-supported guidelines, the Women's Preventive Services Initiative also developed implementation considerations, available at <http://www.womenspreventivehealth.org/>, which provide additional clarity on implementation of the guidelines into clinical practice. The implementation considerations are separate from the clinical recommendations, are informational, and are not part of the formal action by the Administrator under Section 2713.

** Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 20, 2017. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the 2011 guidelines.*

*** (I)(a) Objecting entities—religious beliefs.*

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (I)(a)(2) of this note. Such non-governmental plan sponsors include, but are not limited to, the following entities:

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order;

(B) A nonprofit organization;

(C) A closely held for-profit entity;

(D) A for-profit entity that is not closely held; or

(E) Any other non-governmental employer;

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (I)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted

as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (I)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (I)(a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (I)(a) will apply to the extent that an entity described in paragraph (I)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) Objecting individuals—religious beliefs. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (I)(b), and nothing in 45 CFR 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(II)(a) Objecting entities—moral convictions.

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (II)(a)(2) of this note:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (II)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (II)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (II)(a)(1)(iii), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (II)(a) will apply to the extent that an entity described in paragraph (II)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) Objecting individuals—moral convictions. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (II)(b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(III) Definition. For the purposes of this note, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of these Guidelines.

See Federal Register Notice: [Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act](#) (PDF - 488 kb).

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Women's Preventive Services Guidelines



On December 20, 2016, HRSA updated the HRSA-supported Women's Preventive Services Guidelines. [Read the most current version.](#)

Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 20, 2017. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the 2011 guidelines.

Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being

The Affordable Care Act – the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010 – helps make prevention affordable and accessible for all Americans by requiring health plans to cover preventive services and by eliminating cost sharing for those services. Preventive services that have strong scientific evidence of their health benefits must be covered and plans can no longer charge a patient a copayment, coinsurance or deductible for these services when they are delivered by a network provider.

Women's Preventive Services Guidelines Supported by the Health Resources and Services Administration

Under the Affordable Care Act, women's preventive health care – such as mammograms, screenings for cervical cancer, prenatal care, and other services – generally must be covered with no cost sharing. However, the law recognizes and HHS understands the need to take into account the unique health needs of women throughout their lifespan.

The HRSA-supported health plan coverage guidelines, developed by the Institute of Medicine (IOM), will help ensure that women receive a comprehensive set of preventive services without having to pay a co-payment, co-insurance or a deductible. HHS commissioned an IOM study to review what preventive services are necessary for women's health and well-being and therefore should be considered in the development of comprehensive guidelines for preventive services for women. HRSA is supporting the IOM's recommendations on preventive services that address health needs specific to women and fill gaps in existing guidelines.

Health Resources and Services Administration Women's Preventive Services Guidelines

Non-grandfathered plans (plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) generally are required to provide coverage without cost sharing consistent with these guidelines in the first plan year (in the individual market, policy year) that begins on or after August 1, 2012.

Type of Preventive Service	HHS Guideline for Health	Frequency

Learn More

- [Women's Preventive Services Initiative report](#)
- [2011 IOM Report *Clinical Preventive Services for Women: Closing the Gaps*](#)
- [US Preventive Services Task Force](#)
- [Bright Futures](#)
- [Advisory Committee on Immunization Practices](#)
- [Previous Preventive Services Guidelines \(August 2011\)](#)

For Further Information

Contact
wellwomancare@hrsa.gov

	Insurance Coverage	
Well-woman visits.	Well-woman preventive care visit annually for adult women to obtain the recommended preventive services that are age and developmentally appropriate, including preconception care and many services necessary for prenatal care. This well-woman visit should, where appropriate, include other preventive services listed in this set of guidelines, as well as others referenced in section 2713.	Annual, although HHS recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.* (see note)
Screening for gestational diabetes.	Screening for gestational diabetes.	In pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.
Human papillomavirus testing.	High-risk human papillomavirus DNA testing in women with normal cytology results.	Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections.	Counseling on sexually transmitted infections for all sexually active women.	Annual.
Counseling and screening for human immune-deficiency virus.	Counseling and screening for human immune-deficiency virus infection for all sexually active women.	Annual
Contraceptive methods and counseling. ** (see note)	All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.	As prescribed
Breastfeeding support, supplies, and counseling.	Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment.	In conjunction with each birth
Screening and counseling for interpersonal and domestic violence.	Screening and counseling for interpersonal and domestic violence.	

* Refer to guidance issued by the Center for Consumer Information and Insurance Oversight entitled [Affordable Care Act Implementation FAQs, Set 12, Q10](#).

**** The guidelines concerning contraceptive methods and counseling described above do not apply to women who are participants or beneficiaries in group health plans sponsored by religious employers. Effective August 1, 2013, a religious employer is defined as an employer that is organized and operates as a non-profit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code. HRSA notes that, as of August 1, 2013, group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services under section 2713 of the Public Health Service Act, as incorporated into the Employee Retirement Income Security Act and the Internal Revenue Code. HRSA also notes that, as of January 1, 2014, accommodations are available to group health plans established or maintained by certain eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations, with respect to the contraceptive coverage requirement. See Federal Register Notice: [Coverage of Certain Preventive Services Under the Affordable Care Act](#) (PDF - 327 KB)**

HRSA, in concert with an external review committee, will review, and continually update, the [Women's Preventive Services' Guidelines](#).

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Clinical Preventive Services for Women

Closing the Gaps

Committee on Preventive Services for Women
Board on Population Health and Public Health Practice

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*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*

—Goethe



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This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by **Nancy E. Adler**, Professor of Medical Psychology, Departments of Psychiatry and Pediatrics, and Director, Center for Health and Community, University of California, San Francisco and **Susan J. Curry**, Dean, College of Public Health, University of Iowa. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests entirely with the author committee and the institution.

Preface

As chair of the Committee on Preventive Services for Women, I want to personally thank my fellow committee members for their willingness to serve, for their hard work, and for contributing their remarkable expertise to this study. I have been honored to contribute to this effort. Each of us works in different domains relating to preventive health services, and although the short time frame provided to perform this study presented a challenge, my esteemed colleagues who comprised the committee worked as a team with great dedication and spirit to achieve consensus. It was a pleasure to work with each and every one of them.

The diverse committee involves an impressive array of researchers and practitioners, including two members who served on the United States Preventive Services Task Force (USPSTF) and one who leads USPSTF systematic evidence reviews. Although we could not conduct a USPSTF-style systematic review for any single preventable health condition or determinant of well-being, nor were we expected to do so, I believe that our end product is a study that has important, evidence-based recommendations that provide a road map to improved preventive services for women. Throughout the process we repeatedly asked ourselves whether the disease or condition that we were addressing was of significance to women and especially whether it was more common or more serious in women than in men or whether women experienced different outcomes or benefited from different interventions than men. I believe that the preventive services that we recommend for consideration in this report readily satisfy these questions.

The Patient Protection and Affordable Care Act of 2010 has afforded

us an historic occasion. For the first time, prevention plays a central role within the scope of new health insurance plans in the United States. Also, an ongoing focus on women's preventive services is expected to be included in these efforts. Given the history of inadequate attention to women's health research and preventive services noted by many (including previous Institute of Medicine [IOM] committees), I am truly optimistic that gains in women's health and well-being will ensue. With the multiple roles that women play in society, to invest in the health and well-being of women is to invest in progress for all.

I regret that we were unable to resolve to his satisfaction the issues raised by one committee member, Anthony Lo Sasso. In his statement of dissent, he identifies his main concerns, which are with the constraints of the study's charge and subsequent process. His statement, along with the committee's response, can be found in Appendix D of the report.

I thank the IOM staff, especially our senior project officer, Karen Helsing, and also Jesse Flynn, Suzanne Landi, Chelsea Frakes, and IOM Anniversary Fellow Rebekah Gee. All went above and beyond to support the committee throughout the process. We also are indebted to Rose Marie Martinez, senior director of the Board on Population Health and Public Health Practice, for her presence throughout and her invaluable guidance and support. I am grateful as well to those who presented and attended our committee's open sessions and those who submitted comments and informed our work with their research and opinion pieces. Without their dedicated work this report would not have been possible.

Linda Rosenstock, *Chair*
Committee on Preventive Services for Women

Contents

SUMMARY	1
1 INTRODUCTION	15
Specifics of the Legislation, 15	
Role of Prevention in Addressing Health and Well-Being, 16	
Why Women?, 18	
Preventive Services for Women, 20	
Committee on Preventive Services for Women, 20	
Committee Process, 22	
References, 26	
2 PREVENTIVE SERVICES DEFINED BY THE ACA	29
United States Preventive Services Task Force, 29	
Bright Futures—American Academy of Pediatrics, 37	
Advisory Committee on Immunization Practices, 43	
References, 46	
3 EXISTING COVERAGE PRACTICES OF NATIONAL, STATE, AND PRIVATE HEALTH PLANS	47
Rules Governing Coverage Requirements Before and After the ACA, 48	
Discussion, 64	
References, 64	

4	COMMITTEE METHODOLOGY	67
	Review of USPSTF Recommendations, 67	
	Review of Bright Futures Recommendations, 72	
	Review of ACIP Recommendations, 73	
	Further Committee Considerations, 73	
	Recommendations on Preventive Services to Be Considered in Development of Comprehensive Guidelines, 77	
	References, 77	
5	RECOMMENDATIONS	79
	Diabetes and Gestational Diabetes, 79	
	Cervical Cancer, 88	
	Sexually Transmitted Infections, 94	
	Human Immunodeficiency Virus Infection, 98	
	Preventing Unintended Pregnancy and Promoting Healthy Birth Spacing, 102	
	Breastfeeding, 110	
	Interpersonal and Domestic Violence, 117	
	Well-Woman Preventive Visits, 123	
	References, 135	
6	PROCESS FOR REGULARLY UPDATING THE RECOMMENDATIONS	157
	Guiding Principles and Recommendations, 158	
	A Preventive Services Coverage Commission, 158	
	Role of Evidence-Based Review Bodies, 159	
	Discussion, 160	
	References, 162	
7	FINDINGS AND RECOMMENDATIONS FOR ADDRESSING IDENTIFIED GAPS IN PREVENTIVE SERVICES FOR WOMEN	163
	Concluding Observations from the Committee, 163	
	References, 168	
APPENDIXES		
A	CLARIFICATIONS	171
	Cardiovascular Disease, 171	
	Bone/Skeletal Disease, 178	
	Breast Cancer, 182	

CONTENTS

xiii

	Mental Health, 188	
	Tobacco Use, 193	
	Diet/Physical Activity, 198	
	References, 202	
B	AGENDAS OF PUBLIC MEETINGS HELD BY THE COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN	217
C	COMMITTEE BIOGRAPHIES	223
D	DISSENT AND RESPONSE	231

Summary

BACKGROUND

The Patient Protection and Affordable Care Act of 2010 (ACA) holds much promise—beyond the expansion of health care coverage—for millions of Americans. The preventive health care services and screenings specified in the legislation will be fully covered without requiring a patient copayment. These include the services with Grade A and B recommendations made by the United States Preventive Services Task Force (USPSTF), the Bright Futures recommendations for adolescents from the American Academy of Pediatrics (AAP) in cooperation with the U.S. Department of Health and Human Services (HHS), and vaccinations specified by the Centers for Disease Control and Prevention’s (CDC’s) Advisory Committee on Immunization Practices (ACIP). These three sets of guidelines provide a list of preventive services, such as blood pressure measurement, diabetes and cholesterol tests, and mammography and colonoscopy screenings. As part of the ACA, the list of preventive services specific to women’s health was requested to be reviewed.

