THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA,))
Plaintiff, v.	(WB) 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,

CHAD A. READLER

Acting Assistant Attorney General

ETHAN P. DAVIS

Deputy Assistant Attorney General

JENNIFER D. RICKETTS

Director, Federal Programs Branch

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.

JOEL McELVAIN Assistant Director, Federal Programs Branch

/s/ Justin M. Sandberg

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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

Unite States Department of Justice

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Case: 1851253.7-0000415140111/00311128527120 Prilge: 112/15Date Filge: 102/15/2018

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

COMMONWEALTH OF PENNSYLVANIA,

CIVIL ACTION

Plaintiff,

v.

NO. 17-4540

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.

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; 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).

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

COMMONWEALTH OF PENNSYLVANIA,

CIVIL ACTION

Plaintiff,

 \mathbf{v} .

NO. 17-4540

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.

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." *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 wellbeing 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

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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 quasisovereign 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' fiscs" 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 governmentfunded 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 fiscs.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.

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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). 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. 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

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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. 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

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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 postissuance 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 postissuance 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 postpromulgation 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 Envtl. Prot. v. U.S. Envtl. 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 Defendantsfrom 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.

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

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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.

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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 religions of 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. 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 nocost 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 nocost 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).

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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

An appropriate order follows.

Defendants shall be enjoined from enforcing the New IFRs.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

December 15, 2017

COMMONWEALTH OF PENNSYLVANIA

v.

PRESIDENT UNITED STATES OF AMERICA; ACTING SECRETARY OF UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY OF THE TREASURY; UNITED STATES DEPARTMENT OF THE TREASURY; SECRETARY UNITED STATES DEPARTMENT OF LABOR; UNITED STATES DEPARTMENT OF LABOR;

Appellants

Case: 18-1253 Document: 003112852715 Page: 1 Date Filed: 02/15/2018

STANDING ORDER REGARDING MOTIONS TO EXCEED THE PAGE LIMITATIONS OF THE FEDERAL RULES OF APPELLATE PROCEDURE

Effective Immediately

PRESENT: McKEE, <u>Chief Judge</u>, and SLOVITER, SCIRICA, RENDELL, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, HARDIMAN, GREENAWAY, JR, VANASKIE, ALDISERT, WEIS, GARTH, STAPLETON, GREENBERG, COWEN, NYGAARD, ROTH, BARRY, and VAN ANTWERPEN, <u>Circuit Judges</u>

AND NOW, it being noted that motions to exceed the page/word limitations for briefs are filed in approximately twenty-five percent of cases on appeal, and that seventy-one percent of those motions seek to exceed the page/word limitations by more than twenty percent;

Notice is hereby given that motions to exceed the page or word limitations for briefs are strongly disfavored and will be granted only upon demonstration of extraordinary circumstances. Such circumstances may include multi-appellant consolidated appeals in which the appellee seeks to file a single responsive brief or complex/consolidated proceedings in which the parties are seeking to file jointly or the subject matter clearly requires expansion of the page or word limitations.

Accordingly, it is **ORDERED** that a three-judge Standing Motions Panel is hereby appointed to rule on all motions to exceed the page/word limitations for briefs since the page/word limitations, prescribed by Fed. R. App. P. 32(a)(7), should be sufficient to address all issues in an appeal.

It is further **ORDERED** that Counsel are advised to seek advance approval of requests to exceed the page/word limitations whenever possible or run the risk of rewriting and refiling a compliant brief. Any request to exceed page/word limitations submitted in the absence of such an advance request shall include an explanation of why counsel could not have foreseen any difficulty in complying with the limitations in time to seek advance approval from the panel.

This order shall not apply to capital habeas cases.

By the Court,

/s/ Theodore A. McKee Chief Judge

Date: January 9, 2012

Marcia M. Waldron

Marcia M. Waldron, Clerk

Case: 18-1253 Document: 003112852716 Page: 1 Date Filed: 02/15/2018

OFFICE OF THE CLERK

PATRICIA S. DODSZUWEIT CLERK

United States Court of Appeals

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February 15, 2018

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RE: Commonwealth of Pennsylvania v. President United States, et al

Case Number: 18-1253

District Case Number: 2-17-cv-04540

Effective December 15, 2008, the Court implemented the Electronic Case Files System. Accordingly, attorneys are required to file all documents electronically. See 3d Cir. L.A.R. 113 (2008) and the Court's CM/ECF website at www.ca3.uscourts.gov/cmecf-case-managementelectronic-case-files.

To All Parties:

Enclosed is case opening information regarding the above-captioned appeal filed by United States Department of Labor, Acting Secretary United States Department of Health and Human Services, United States Department of Health and Human Services, President United States of America, Secretary United States Department of Labor, Secretary United States Department of Treasury, docketed at No.18-1253. All inquiries should be directed to your Case Manager in writing or by calling the Clerk's Office at 215-597-2995. This Court's rules, forms, and case information are available on our website at http://www.ca3.uscourts.gov.

On December 1, 2009, the Federal Rules of Appellate and Civil Procedure were amended modifying deadlines and calculation of time. In particular those motions which will toll the time for filing a notice of appeal under Fed.R.App.P. 4(a)(4), other than a motion for attorney's fees under Fed.R.Civ.P. 54, will be considered timely if filed no later than 28 days after the entry of judgment. Should a party file one of the motions listed in Fed.R.App.P 4(a)(4) after a notice of appeal has been filed, that party must immediately inform the Clerk of the Court of Appeals in writing of the date and type of motion that was filed. The case in the court of appeals will not be stayed absent such notification.

Counsel for Appellant

As counsel for Appellant(s), you must file:

- 1. Application for Admission (if applicable)
- 2. Appearance Form
- 3. Civil Information Statement
- 4. Disclosure Statement (except governmental entities)
- 5. Concise Summary of the Case
- 6. Transcript Purchase Order Form.

These forms must be filed within fourteen (14) days of the date of this letter.

Failure of Appellant(s) to comply with any of these requirements by the deadline will result in the DISMISSAL of the case without further notice. 3rd Circuit LAR Misc. 107.2.

Counsel for Appellee

As counsel for Appellee(s), you must file:

- 1. Application for Admission (if applicable)
- 2. Appearance Form
- 3. Disclosure Statement (except governmental entities)

These forms must be filed within **fourteen (14) days** of the date of this letter.

Case: 18-1253 Document: 003112852716 Page: 3 Date Filed: 02/15/2018

Parties who do not intend to participate in the appeal must notify the Court in writing. This notice must be served on all parties.

Attached is a copy of the full caption in this matter as it is titled in the district court. Please review the caption carefully and promptly advise this office in writing of any discrepancies.

Very truly yours,

<u>s/ Patricia S. Dodzuweit</u> Clerk

By: Case Manager/slc 267-299-4959

cc: Nicole J. Boland
Nikole Brock
Nicholas M. Centrella
Michael J. Fischer
Jonathan S. Goldman
Jamie A. Levitt
Francis J. Manion
Mark L. Rienzi
Lauren E. Sulcove
Lori H. Windham
Jonathan B. Miller