CHARGE TO THE COMMITTEE

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of HHS provided funds for the Institute of Medicine (IOM) to conduct a review of effective preventive services to ensure women’s health and well-being. The charge to the committee for the project is presented in Box S-1.

BOX S-1
Statement of Task to the Committee on
Preventive Services for Women

The Institute of Medicine will convene an expert committee to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. The committee will also provide guidance on a process for regularly updating the preventive screenings and services to be considered. In conducting its work, the committee will: conduct a series of meetings to examine existing prevention guidelines, obtain input from stakeholders, identify gaps that may exist in recommended preventive services for USPSTF Grade A and B preventive services guidelines for women and in Bright Futures and USPSTF Grade A and B guidelines for adolescents, and highlight specific services and screenings that could supplement currently recommended preventive services for women. Specifically, the committee will consider the following questions:

- What is the scope of preventive services for women not included in those graded A and B by the USPSTF?
- What additional screenings and preventive services have been shown to be effective for women? Consideration may be given to those services shown to be effective but not well utilized among women disproportionately affected by preventable chronic illnesses.
- What services and screenings are needed to fill gaps in recommended preventive services for women?
- What models could HHS and its agencies use to coordinate regular updates of the comprehensive guidelines for preventive services and screenings for women and adolescent girls?

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) on behalf of the U.S. Department of Health and Human Services (HHS) has been charged to examine recommendations for women's preventive services. ASPE will use the information and recommendations from the committee's report to guide policy and program development related to provisions in the Affordable Care Act addressing preventive services for women.

In response, the IOM convened a committee of 16 members—including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines—to develop a set of recommendations for consideration by the ASPE of HHS.

The committee sought clarification from ASPE on a number of issues regarding its charge. In summary:

- Preventive services were specified to be applicable to females aged 10 to 65 years;

- The mammography screenings specified in the ACA legislation used USPSTF guidelines from 2002, which specify that such screenings be performed every one to two years for women aged 40 years and older;
- The cost-effectiveness of screenings or services could not be a factor for the committee to consider in its analyses leading to its recommendations;
- The committee was not intended to duplicate the processes used by the USPSTF and thus should look to other bodies of evidence beyond systematic evidence-based reviews; and
- Preventive services were specified for clinical settings, and thus community-based prevention activities were considered beyond the scope of committee consideration.

COMMITTEE'S APPROACH TO ITS CHARGE

The committee met five times within six months. The committee held three open information-gathering sessions at which the members heard from a diverse group of stakeholders, researchers, members of advocacy organizations, and the public. Box S-2 provides the committee definition of preventive health services.

BOX S-2 **Definition of Preventive Health Services**

For the purposes of this study, the Committee on Preventive Services for Women defines preventive health services to be measures—including medications, procedures, devices, tests, education and counseling—shown to improve well-being, and/or decrease the likelihood or delay the onset of a targeted disease or condition.

COMMITTEE'S METHODOLOGY

The committee's methodology to identify preventive services necessary for women's health and well-being and to identify specific services that could supplement the current list of recommended preventive services for women under the ACA follows.

The committee's first step was to review and reach an understanding of existing guidelines. The second step was to assemble and assess additional evidence, including reviews of the literature, federal health priority goals

and objectives, federal reimbursement policies, and the clinical guidelines of health care professional organizations. The committee also considered the public comments that it received. Finally, the committee formulated a list of recommendations to be considered by the Secretary of HHS in developing a comprehensive package of preventive services for women to be included under the ACA.

USPSTF Recommendations

The USPSTF process for developing recommendations is a disease-focused one. The intent of its recommendations has been to provide guidance to primary care providers. The IOM committee's approach to identifying gaps in existing services accounts for contextual issues beyond traditional research evidence used by the USPSTF. The committee looked at women's preventive service needs more broadly to account for women's health and well-being. The committee found that its interpretation of the Grade A and B recommendations was important in those cases in which ambiguity was found regarding periodicity of screenings. Furthermore, the committee compared USPSTF guidelines with those of numerous health care professional organizations to identify potential gaps.

The committee recognized that USPSTF Grade C recommendations and I statements warranted further analysis because the USPSTF did not develop and has not used these grades as support to offer or deny coverage of a preventive service. The USPSTF Grade C recommendations are made when the balance of potential benefits and harms does not strongly favor the clinician recommending the preventive service to all patients, although it may be appropriate in some cases.

The USPSTF I statements identify services for which the evidence is insufficient to suggest the effectiveness of a service because evidence is lacking, of lower quality, or conflicting. The committee notes that from a coverage perspective, the evidence supporting many clinical interventions in common use, whether in prevention or in general medical practice, is insufficient or unclear, and coverage decisions may be or have been made on the basis of other factors.

For example, although physician knowledge of the evidence of the benefits associated with a counseling service will inform a physician's decision for each patient, in many instances, it is difficult for researchers to show or conclude that outcomes are positive. Many preventive interventions that are intended to be conducted early in the life span (e.g., skin cancer prevention) require decades to demonstrate effectiveness.

Thus, each of the USPSTF Grade C and I statement recommendations and the evidence supporting them were collected and reviewed. The committee's evaluation included reviewing relevant supporting USPSTF

publications, other peer-reviewed research and clinical articles, and clinician fact sheets. Additional literature searches were conducted to identify randomized control trials published after the USPSTF recommendation was released. Furthermore, the committee compared the Grade C and I statement guidelines with guidelines from other professional organizations. The committee did not reexamine the services with Grade D recommendations, because the USPSTF recommends against providing these services.

Bright Futures Recommendations

The committee reviewed all Bright Futures guidelines and compared them with the USPSTF guidelines for adolescents. The committee noted that the methodology that Bright Futures uses is quite different from that which the USPSTF uses. Bright Futures makes decisions through a consensus-driven process; thus, expert opinion is at the core of its development of recommendations.

The committee interpreted the sample questions and advice suggested in the anticipatory guidance section of the *Bright Futures* report (AAP, 2008) to describe topics to be covered as preventive services under the ACA and addressed in an annual health care visit of sufficient length to cover age- and sex-appropriate topics in the health domain. The committee assumes that physicians will identify priorities from this section of the *Bright Futures* report on the basis of the unique circumstances of each patient.

ACIP Recommendations

The committee reviewed ACIP General Recommendations on Immunizations, which include all of the Food and Drug Administration-approved immunizations recommended for the general population of adolescent and adult women. Although literature searches were conducted to identify areas where supplemental immunization recommendations might be warranted, the committee identified little evidence to clearly indicate deficiencies in existing ACIP recommendations.

Further Committee Considerations

The committee reviewed oral and written comments submitted throughout the course of the study. The committee also invited researchers and leaders of organizations to deliver presentations in areas in which the committee believed that it could benefit from their expertise. In addition, the committee reviewed HHS documents relating to prevention priorities and reimbursement policies. It also reviewed the existing coverage practices of national, state, and private health plans. In some cases, current practice

in clinical care was also identified. Finally, the committee used the 2011 IOM report *Leading Health Indicators for Healthy People 2020* as a tool to perform horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify potential gaps (IOM, 2011).

COMMITTEE ANALYSIS

The product of these reviews was an array of potential areas where supplemental preventive measures might be warranted. Some of these areas were identified on the basis of traditional indicators, such as morbidity and mortality, whereas others were identified as being more generally supportive of a woman's well-being. The committee focused on conditions unique to women or that affected women in some specific or disproportionate way. The committee moved forward using criteria adapted from the USPSTF that considered frequency, severity, morbidity, mortality, and quality of life to bring consistency to the analyses.

For each potential supplemental preventive measure considered, the committee conducted an extensive comparison of the guidelines of professional organizations to understand the development of the guidelines and the evidence that the organizations used to reach their conclusions. The committee also performed targeted literature searches. However, it should be noted that the committee did not have adequate time or resources to conduct its own meta-analyses or comprehensive systematic review of each preventive service.

Supplemental Preventive Measures

The committee attempted to identify preventive measures that were aimed at filling the gaps that it had identified. In most cases, the committee found that measures had already been proposed in the guidelines of other professional organizations. The committee also eliminated preventive measures that, even at this early stage in the analysis, were clearly not developed, tested, or known well enough to have a measurable impact. The resulting product of this step was a series of preventive service areas with gaps in coverage and the accompanying preventive measure or measures that could be considered by HHS. The core of the committee's task was to assemble the evidence that would allow it to recommend consideration of a preventive service.

Coverage Decisions

As noted above, the USPSTF, Bright Futures, and ACIP guidelines focus on guidance for primary care providers and patients. Coverage decisions

SUMMARY

7

often consider a host of other issues, such as established practice; patient and clinician preferences; availability; ethical, legal, and social issues; and availability of alternatives. Further complicating matters, special population groups such as minority populations, disabled women, recent immigrants, lesbians, prisoners, and those employed in high-risk environments, may have different health needs or benefit from different preventive services. High-risk groups, population subsets, and special populations are unevenly identified and addressed to varying degrees in current guidelines. Finally, cost-effectiveness was explicitly excluded as a factor that the committee could use in developing recommendations, and so the committee process could not evaluate preventive services on this basis.

Committee Approach

The committee developed a hybrid approach that collected relevant evidence for each measure. Four categories of evidence—posed in the form of questions—to be examined for each potential preventive measure were developed. The committee did not formally rank or assign weights to the categories, nor did it stipulate that evidence in any one category would automatically result in a recommendation for a measure or service to be considered. Instead, the queries and categories were used to consider the range of evidence and to ensure consistency in the committee's analysis and deliberations. Many of the recommendations are supported by more than one category of evidence.

Category I. Are high-quality systematic evidence reviews available indicating that the service is effective in women?

Category II. Are quality peer-reviewed studies available demonstrating effectiveness of the service in women?

Category III. Has the measure been identified as a federal priority to address in women's preventive services?

Category IV. Are there existing federal, state, or international practices, professional guidelines, or federal reimbursement policies that support the use of the measure?

RECOMMENDATIONS

Subcommittees were formed, and each subcommittee reviewed the available evidence applicable to its identified potential preventive measure(s) and assigned the evidence to one or more of the above categories. Each subcommittee then brought its analysis of the range of evidence before the full committee for deliberation. The committee then combined the burden of the condition and its potential impact on health and well-being with the array of available evidence and support to reach a consensus regarding

whether to recommend a specific preventive measure for that condition. As is true in most analytical processes in decision making, evidence and expert judgment are inextricably linked; thus, the expert judgments of the committee members also played a role in decision making.

In general, the preventive measures recommended by the committee for consideration of coverage (see Table S-1) met the following criteria:

- The condition to be prevented affects a broad population;
- The condition to be prevented has a large potential impact on health and well-being; and
- The quality and strength of the evidence is supportive.

Ultimately, the decision to develop a recommendation for a preventive service to be considered was made after a thoughtful review and debate of each of the subcommittee reports and when the committee found the evidence to be compelling.

TABLE S-1 Summary of the Committee’s Recommendations on Preventive Services for Women

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Screening for gestational diabetes	I	The evidence provided to support a recommendation for screening for gestational diabetes is based on current federal practice policy from the U.S. Indian Health Service, the U.S. Department of Veterans Affairs, as well as current practice and clinical professional guidelines such as those set forth by the American Academy of Family Physicians and the American Congress of Obstetricians and Gynecologists.	Recommendation 5.1 The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Human papillomavirus testing (HPV)	I	The evidence provided to support a recommendation to support testing for HPV is based on federal practice policy from the U.S. Department of Defense. Peer-reviewed studies demonstrate that improved testing technologies, particularly combined screening using both conventional cytology and high-risk HPV DNA testing, may significantly improve the rate of detection of cervical cancer precursors and facilitate the safe lengthening of the interval for screening.	Recommendation 5.2 The committee recommends for consideration as a preventive service for women: the addition of high-risk human papillomavirus DNA testing in addition to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections (STIs)	I	The evidence provided to support a recommendation related to STI counseling is based on federal goals from the Centers for Disease Control and Prevention and <i>Healthy People 2020</i> , as well as recommendations from the American Medical Association and the American College of Obstetricians and Gynecologists.	Recommendation 5.3 The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for sexually active women.

continued

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Counseling and screening for human immuno-deficiency virus (HIV)	C	The evidence provided to support a recommendation for expanding screening for HIV is based on federal goals from the Centers for Disease Control and Prevention, as well as clinical professional guidelines, such as those from the American College of Physicians, the Infectious Diseases Society of America, the American Medical Association, and the American College of Obstetricians and Gynecologists.	Recommendation 5.4 The committee recommends for consideration as a preventive service for women: counseling and screening for human immunodeficiency virus infection on an annual basis for sexually active women.
Contraceptive methods and counseling	Not Addressed	The evidence provided to support a recommendation related to unintended pregnancy is based on systematic evidence reviews and other peer-reviewed studies, which indicate that contraception and contraceptive counseling are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling, and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in <i>Healthy People 2010</i> and <i>Healthy People 2020</i> .	Recommendation 5.5 The committee recommends for consideration as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Breastfeeding support, supplies, and counseling	B	The evidence provided to support a recommendation regarding the inclusion of breastfeeding services is based on systematic evidence reviews, federal and international goals (such as the U.S. Surgeon General, Health Resources and Services Administration [HRSA], <i>Healthy People 2020</i> , World Health Organization and UNICEF) and clinical professional guidelines such as those set forth by the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists.	Recommendation 5.6 The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)
Screening and counseling for interpersonal and domestic violence	I	The evidence provided to support a recommendation related to increasing detection of and counseling for domestic violence and abuse is based on peer-review studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the American Medical Association and the American College of Obstetricians and Gynecologists.	Recommendation 5.7 The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

continued

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Well-woman visits	Not Addressed	The evidence provided to support a recommendation for including well-woman visits is based on federal and state policies (such as included in Medicaid, Medicare and the state of Massachusetts), clinical professional guidelines (such as those of the American Medical Association and the American Academy of Family Practitioners), and private health plan policies (such as those of Kaiser Permanente).	Recommendation 5.8 The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

UPDATING GUIDELINES

Developing and maintaining a comprehensive list of covered preventive services for women is not currently under the specific purview of any HHS entity. Thus, the committee believes that it will be necessary to develop structures, accountability, and processes to ensure that preventive services meeting evidence-based standards are considered in the context of the general approach taken to identify and update preventive services for women. The committee recommends a process supported by guiding principles that separates evidence assessment and coverage decisions.

Recommendation 6.1: The committee recommends that the process for updating the preventive services for women be:

- Independent;
- Free of conflict of interest;
- Evidence-based;
- Gender-specific;
- Life-course oriented;
- Transparent;
- Informed by systematic surveillance and monitoring;

SUMMARY

13

- Cognizant of the need to integrate clinical preventive services with effective interventions in public health, the community, work place, and environment; and
- Appropriately resourced to meet its mandate.

Recommendation 6.2: The committee recommends that the Secretary of HHS establish a commission to recommend coverage of new preventive services for women to be covered under the ACA.

In carrying out its work the commission should:

- Be independent of bodies conducting evidence reviews, free of conflict of interest, and transparent;
- Set goals for prevention (it may use available HHS reports and products or commission its own at its discretion);
- Design and implement a coverage decision making methodology to consider information from evidence review bodies (and other clinical guideline bodies) and coverage factors (e.g., cost, cost-effectiveness, legal, ethical);
- Conduct horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify new information on significant health conditions, preventive interventions, new evidence regarding efficacy, effectiveness, periodicity, and safety;
- Focus on the general population, but also search for conditions that may differentially affect women and high-risk subpopulations of women;
- Assign evidence review topics and set review priorities for the bodies reviewing clinical effectiveness;
- Set timetables and processes for updating clinical practice guidelines and coverage recommendations; and
- Submit its coverage recommendations to the Secretary of HHS.

Recommendation 6.3: The committee recommends that the Secretary of HHS identify existing bodies or appoint new ones as needed to review the evidence and develop clinical practice guidelines to be reviewed by a preventive services coverage commission.

Bringing clinical preventive services into rational alignment with the coverage for other health care services under the ACA will be a major task. The committee notes that many of the individual components for review of the evidence are already managed within HHS but currently lack effective coordination for the purposes outlined in the ACA and that some functions are entirely new. The structure might be effectively built over time by using

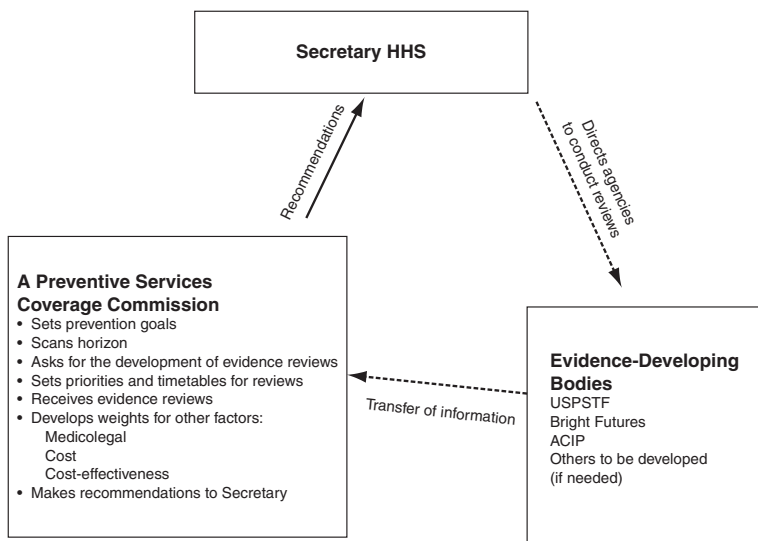


FIGURE S-1 Suggested structure for updating preventive services under the ACA.

some current bodies and adding new ones as resources permit. The committee does not believe that it has enough information to recommend which unit in HHS should implement the recommendations. Figure S-1 illustrates the committee's suggested structure.

In view of the critical importance of community-based preventive services in achieving clinical aims, the committee encourages the Secretary to consider widening the scope of authority to include public health efforts to more comprehensively address prevention. It will be critical for a preventive services coverage commission to coordinate with the new and existing committees that are charged with overseeing other elements of the ACA.

Finally, the committee notes that it would make the most sense to consider preventive services for women, men, children, and adolescents in the same way. Thus, although the committee's recommendations address women's preventive services, a parallel approach could be equally useful for determining covered preventive services for men, children, and male adolescents.

REFERENCES

- AAP (American Academy of Pediatrics). 2008. *Bright Futures: Guidelines for health supervision of infants, children and adolescents*, 3rd ed. (J. F. Hagan, J. S. Shaw, and P. M. Duncan, eds.). Elk Grove Village, IL: American Academy of Pediatrics.
- IOM (Institute of Medicine). 2011. *Leading health indicators for Healthy People 2020 Report*. Washington, DC: The National Academies Press.

1

Introduction

The passage of the Patient Protection and Affordable Care Act of 2010 (ACA) provides the United States with an opportunity to offer an unprecedented level of population health care coverage and dramatically reduce existing health disparities. The expansion of coverage to millions of uninsured Americans and the new standards for coverage of preventive services that are included in the ACA have the potential to increase the use of preventive health care services and screenings and in turn improve the health and well-being of individuals across the United States.

SPECIFICS OF THE LEGISLATION

The approaches to prevention and wellness offered within the Act are broad based and range from new coverage requirements and incentives to expand workplace wellness activities to new investments. Among these are prohibition of the imposition of cost-sharing requirements for recommended preventive services (an overview of the Act is provided in Box 1-1, and the preventive services are listed and described in detail in Chapter 2), the requirement to link health insurance premiums to participation in health promotion programs, public health workforce development (the ACA authorizes new training and placement programs for public health workers), and community-based prevention activities.

This report focuses on the preventive services for women specified in Section 2713 of the Public Health Service Act. These services were added by the ACA and are detailed in the last bulleted item in Box 1-1 (HHS, 2010; *Federal Register*, 2010).

BOX 1-1
Overview of Regulations in Section 2713
of the Public Health Service Act

Section 2713 of the Public Health Service Act, Coverage of Preventive Health Services, which was added by the Affordable Care Act, and the interim final regulations (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130) require that group health plans and health insurance issuers offering health insurance coverage for groups or individuals provide benefits and prohibit the imposition of cost-sharing requirements for

- Medical devices or services that are evidence based and that have, in effect, a rating of Grade A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF) for the individual involved.
- Immunizations for routine use in children, adolescents, and adults that have, in effect, a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) for the individual involved. A recommended ACIP immunization is considered to be “in effect” after it has been adopted by the CDC director. A recommended immunization is considered to be for routine use if it appears on the immunization schedules of the Centers for Disease Control and Prevention.
- Preventive health care and screenings for infants, children, and adolescents informed by scientific evidence and provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- Preventive health care and screenings for women informed by scientific evidence and provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the USPSTF). The U.S. Department of Health and Human Services is developing these guidelines and expects to issue them no later than August 1, 2011.

The complete list of recommendations and guidelines that these interim final regulations are required to cover can be found at <http://www.HealthCare.gov/center/regulations/prevention.html>.

ROLE OF PREVENTION IN ADDRESSING
HEALTH AND WELL-BEING

Prevention is a well-recognized, effective tool in improving health and well-being and has been shown to be cost-effective in addressing many conditions early (Maciosek et al., 2010). Prevention goes beyond the use of disease prevention measures. For example, interventions to prevent injuries and binge drinking can increase positive health outcomes and reduce harm.

Historically, the many disparate components of the U.S. health care system have relied more on responding to acute problems and the urgent

needs of patients than on prevention. Although these functions are appropriate for acute and episodic health problems, a notable disparity occurs when this model of care is applied to the prevention and management of chronic conditions. The provision of preventive health care services is thus inherently different from the treatment of acute problems, but the U.S. health care system has fallen short in the provision of such services. Compared with a system that prevents avoidable conditions early, a system that responds to the acute health care needs of patients can be inefficient and costly, and a focus on response instead of prevention is a major barrier to the achievement of optimal health and well-being by Americans.

Nearly half of all deaths in the United States are caused by modifiable health behaviors (McGinnis and Foege, 1993). Maciosek and colleagues found that an increase in the use of clinical preventive services in the United States could result in the saving of more than 2 million life-years annually (Maciosek et al., 2010). Because of the numbers of diseases and conditions that are preventable, inclusion of support for prevention has become more routine during clinical health care visits (Sussman et al., 2006). When patients are systematically provided with the tools and information that they need to reduce their health risks, the likelihood that they will take steps to, for example, reduce substance use, stop using tobacco products, practice safe sex, eat healthful foods, and engage in physical activity increases (WHO, 2002). Therefore, physicians who routinely educate patients on risk-reducing behaviors may reduce the long-term burden and health care demands of chronic conditions. Stimulating the commitment and action of patients, families, and health care teams is also necessary to promote prevention and improve overall population well-being.

Evidence-based testing, diagnosis, and relief of symptoms are also hallmarks of contemporary health care, but these services are often underutilized. A well-cited reason for this underutilization is, for example, the high cost of prescription copayments, with the result being that patients do not fill their prescribed medications, resulting in the loss of lives and dollars (Shrank et al., 2010). Moreover, a recent study by The Commonwealth Fund that analyzed the responses of U.S. adults to a questionnaire indicated that U.S. adults were significantly less likely than adults in all other countries studied to have confidence in their ability to afford health care (Schoen et al., 2009).

About 51 million Americans lacked health insurance in 2009 (DeNavas-Walt et al., 2010). This is in addition to the millions of underinsured Americans who lack access to the appropriate screenings and services needed to detect and address preventable health conditions and diseases. Furthermore, health care workers have often failed to seize patient interactions as opportunities to promote health and well-being and to inform patients about disease prevention strategies (WHO, 2002). This failure to

inform patients has been found to be due to time constraints in the clinical setting, a lack of reimbursement for provision of these services, and a lack of consensus and provider knowledge about what services to prioritize for their patients. The ACA intends to mitigate these issues.

WHY WOMEN?

The ACA has the potential to transform the way in which the U.S. health care system addresses women's health issues in many ways. It expands access to coverage to millions of uninsured women, ends discriminatory practices such as gender rating in the insurance market, eliminates exclusions for preexisting conditions, and improves women's access to affordable, necessary care. The Women's Health Amendment (*Federal Register*, 2010), which was introduced by Senator Barbara Mikulski and which was added to the ACA, expands on these improvements by requiring that all private health plans cover—with no cost-sharing requirements—a newly identified set of preventive health care services for women. Defining appropriate preventive services for women and ensuring that those services can be accessed without cost sharing are important strategies to improve women's health and well-being (Bernstein et al., 2010; Blustein, 1995).

Many reasons exist for expanding the list of preventive care and screening services for women beyond those included in the guidelines of the United States Preventive Services Task Force (USPSTF) Grade A and B guidelines, the Advisory Committee on Immunization Practices (ACIP), and Bright Futures (for adolescents) stipulated in the ACA (USPSTF, ACIP, and Bright Futures and their guidelines are described in detail in Chapter 2). Even though women have longer life expectancies than men, women suffer from chronic disease and disability at rates disproportionate to those of men, with consequences for their own health and the health of their families (Wood et al., 2010). Furthermore, mounting evidence suggests that women not only have different health care needs than men (because of reproductive differences) but also manifest different symptoms and responses to treatment modalities (IOM, 2010). Behavioral factors that are shown to contribute to morbidity and mortality in women, include smoking, eating habits, physical activity, sexual risk-taking, and alcohol use (IOM, 2010). Pregnancy and childbirth also carry risks to women's health including maternal mortality (CDC, 2008). Figure 1-1 illustrates preventable mortality in women.

Health outcomes occur because of multiple factors including biology, behavior, and the social, cultural, and environmental contexts in which women live. Smoking, eating habits, physical activity, and other health-related behaviors are shaped by cultural and social contexts, including factors associated with social disadvantage. The marked differences in

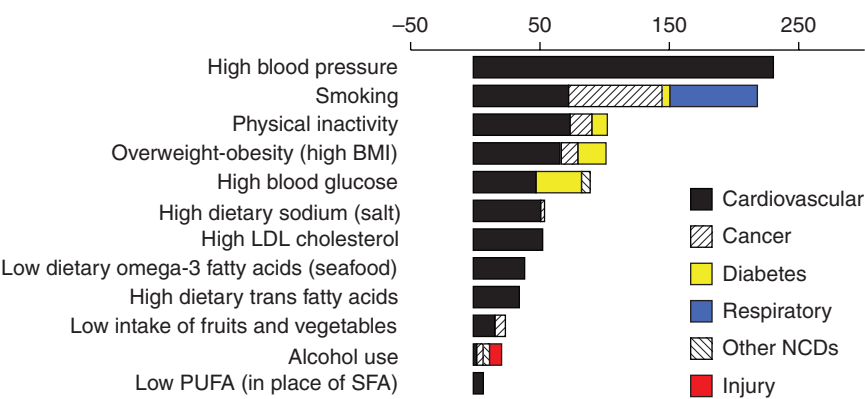


FIGURE 1-1 Deaths in women attributable to total effects of individual risk factors (in thousands), by disease.

ABBREVIATIONS: BMI, body-mass index; LDL, low-density lipoproteins; NCD, non-communicable disease; PUFA, polyunsaturated fatty acid; SFA, saturated fatty acid.

SOURCE: Danaei et al. (2009).

condition prevalence and mortality in women who experience social disadvantage are associated with minority race/ethnicity, lower education, low income, and differential exposure to stressors such as domestic violence. Such exposures are related to outcomes as varied as injury and trauma, depression, asthma, heart disease, human immunodeficiency virus (HIV) infection, and other sexually transmitted infections (Campbell et al., 2002; Coker et al., 2000; Ozer and Weinstein, 2004; Tjaden and Thoennes, 1998).

On average, women need to use more preventive care than men (Asch et al., 2006; HHS, 2001), owing to reproductive and gender-specific conditions, causing significant out-of-pocket expenditures for women (Bertakis et al., 2000; Kjerulff et al., 2007). This creates a particular challenge to women, who typically earn less than men and who disproportionately have low incomes. Indeed, women are consistently more likely than men to report a wide range of cost-related barriers to receiving or delaying medical tests and treatments and to filling prescriptions for themselves and their families (KFF, 2010). For example, women have been shown to be more likely than men to forgo preventive services such as cancer screenings and dental examinations because of cost (Rustgi et al., 2009). Studies have also shown that even moderate copayments for preventive services such as mammograms and Pap smears deter patients from receiving those services (Solanki et al., 2000; Trivedi et al., 2010). A 2010 Commonwealth Fund

survey found that 44 percent of adult women (compared with 35 percent of adult men) either reported that they had a problem paying medical bills or indicated that they were paying off medical debt over time, an increase from 38 percent in 2005 (Robertson and Collins, 2011). The same survey indicated that less than half of women are up to date with recommended preventive care screenings and services (Robertson and Collins, 2011).

Most women and men in the United States are covered by insurance obtained through the workplace. However, women with employer-based insurance are almost twice as likely as men to be covered as dependents, increasing their vulnerability to losing their insurance if they divorce, their partners lose their jobs, or they become widowed (KFF, 2010). Even though results of studies indicate that evidence-based preventive care services lower the burden of disease, are often cost-effective, increase the efficiency of health care spending, and contribute to the creation of a more productive and prosperous America, many financial barriers exist that prevent women from achieving health and well-being for themselves and their families.

PREVENTIVE SERVICES FOR WOMEN

Preventive services for women are services that prevent conditions harmful to women's health and well-being. "Conditions" are considered diseases, disabilities, injuries, behaviors, and functional states that have direct implications for women's health and well-being. These conditions may be specific to women, such as gynecologic infections and unintended pregnancy; they may be more common or more serious in women, such as autoimmune diseases and depression; they may have distinct causes or manifestations in women, such as alcohol abuse, obesity, and interpersonal violence-related posttraumatic stress disorder; or they may have different outcomes in women or different treatments, such as cardiovascular disease and diabetes (IOM, 2010). To "prevent" is to forestall the onset of a condition; detect a condition at an early stage, when it is more treatable; or slow the progress of a condition that may worsen or result in additional harm. Preventive services may therefore include the provision of immunizations, screening tests, counseling and education, Food and Drug Administration-approved medications and devices, procedures, and over-the-counter medications and devices.

COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS) asked the Institute of Medicine to convene a diverse committee of experts in disease prevention, women's health issues, adolescent health issues, and

evidence-based guidelines to review existing guidelines, identify existing coverage gaps, and recommend services and screenings for HHS to consider in order to fill those gaps (Box 1-2). A 16-member committee was selected to complete the statement of task.

In subsequent guidance to the committee, HHS sponsors at ASPE directed the committee to limit its focus to females between the ages of 10 and 65 years.

BOX 1-2
Statement of Task to the Committee on
Preventive Services for Women

The Institute of Medicine will convene an expert committee to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. The committee will also provide guidance on a process for regularly updating the preventive screenings and services to be considered. In conducting its work, the committee will: conduct a series of meetings to examine existing prevention guidelines, obtain input from stakeholders, identify gaps that may exist in recommended preventive services for USPSTF Grade A and B preventive services guidelines for women and in Bright Futures and USPSTF Grade A and B guidelines for adolescents, and highlight specific services and screenings that could supplement currently recommended preventive services for women. Specifically, the committee will consider the following questions:

- What is the scope of preventive services for women not included in those graded A and B by the USPSTF?
- What additional screenings and preventive services have been shown to be effective for women? Consideration may be given to those services shown to be effective but not well utilized among women disproportionately affected by preventable chronic illnesses.
- What services and screenings are needed to fill gaps in recommended preventive services for women?
- What models could HHS and its agencies use to coordinate regular updates of the comprehensive guidelines for preventive services and screenings for women and adolescent girls?

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) on behalf of the U.S. Department of Health and Human Services (HHS) has been charged to examine recommendations for women's preventive services. ASPE will use the information and recommendations from the committee's report to guide policy and program development related to provisions in the Affordable Care Act addressing preventive services for women.

The ACA defines the current USPSTF recommendations regarding breast cancer screening, mammography, and breast cancer prevention to be “the most current other than those issued in or around November 2009.” Thus, coverage for screening mammography is guided by the 2002 USPSTF guideline, which specifies that such screenings be performed every one to two years for women aged 40 years and older.

Furthermore, for consistency in approach with the other three guidelines used by the ACA and given the time limitations for this study, the committee was restricted from considering cost-effectiveness in its process for identifying gaps in current recommendations. Finally, despite the potential health and well-being benefits to some women, abortion services were considered to be outside of the project’s scope, given the restrictions contained in the ACA.

The committee received clarification from ASPE that its work was not intended to duplicate the processes used by the USPSTF or Bright Futures. Thus, the committee interpreted this guidance to indicate that evidence ranging from systematic reviews of the evidence to other bodies of evidence could be considered. This appears to be consistent with the process that led to the current preventive services within the ACA.

The committee was also directed to limit its work to identifying clinical preventive service coverage gaps and not to make recommendations regarding community-based prevention activities.

The committee recognizes that many factors that shape the health and well-being of women fall outside the realm of clinical services. These include, for example, changes to the environment and the workplace to promote health, changes in women’s concept of self-efficacy to promote health, and changes in women’s self-empowerment to address their own health and wellness. These factors and determinants of health are elements of models such as the Whitehead and Dahlgren (1991) determinants-of-health model and encompass biological, behavioral, and social factors. Nevertheless, evaluation of these factors and determinants of health were outside of the committee’s purview.

HHS will consider the committee’s recommendations as it develops guidelines to support the delivery of effective preventive services for women. If they are enacted, the recommendations from this study, along with the other coverage requirements in the ACA, will provide a comprehensive package of clinical preventive services for women.

COMMITTEE PROCESS

To meet its charge, the committee held three information-gathering meetings on preventive services for women and reviewed the relevant literature. Before the first meeting and throughout the committee’s delibera-

tions, the committee gathered extensive information on numerous topics related to health and health care services for women, including chronic and mental health conditions, cancers, sexually transmitted infections, bone diseases, breastfeeding, interpersonal violence, unintended pregnancy, and a variety of behavioral health issues. During the public forums, representatives from women's health organizations, national health interest groups, health coverage providers, employer interest groups, and other experts presented statements to the committee on the latest status and developments in their respective fields (see Appendix B for the meeting agendas). Committee members questioned the speakers to address additional concerns that they did not cover in their statements. The committee also invited comments (both written and oral) from the general public and representatives from numerous organizations with interest in women's preventive services.

The committee first met in November 2010 and held its last meeting in May 2011. Within that time frame, it should be noted that the committee did not have adequate time or resources to conduct its own meta-analyses or comprehensive systematic review for each preventive service or for every special population group that may have different health needs or benefit from different preventive services, such as minority populations, disabled women, recent immigrants, lesbians, prisoners, and those employed in high-risk environments.

Box 1-3 details the committee's definition of preventive health services, which was used as a starting point for the study.

This definition of preventive health services is primarily derived from a blend of definitions from multiple health care organizations and agencies, including the USPSTF and the World Health Organization, with the text regarding well-being possessing the most original phrasing by the committee and stems from the statement of task. In addition, other key definitions are included in Box 1-4. These definitions were adapted from the Five Major Steps to Intervention of the Agency for Healthcare Research

BOX 1-3
Definition of Preventive Health Services

For the purposes of this study, the Committee on Preventive Services for Women defines preventive health services to be measures—including medications, procedures, devices, tests, education, and counseling—shown to improve well-being and/or decrease the likelihood or delay the onset of a targeted disease or condition.

BOX 1-4 Key Definitions: Preventive Interventions

Preventive interventions come in several forms: screening, testing, counseling, immunization, preventive medication, and preventive treatment.

- **Screening** is best described as tests that assess the likelihood of the presence of a disease or condition in an apparently healthy individual. Screening methods use, for example, laboratory analyses and X rays and similar technologies. Screening also includes questions from clinicians. Screening may be targeted to people at increased risk because of age, gender, family or personal history, and other factors. Each screening tool is different in design and method, affecting the sensitivity (ability to correctly identify those with the disease), specificity (ability to correctly identify those without the disease), and positive and negative predictive values of the tool. Ideally, screening tests are rapid, simple, and safe. Screening is not a definitive diagnostic test, and a positive result on a screening test merely indicates that the screened individual has a higher likelihood of having the disease or condition for which the individual is being screened. Individuals who screen positive on such tests should have confirmatory diagnostic tests to ensure an accurate diagnosis.
- **Testing** refers to any process used to determine whether a condition is present or to assess the status of a condition. Testing may involve questioning patients (e.g., asking a patient about tobacco use), physical examination (e.g., mammography screening to detect potential breast cancers), or examining blood, body fluids, or tissues (e.g., to see if a cancer is present in a biopsy sample). Testing may also require the use of sophisticated technology, such as computed tomography and magnetic resonance imaging scans and other X rays, or invasive procedures, such as heart catheterization to detect blockage of coronary arteries. Tests may be used to
 1. Screen individuals who have risk factors but no indication of having the condition,
 2. Diagnose a disease or condition in individuals who have symptoms and signs but for whom a test will add certainty about the diagnosis, or
 3. Monitor the progress of an individual who is being treated or being considered for treatment, such as monitoring blood pressure over time.
- **Counseling** refers to a discussion between a clinician and patient about ways that changes in personal behavior can reduce the risk of illness or injury. The goal of counseling is for clinicians to educate patients about their health risks as well as to provide them with the skills, motivation, and knowledge that they need to address their risk behaviors (e.g., the “5 A” framework for tobacco cessation: **ask, advise, assess, assist, arrange**). A special kind of counseling, informed decision making, recognizes that different people will make different decisions, even though their situations may seem to be similar. Informed decision making is structured to give an individual all the information needed

BOX 1-4 Continued

to choose from among different clinical options, such as whether to undergo genetic testing.

- **Immunization** protects an individual from a specific communicable disease (e.g., hepatitis) by exposing the individual to an antigen or a trace amount of an inactivated disease-causing agent, spurring the development of natural immunity.
- **Preventive medications** are used to prevent the onset of a disease or a condition (e.g., aspirin therapy to prevent cardiovascular events).
- **Preventive treatment** involves a procedure intended to prevent the occurrence of a disease or condition or to prevent the progression of a disease from one stage to another. Preventive treatments usually refer to the use of prescription or nonprescription (over-the-counter) medications, but they may also involve the use of prescriptions for lifestyle changes (e.g., exercise or diet change) or other interventions. Some surgical procedures may be considered preventive treatment, such as removal of polyps in the colon identified during a screening colonoscopy to prevent their progression to cancer lesions.

SOURCES: AHRQ, 2011; NBGH, 2005.

and Quality (AHRQ, 2011) and the National Business Group on Health's *Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage* (NBGH, 2005).

The report that follows is organized into seven chapters, summarized below.

- In Chapter 2, the report reviews the three existing guidelines used in the ACA to determine coverage.
- Chapter 3 details the existing practices of national, state, and selected private health plans.
- In Chapter 4, the committee discusses its framework for identifying gaps in existing preventive services and its process for selecting how to fill those gaps.
- Chapter 5 provides a description of the gaps identified through the committee's work.
- The committee's recommendations for updating guidelines for preventive services are proposed in Chapter 6.
- Chapter 7 includes committee conclusions and summarizes committee recommendations while identifying the limitations under which the committee performed its work.

- Appendix A includes a review of the conditions that the committee considered as part of its deliberations. Although no new recommendations were developed, the committee made clarifying statements or suggestions of ways to use preventive services to address these conditions.
- Appendix B provides agendas for the committee's three public meetings.
- Appendix C includes condensed biographies of committee members.
- Appendix D contains one committee member's statement of dissent and a response from all other committee members.

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the stage of HIV progression actually reduced their risk of transmitting the virus to their partners by 96 percent (NIAID, 2011).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that current screening recommendations by the USPSTF are limited in scope; that is, they are limited to pregnant women and high-risk adolescents and adults.

The evidence provided to support a recommendation for expanding screening is based on federal goals from the CDC, as well as clinical professional guidelines, such as those from the ACP, IDSA, AMA, and ACOG.

Recommendation 5.4: The committee recommends for consideration as a preventive service for women: counseling and screening for HIV infection on an annual basis for sexually active women.

PREVENTING UNINTENDED PREGNANCY AND PROMOTING HEALTHY BIRTH SPACING

Unintended pregnancy is defined as a pregnancy that is either unwanted or mistimed at the time of conception (Finer and Henshaw, 2006) and affects women with reproductive capacity, that is, from the time of menarche to menopause. Family planning services that are provided to prevent unintended pregnancies include contraception (i.e., all FDA-approved contraceptive drugs and devices, sterilization procedures) as well as patient education and counseling.

Prevalence/Burden

Unintended pregnancy is highly prevalent in the United States. In 2001, an estimated 49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception—according to the National Survey of Family Growth (Finer and Henshaw, 2006). The unintended pregnancy rate is much lower in other developed countries (Trussell and Wynn, 2008). In 2001, 42 percent of U.S. unintended pregnancies ended in abortion (Finer and Henshaw, 2006). Although 1 in 20 American women has an unintended pregnancy each year, unintended pregnancy is more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group (Finer and Henshaw, 2006).

The consequences of an unintended pregnancy for the mother and the baby have been documented, although for some outcomes, research is limited. Because women experiencing an unintended pregnancy may not immediately be aware that they are pregnant; their entry into prenatal care may be delayed, they may not be motivated to discontinue behaviors that present risks for the developing fetus; and they may experience depression, anxiety, or other conditions. According to the IOM Committee on Unintended Pregnancy, women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy (IOM, 1995).

A more recent literature review found that U.S. children born as the result of unintended pregnancies are less likely to be breastfed or are breastfed for a shorter duration than children born as the result of intended pregnancies and that mothers who have experienced any unwanted birth report higher levels of depression and lower levels of happiness (Gipson et al., 2008). Finally, a recent systematic literature review found significantly increased odds of preterm birth and low birth weight among unintended pregnancies ending in live births compared with pregnancies that were intended (Shah et al., 2008).

The risk factors for unintended pregnancy are female gender and reproductive capacity. Although certain subgroups of women are at greater risk for unintended pregnancy than others (e.g., women aged 18 to 24 years, unmarried women, women with low incomes, women who are not high school graduates, and women who are members of a racial or ethnic minority group), all sexually active women with reproductive capacity are at risk for unintended pregnancy. In 2008, approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years) were estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant (Frost et al., 2010). More than 99 percent of U.S. women aged 15 to 44 years who have ever had sexual intercourse with a male have used at least one contraceptive method (Mosher and Jones, 2010).

Pregnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy). Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small for gestational age births (Conde-Agudelo et al., 2006; Fuentes-Afflick and Hessol, 2000; Zhu, 2005). In addition, women with certain chronic medical conditions (e.g., diabetes and obesity) may need to postpone pregnancy until appropriate weight loss or glycemic control has been achieved (ADA, 2004; Johnson et al., 2006). Finally, pregnancy may be contraindicated for women with serious medical conditions such as pulmonary hyper-

tension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and for women with the Marfan Syndrome (Meijboom et al., 2005; Regitz-Zagrosek et al., 2008; Warnes, 2004).

Existing Guidelines and Recommendations

Numerous health care professional associations and other organizations recommend the use of family planning services as part of preventive care for women, including ACOG, AAFP, the American Academy of Pediatrics (AAP), the Society of Adolescent Medicine, the AMA, the American Public Health Association, the Association of Women's Health, Obstetric and Neonatal Nurses, and the March of Dimes. In addition, the CDC recommends family planning services as part of preventive visits for preconception health (Johnson et al., 2006).

The USPSTF does not address prevention of unintended pregnancy. Bright Futures recommends that information about contraception be offered to all sexually active adolescents and those who plan to become sexually active (AAP, 2008).

The IOM Committee on Women's Health Research recently identified unintended pregnancy to be a health condition of women for which little progress in prevention has been made, despite the availability of safe and effective preventive methods (IOM, 2010b). This report also found that progress in reducing the rate of unintended pregnancy would be possible by "making contraceptives more available, accessible, and acceptable through improved services (IOM, 2010b). Another IOM report on unintended pregnancy recommended that "all pregnancies should be intended" at the time of conception and set a goal to increase access to contraception in the United States (IOM, 1995). *Healthy People 2020* (HHS, 2011a), which sets health goals for the United States, includes a national objective of increasing the proportion of pregnancies that are intended from 51 to 56 percent. In addition, *Healthy People 2020* sets goals to increase the number of insurance plans that offer contraceptive supplies and services, to reduce the proportion of pregnancies conceived within 18 months of a previous birth, and to increase the proportion of females or their partners at risk of unintended pregnancy who used contraception during the most recent sexual intercourse (HHS, 2011a).

Effective Interventions

Family planning services are preventive services that enable women and couples to avoid an unwanted pregnancy and to space their pregnancies to promote optimal birth outcomes. A wide array of safe and highly

effective FDA-approved methods of contraception is available, including barrier methods, hormonal methods, emergency contraception, and implanted devices; sterilization is also available for women and for men (FDA, 2010). This range of methods provides options for women depending upon their life stage, sexual practices, and health status. Some methods, such as condoms, spermicides, and emergency contraceptives, are available without a prescription, whereas the more effective hormonal and long-acting reversible methods, such as oral contraceptives and intrauterine devices, are available by prescription or require insertion by a medical professional. Sterilization is a surgical procedure. For women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated. These can be assessed clinically so that an appropriate method can be selected for the individual (CDC, 2010; Dragoman et al., 2010).

The effectiveness of contraceptives is determined by studying the rate of failure (i.e., having an unintended pregnancy) in the first year of use (Table 5-3). The failure rates of all FDA-approved methods in both U.S. and international populations have been well documented and are negligible with proper use (Amy and Tripathi, 2009; Hatcher et al., 2007; Kost et al., 2008; Mansour et al., 2010). Female sterilization, the intrauterine device, and the contraceptive implant have failure rates of 1 percent or less in the first 12 months of use (Fu et al., 1999; Hatcher et al., 2007). Injectable and oral contraceptives have use failure rates of seven and 9 percent, respectively, because some women miss or delay an injection or pill (Kost et al., 2008). Failure rates for both male and female condoms and other barrier methods are higher (e.g., 15 percent for the male condom) (Amy and Tripathi, 2009). These rates compare with an 85 percent chance of an unintended pregnancy within 12 months among couples using no method of contraception (Hatcher et al., 2007; Trussell and Kost, 1987).

In addition to this evidence of method effectiveness, evidence exists that greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally. Studies show that as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined (Boonstra et al., 2006). Other studies show that increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use (Santelli and Melnikas, 2010).

As with all pharmaceuticals and medical procedures, contraceptive methods have both risks and benefits. Side effects are generally considered minimal (ACOG, 2011a,b,c; Burkman et al., 2004). Death rates associated with contraceptive use are low and, except for oral contraceptive users who

TABLE 5-3 Percentage of U.S. Women Experiencing an Unintended Pregnancy During First Year of Typical Use and First Year of Perfect Use, by Contraceptive Method

Method	% Experiencing Unintended Pregnancy in First Year of	
	Typical Use ^a	Perfect Use ^b
None	85	85
Spermicides (foams, creams, gels, vaginal suppositories, and vaginal film)	29	18
Withdrawal	27	4
Fertility awareness-based methods ^c	25	
Standard days method		5
Two-day method		4
Ovulation method		3
Sponge		
Parous women	32	20
Nulliparous women	16	9
Diaphragm (with spermicidal cream or jelly)	16	6
Condom (without spermicides)		
Female	21	5
Male	15	2
Combined pill and progestin-only pill	8	0.30
Evra patch	8	0.30
NuvaRing	8	0.30
Depro-Provera	3	0.30
Intrauterine Device		
ParaGard (copper T)	0.80	0.60
Mirena (LNG-IUS)	0.20	0.20
Implanon	0.05	0.05
Female sterilization	0.50	0.50
Male sterilization	0.15	0.10

^a Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

^b Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

^c The ovulation and 2-day methods are based on evaluation of cervical mucus. The standard day method avoids intercourse on cycle days 8 through 19.

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smoke, lower than the U.S. maternal mortality rate (Hatcher et al., 1998). For example, the oral contraceptive death rate per 100,000 users under the age of 35 years who are nonsmokers was 1.5 per 100,000 live births (Hatcher et al., 1998), compared with 11.2 maternal deaths per 100,000 live births in 2006 (age adjusted) (CDC, 2010c).

Contraceptive methods often have benefits separate from the ability to plan one's family and attain optimal birth spacing. For example, the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain (ACOG, 2010a). Long-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).

Education and counseling are important components of family planning services because they provide information about the availability of contraceptive options, elucidate method-specific risks and benefits for the individual woman, and provide instruction in effective use of the chosen method (NBGH, 2005; Shulman, 2006). Research on the effectiveness of structured contraceptive counseling is limited (Halpern et al., 2006; Lopez et al., 2010b; Moos et al., 2003). However, studies show that postpartum contraceptive counseling increases contraceptive use and decreases unplanned pregnancy (Lopez et al., 2010a), that counseling increases method use among adolescents in family planning clinics (Kirby, 2007), that counseling decreases nonuse of contraception in older women of reproductive age (35 to 44 years) who do not want a future baby (Upson et al., 2010), and that counseling of adult women in primary care settings is associated with greater contraceptive use and the use of more effective methods (Lee et al., 2011; Weisman et al., 2002).

Although it is beyond the scope of the committee's consideration, it should be noted that contraception is highly cost-effective. The direct medical cost of unintended pregnancy in the United States was estimated to be nearly \$5 billion in 2002, with the cost savings due to contraceptive use estimated to be \$19.3 billion (Trussell, 2007). The cost-effectiveness of family planning is also documented in an evaluation of FamilyPact, California's 1115 Medicaid Family Planning Waiver Program. The unintended pregnancies averted in this program in 2002 would have cost the state \$1.1 billion within two years, and \$2.2 billion within five years, for public-sector health and social services that otherwise would have been needed (Amaral et al., 2007).

In a study of the cost-effectiveness of specific contraceptive methods, all contraceptive methods were found to be more cost-effective than no

method, and the most cost-effective methods were long-acting contraceptives that do not rely on user compliance (Trussell et al., 2009). The most common contraceptive methods used in the United States are the oral contraceptive pill and female sterilization. It is thought that greater use of long-acting, reversible contraceptive methods—including intrauterine devices and contraceptive implants that require less action by the woman and therefore have lower use failure rates—might help further reduce unintended pregnancy rates (Blumenthal et al., 2011). Cost barriers to use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods and sterilization have high up-front costs (Trussell et al., 2009).

Contraceptive coverage has become standard practice for most private insurance and federally funded insurance programs. For example, contraceptive services are covered for all federal employees and individuals who obtain their care through federally financed programs, such as VA, TRICARE for active-duty military and their dependents, and IHS. Federal programs provide funding for family planning services in community health centers through the Public Health Service Act, in family planning centers through Title X [Population Research and Voluntary Family Planning Programs (P.L. 91-572)], through the Maternal and Child Health Block Grant, and through the Medicaid program.

Since 1972, Medicaid, the state-federal program for certain low-income individuals, has required coverage for family planning in all state programs and has exempted family planning services and supplies from cost-sharing requirements. In addition, 26 states currently operate special Medicaid-funded family planning programs for low-income women who either no longer qualify for Medicaid or do not meet the program's categorical requirements. In Massachusetts, family planning services with no copayments will be included as part of the preventive benefits offered to members of Commonwealth Care, a program of subsidized health insurance for low- and moderate-income people (Personal communication, Stephanie Chrobak and Nancy Turnbull, Massachusetts Health Connector, May 10, 2011).

Private employers have also expanded their coverage of contraceptives as part of the basic benefits packages of most policies. This expansion has occurred in response to state and federal policies. Twenty-eight states now have regulations requiring private insurers to cover contraceptives, and 17 of these states also require that insurance cover the associated outpatient visit costs (Guttmacher Institute, 2011) (see Chapter 3). A federal court ruling issued in 2000 by the Equal Employment Opportunity Commission found an employer's failure to cover prescription contraceptive drugs and devices in a health plan that covers other drugs, devices, and preventive care to be discrimination against women in violation of Title VII of the Civil Rights Act (EEOC, 2000).

In 2007, NBGH recommended that employer-sponsored health plans include coverage of family planning services, without cost sharing, as part of a minimum set of benefits for preventive care. The Guttmacher Institute also calls comprehensive coverage of contraceptive services and supplies “the current insurance industry standard,” with more than 89 percent of insurance plans covering contraceptive methods in 2002 (Camp, 2011). A more recent 2010 survey of employers found that 85 percent of large employers and 62 of small employers offered coverage of FDA-approved contraceptives (Claxton et al., 2010).

Despite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years. In fact, a review of the research on the impact of cost sharing on the use of health care services found that cost-sharing requirements, such as deductibles and copayments, can pose barriers to care and result in reduced use of preventive and primary care services, particularly for low-income populations (Hudman and O’Malley, 2003). Even small increments in cost sharing have been shown to reduce the use of preventive services, such as mammograms (Trivedi et al., 2008). The elimination of cost sharing for contraception therefore could greatly increase its use, including use of the more effective and longer-acting methods, especially among poor and low-income women most at risk for unintended pregnancy. A recent study conducted by Kaiser Permanente found that when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods (Postlethwaite et al., 2007).

Identified Gaps

Contraception and contraceptive counseling are not currently in the array of preventive services available to women under the ACA.

Systematic evidence reviews and other peer-reviewed studies provide evidence that contraception and contraceptive counseling are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020* (HHS, 2000, 2011a).

Recommendation 5.5: The committee recommends for consideration as a preventive service for women: the full range of Food and Drug

Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

BREASTFEEDING

Breastfeeding benefits the mother, the child, and society. The challenge is to ensure that the majority of mothers initiate breastfeeding and exclusively breastfeed their children during the first six months, with breastfeeding continuing to a year or beyond for every child (Gartner et al., 1997).

Prevalence/Burden

An AHRQ report from 2007 includes a summary of systematic reviews and meta-analyses on breastfeeding and maternal and infant health outcomes (Ip et al., 2007). The evidence is clear that breastfeeding reduces Sudden Infant Death Syndrome, gastrointestinal infections, upper and lower respiratory diseases, childhood leukemia, asthma, ear infections, childhood obesity, and diabetes mellitus type 2 risk for children, as well as rates of hospitalization (Table 5-4). They also concluded that sufficient results are available to be able to state that breastfeeding significantly lowers the maternal risk of breast and ovarian cancers (Table 5-4). Breastfeeding soon after birth may reduce the risk of maternal blood loss and enhance maternal-infant bonding (ACNM, 2004). A recent study concluded that if 90 percent of all children were exclusively breastfed during the first six months of life, the United States would save \$13 billion per year and prevent an excess of 911 deaths (Bartick and Reinhold, 2010). If only 80 percent of U.S. families complied, \$10.5 billion would be saved and 741 deaths would be prevented each year.

In the United States, the majority of pregnant women plan to breastfeed (DiGirolamo et al., 2005), and yet there is a clear gap between the proportion of women who prenatally intend to breastfeed and those who actually do so by the time they are discharged after a brief hospital stay (California WIC Association and U.C. Davis Human Lactation Center, 2008; CDC, 2007b). The National Immunization Survey found that among the mothers of children born in 2007, 75 percent of mothers initiated breastfeeding, 43 percent were breastfeeding at six months, and 22 percent were breastfeeding at 12 months (CDC, 2007b). Although considerable progress has been made through overall promotion of breastfeeding in the United States, gains in breastfeeding rates have not been made equally across geographic, racial, and socioeconomic groups (Table 5-5).

Contrary to popular conception, breastfeeding appears to be a learned skill and the mother must be supported to be successful. Nevertheless,



Policy Matters

The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women



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ABSTRACT

Objectives: The Affordable Care Act (ACA) contraceptive coverage mandate issued in August 2012 requires most private health insurance plans to cover all U.S. Food and Drug Administration-approved contraceptive methods without cost sharing. We evaluate the impact of this policy on out-of-pocket costs and use of long-acting reversible contraceptives (LARCs) and other prescription methods through 2014.

Methods: Data from Truven Health MarketScan were used to examine out-of-pocket costs and contraceptive use patterns for all reversible prescription contraceptives before and after the implementation of the contraceptive mandate for privately insured women ages 13 to 45. Costs were estimated by combining copayment, coinsurance, and deductible payments for both contraception and insertion fees for LARCs. Contraceptive use rates were examined and multivariable logistic regression analysis of LARC insertions before and after the ACA was conducted.

Results: Out-of-pocket costs for all reversible contraceptives, including LARCs, decreased sharply after the ACA contraceptive mandate. The greatest proportion of women in each year was oral contraceptive users (24.3%–26.1%). Rates of new LARC insertions increased significantly after the ACA, when controlling for cohort year, age group, geographic region, and rural versus urban setting (adjusted odds ratio, 1.03; 95% confidence interval, 1.02–1.04).

Conclusions: Our study adds to the current literature with the inclusion of 2014 data and confirms previous findings of a post-ACA decrease in out-of-pocket contraceptive costs. In addition, there was a small but statistically significant increase in LARC insertions after the ACA. This finding indicates the importance of reduced cost sharing for increasing use of the most effective contraceptives.

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Long-acting reversible contraceptives (LARCs), which include the intrauterine device (IUD) and contraceptive implant, are highly effective forms of prescription contraception. LARCs have become more affordable to insured women as a result of the contraceptive coverage mandate of the Affordable Care Act (ACA), which took effect in August 2012. The mandate requires most private health insurance plans to cover all U.S. Food and Drug Administration-approved contraceptive methods without cost-sharing (Henry J. Kaiser Family Foundation, 2015; U.S. Department of Health and Human Services, 2016). Before the

ACA, the greater upfront out-of-pocket costs of LARCs likely discouraged women from choosing them over less effective prescription birth control methods with lower upfront costs (Chuang et al., 2015). Nevertheless, LARC use increased from 2.4% of all contraceptive users in 2002 to 14.3% in 2014, according to the National Survey of Family Growth (Daniels, Daugherty, Jones, & Mosher, 2015; Guttmacher Institute, 2014; Kavanaugh & Jerman, 2018; Xu, Macaluso, Ouyang, Kulczycki, & Grosse, 2012).

Several studies have examined the effect of the ACA contraceptive coverage mandate on out-of-pocket costs for contraception (Bearak, Finer, Jerman, & Kavanaugh, 2016; Becker & Polsky, 2015; Finer, Sonfield, & Jones, 2014; Sonfield, Tapales, Jones, & Finer, 2015), and all show decreasing out-of-pocket costs to women after 2012. Other studies have examined both out-of-pocket costs and types of contraception women use after

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the ACA. Using claims data from a regional health plan, [Carlin, Fertig, and Dowd \(2016\)](#) found that reduced cost sharing was associated with increased use of prescription contraceptives, including LARCs, among Midwestern women. Using a national health claims database, [Law et al. \(2016\)](#) found a steep decline in out-of-pocket costs for LARCs after the ACA contraceptive provision and an increase in IUD claims from 1.2% in 2011, to 1.3% in 2012, to 1.6% in 2013. [Pace, Dusetzina, and Keating \(2016\)](#) found that the proportion of claims without cost-sharing for IUDs and implants increased over time but found no significant increase in LARC uptake post-ACA implementation as of 2013. Using survey data, [Bearak and Jones \(2017\)](#) observed no changes in patterns of contraceptive use between two time points: fall of 2012 (pre-ACA) and spring of 2015 (post-ACA).

In this study, we examine the out-of-pocket costs for prescription contraception and contraceptive use patterns between 2006 and 2014 using a large national database of health claims for privately insured women. This is the first study, to our knowledge, with post-ACA claims data through 2014. We hypothesize that the post-ACA out-of-pocket costs for prescription contraception will be decreased and that the use of LARCs will increase.

Materials and Methods

Data Source and Inclusion Criteria

Data are from the Truven Health Analytics MarketScan database, which consists of reimbursed health care claims for employees, retirees, and their dependents from more than 250 employers and health plans from all 50 states and the District of Columbia. Individuals included in the database are covered under commercial (private) insurance plans. This large, national database includes an annual population of more than 50 million people and captures administrative claims with data from inpatient visits, outpatient visits, and pharmacy claims deidentified at the patient level. This study was approved by the Penn State College of Medicine Institutional Review Board.

We conducted a retrospective cohort analysis to examine claims and out-of-pocket costs for prescription contraceptive methods used by women before and after implementation of the ACA contraceptive mandate in August 2012. We consider 2013 as the first post-ACA year because it is the first benefits year in which contraceptive coverage without cost-sharing would have been implemented. Study cohorts were created for each calendar year between 2006 and 2014 (the most recent year for which data are available) that included women ages 13 to 45 who had continuous medical and pharmacy coverage during that year. We were unable to identify whether women belonged to employer groups that were exempt from the contraceptive mandate.

Measures of Contraceptive Use

Contraceptive claims were identified using Healthcare Common Procedure Coding System (HCPCS), *International Classification of Diseases*, 9th edition (ICD-9), National Drug Code, and Current Procedural Terminology (CPT)-4 codes. IUD insertions were identified using ICD-9 codes V25.11 and 69.7, CPT-4 code 58300, or HCPCS codes J7300, J7301, J7302, S4981, and S4989. Implant insertions were identified using ICD-9 code V25.5, CPT-4 code 11981, and HCPCS codes J7306 and J7307. Because the CPT-4 code for implant insertion is not contraceptive specific, the CPT-4 code was combined with the

contraceptive-specific ICD-9 and HCPCS codes to ensure only the capture of contraceptive implant insertions. The LARC insertion rate was defined as the percent of women in each cohort year who had a LARC insertion claim. The LARC insertion rate does not represent the total proportion of contraceptors using LARC methods during that year, because some LARC users will have had their LARC inserted in previous years. The LARC insertion rate is not comparable with the LARC use rate reported based on surveys such as the National Survey of Family Growth, which include both insured and uninsured women and self-reported contraceptive use.

For non-LARC methods, pharmacy claims were searched for oral contraceptive pills, patches, injection, and the contraceptive ring. Injections were additionally identified using procedure codes. Women with pharmacy claims for more than one type of non-LARC method in a calendar year were coded as using the method that was in use for the longest period of time in that year. Use rates of non-LARC methods were defined as the percent of women using each of the contraceptive methods during each cohort year. Nonprescription contraceptive methods could not be accounted for because they do not generate claims.

Measures of Contraceptive Costs

Individual out-of-pocket costs for each type of contraception were estimated by combining copayment, coinsurance, and deductible payments for both contraception and insertion fees (in the case of LARCs). Costs for LARCs are reported as out-of-pocket cost for insertion (including device and insertion fees). Oral contraceptives, patches, and rings are reported as cost per 28-day supply obtained (e.g., a pack of contraceptive pills). Injection is reported as cost per injection. All costs were adjusted for inflation to 2015 dollars using the Consumer Price Index.

Measures of Covariates

Contraceptive choices are influenced by other variables in addition to cost ([Weisman, Lehman, Legro, Velott, & Chuang, 2015](#)), but covariates available for this analysis are limited. The MarketScan database includes limited information on the patient, and key sociodemographic variables such as educational level, race/ethnicity, and marital status are not available. We were able to control for age group, with age groups defined as 13 to 17, 18 to 25, 26 to 35, and 36 to 45 years. Geographic region was included as a covariate to account for possible variations in prescribing patterns; region is precoded in the dataset as northeast, north central, south, and west. Finally, urban versus rural residence, which is measured in the dataset based on the Metropolitan Statistical Area, was included because the availability of providers for LARCs is likely to be higher in urban areas.

Statistical Analysis

For each study year, we report the mean and median out-of-pocket costs for each contraceptive method in 2015 dollars, using the medical care component of the Consumer Price Index. For method use, we report the IUD and implant insertion rates and percent of women using oral contraceptives, injections, ring, and patch in each study year. To test whether the trend in LARC use can be attributed to the ACA, we estimate the likelihood of LARC insertion post-ACA implementation compared with pre-ACA

Table 1
Characteristics of Sample of Privately Insured Reproductive-age Women, by Study Year (Percentages)

Year	Base n (Millions)	Age (y)				Region*				Rural Residence [†]
		13-17	18-25	26-35	36-45	Northeast	North Central	South	West	
2006	3.88	17	18	27	38	12	23	48	17	16
2007	4.44	17	18	27	38	11	24	47	18	17
2008	5.68	17	18	28	37	14	26	43	16	15
2009	5.86	16	19	29	37	11	28	43	17	14
2010	6.31	16	19	29	36	14	26	40	20	14
2011	7.13	16	22	28	35	16	24	40	19	15
2012	7.32	15	23	28	34	16	24	38	20	15
2013	6.26	15	24	27	34	17	22	36	22	15
2014	6.47	15	24	27	34	19	20	40	18	15

Note: Percentages for each category may not sum to 100% owing to rounding.

Data Source: Truven Health Analytics MarketScan.

* Region is a predefined variable in the database.

[†] Urban versus rural residence is determined by the Metropolitan Statistical Area.

using multivariable logistic regression adjusting for covariates and year (to account for secular trends). Statistical analyses were performed using SAS version 9.4 (SAS, Inc, Cary, NC).

Results

Table 1 describes the characteristics of the study sample, which consists of more than 3 million women in each study year. The sample size changes year to year because of changes in the number of employers and health plans that contribute data to MarketScan, or because of changes in the number of enrollees. The sample distribution by age, region, and urban versus rural residence is similar over time, with one exception: the greater proportion of women ages 18 to 25 after 2010 could reflect increased dependent coverage under ACA.

Table 2 shows the mean and median out-of-pocket costs for each prescription contraceptive method in each study year. After the ACA contraceptive coverage mandate (2013–2014), the mean out-of-pocket cost for all types of contraception decreased sharply. Similarly, the median out-of-pocket cost for all types of prescription contraception decreased to \$0. In 2014 (data not shown), 91.5% of IUD recipients and 87.1% of implant recipients paid \$0 out of pocket.

Table 3 shows the trend in prescription contraceptive use over successive cohort years. Each year, the greatest proportion of women was oral contraceptive users (about 1 in 4 women each year). The IUD insertion rate was 0.6% in 2006 and increased steadily over time to 2.0% in 2014. The contraceptive implant

insertion rate was less than 0.1% in 2006 and increased to 0.4% in 2014.

Table 4 shows that there was a statistically significant increased odds of LARC insertion (adjusted odds ratio, 1.03; 95% confidence interval, 1.02–1.04) after the contraceptive mandate was implemented, when adjusting for covariates. There was a statistically significant 14% increased odds of LARC insertion with each subsequent year from 2006 to 2014. Compared with the oldest age group, girls 13 to 17 years old were significantly less likely to have a LARC insertion, whereas women aged 18 to 25 and 26 to 35 had increased odds of LARC insertions. Women living in the Northeast had decreased odds of LARC insertions, whereas women in the South and West had increased odds of LARC insertions compared with women living in the North central region. There was no difference in LARC insertion for women in rural versus urban areas.

Discussion

This study confirms prior studies showing a dramatic decrease in out-of-pocket costs for prescription contraceptive methods, including LARCs, after the ACA contraceptive coverage mandate was implemented. This study extends this finding using national claims data for privately insured women through 2014. Although most women had no out-of-pocket costs for LARCs after 2012, the mean cost for an IUD was still between \$17 and \$22. These post-2012 costs may be attributable to grandfathered plans, employers with religious exemptions to the contraceptive

Table 2
Mean and Median Out-of-Pocket Costs by Contraceptive Type, 2006–2014 (Dollars)

Year	Oral Contraceptive		Injection		Ring		IUD		Implant		Patch	
	Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median
2006	31	18	13	8	60	18	78	23	50	46	25	18
2007	24	16	13	9	62	29	79	29	107	72	24	16
2008	20	14	11	6	80	43	74	27	87	27	23	16
2009	19	13	11	6	70	39	80	26	91	26	20	15
2010	18	12	11	6	88	44	94	25	98	25	20	15
2011	17	12	12	6	64	35	101	23	103	23	19	13
2012	15	10	11	6	82	34	114	21	139	38	18	12
2013	6	0	5	1	35	0	22	0	31	0	9	0
2014	5	0	4	0	7	0	17	0	24	0	8	0

Note: Dollars are adjusted for inflation to 2015 dollars using the medical care component of the Consumer Price Index. Intrauterine device (IUD) and implant cost presented as out-of-pocket cost in dollars per insertion. Injection cost is presented as out-of-pocket cost in dollars per injection. Cost for other methods (oral contraceptive, ring, and patch) presented as out-of-pocket cost per 28-day supply obtained.

Table 3
Contraceptive Use by Year, 2006–2014 (Percent of Women Ages 13–45)

Year	Oral Contraceptive	Injection	Ring	IUD Insertions	Implant Insertions	Patch
2006	24.8	2.3	1.3	0.6	<0.1	<0.1
2007	24.3	2.3	1.5	0.8	<0.1	<0.1
2008	25.2	2.3	1.7	1.2	0.1	<0.1
2009	26.1	1.4	2.3	1.3	0.1	<0.1
2010	25.3	1.4	2.4	1.3	0.1	<0.1
2011	25.7	2.4	1.8	1.4	0.2	<0.1
2012	25.6	2.5	1.8	1.5	0.2	<0.1
2013	25.5	1.8	1.7	1.8	0.3	<0.1
2014	26.1	1.9	1.7	2.0	0.4	<0.1

Abbreviation: IUD, intrauterine device.

mandate, noncompliance with the ACA contraceptive mandate, or failure to cover all types of LARCs (Tschann & Soon, 2015). Currently, the future of contraceptive coverage without cost-sharing is uncertain. If more health plans were to become exempt from coverage, out-of-pocket spending for contraception would be expected to increase.

The rate of new LARC insertions increased over the study period, with a statistically significant 3% increased odds of insertion after implementation of the ACA contraceptive coverage requirement. A 3% increase across the millions of privately insured reproductive-age women nationally is highly significant from a population perspective. This finding is promising and suggests that the removal of the cost barrier to IUDs and implants has increased their rate of adoption after the ACA.

As noted, the 2013 plan year is the first year in which the ACA contraceptive coverage benefit would have been in effect for most privately insured women, and to date we have claims data only through 2014. Because many privately insured women were not aware of the ACA contraceptive coverage benefit during this timeframe (Chuang et al., 2015), their contraceptive choices might not yet have changed despite having no-cost coverage. Cost could be a leading indicator in that, once more women experience no-cost coverage for their contraceptive prescriptions, their behavior with regard to contraceptive choices could change.

A limitation of this study is that the MarketScan claims database does not include all private insurers, and it does not include those covered by Medicaid or the uninsured. This limitation made it difficult to make meaningful comparisons with

Table 4
Adjusted Odds of LARC (IUD or Implant) Insertion

	Adjusted OR (95% CI)
Post-ACA	1.03 (1.02–1.04)
Pre-ACA	Reference
Cohort year (1 year increments, 2006–2014)	1.14 (1.13–1.14)
Age group (y)	
13–17	0.37 (0.37–0.38)
18–25	1.63 (1.62–1.64)
26–35	2.24 (2.23–2.26)
36–45	Reference
U.S. region	
Northeast	0.90 (0.89–0.90)
North Central	Reference
South	1.04 (1.04–1.05)
West	1.20 (1.19–1.21)
Urban residence	1.00 (1.00–1.00)
Rural residence	Reference

Abbreviations: ACA, Affordable Care Act; CI, confidence interval; IUD, intrauterine device; LARC, long-acting reversible contraceptive; OR, odds ratio.

Note: Hosmer and Lemeshow goodness-of-fit test χ^2 statistic 3545.9 ($p < .0001$).

National Survey of Family Growth data, which are based on nationally representative surveys that include Medicaid patients and uninsured women. Because this is a claims database, we cannot account for all relevant covariates, or for the use of nonprescription contraceptive methods, or for prescription methods obtained for which a claim was not generated (e.g., in family planning or school-based clinics). In addition, we could not account for ongoing LARC use by women who obtained the method in a year outside of our period of observation. This limitation underestimates LARC use for each year. Strengths of this database include its large size and national scope over many years, including 2 full years after the ACA mandate implementation.

Conclusions

The ACA contraceptive mandate has dramatically reduced out-of-pocket costs for prescription contraceptives including LARCs. After the ACA, there was a small but statistically significant increase in LARC insertions.

Implications for Practice and/or Policy

Increased LARC insertions after the ACA in this database of privately insured women is an important finding that indicates the importance of reduced cost-sharing for increasing use of the most effective contraceptives and preventing unintended pregnancy.

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Author Descriptions

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CERTIFICATE OF SERVICE

I hereby certify that on February 15, 2019, I electronically filed the foregoing appendix with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Lowell V. Sturgill Jr.
Lowell V. Sturgill Jr.