UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiffs the Commonwealth of Pennsylvania and the State of New Jersey, by and through their undersigned counsel, hereby file this Motion, requesting that this Court grant them Summary Judgment against all Defendants on Counts I-V of the Amended Complaint filed on December 14, 2018, and vacate the following rules (the "Rules"):

a) Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018); and

b) Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018)

As set forth in the contemporaneously filed Memorandum of Law, there are no genuine issues of material fact, and Movants are entitled to judgment as a matter of law. The Rules are unlawful for the following reasons:

1. The violate the principle of Equal Protection of the Laws (Count I);
2. They violate Title VII of the Civil Rights Act (Count II);
3. They were issued in violation of the procedural requirements of the Administrative Procedure Act (Count III);
4. They were issued in violation of the substantive requirements of the Administrative Procedure Act, as they violate multiple provisions of the Affordable Care Act and other laws and are arbitrary and capricious (Count IV); and
5. The violate the Establishment Clause of the First Amendment (Count V).

This Motion is supported by the contemporaneously filed Memorandum of Law, Plaintiffs' Statement of Undisputed Facts, the Joint Appendix submitted in this matter, and any additional submissions that may be considered by the Court.

May 15, 2019

Respectfully submitted,

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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Plaintiffs the Commonwealth of Pennsylvania and the State of New Jersey respectfully move for summary judgment on all counts of their amended complaint. The Rules at issue in this litigation authorize virtually limitless exemptions from a mandatory obligation for health plans to provide women with coverage for contraceptive services without imposing cost-sharing requirements. This Court has twice held that plaintiffs are likely to succeed on their claims that the Rules violate the Administrative Procedure Act (APA) and blocked defendants from enforcing them.[1] Those decisions were correct: the Agencies disregarded the procedural requirements of the APA in issuing the Rules, and the Rules themselves are contrary to law and otherwise inconsistent with the APA's substantive requirements.

The Rules are unlawful for multiple other reasons. By singling out women for differential treatment, they violate the principle of equal protection of the laws, which applies to the federal government through the Fifth Amendment to the Constitution. For the same reason, they violate Title VII of the Civil Rights Act. In addition, they violate the Establishment Clause of the First Amendment by imposing the religious beliefs of employers on their employees. And they violate multiple provisions of the Affordable Care Act, in addition to those provisions the Court has already addressed.

For these reasons, this Court should grant the States' motion, enter summary judgment in their favor, and vacate the Rules.

BACKGROUND

This action challenges two regulations issued by the federal agency defendants ("the Agencies") on November 7, 2018 (the "Rules"). J.A. 1–55 (Final Religious Exemption Rule;

[1] *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019); *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017).

J.A. 56–95 (Final Moral Exemption Rule). Those two regulations "finalize" two earlier interim final regulations issued by the Agencies on October 6, 2017. J.A. 98-41 (Interim Religious Exemption Rule; J.A. 142-46 (Interim Moral Exemption Rule). The Rules were to become effective on January 14, 2019, but were enjoined by this Court on that day. 351 F. Supp. 3d at 835.

The Rules create broad exemptions to the requirement under the Affordable Care Act[2] that certain health plans provide coverage, without imposing cost-sharing requirements, for all FDA-approved contraceptive methods, sterilization, and counseling services. That requirement was imposed pursuant to the Women's Health Amendment, which was adopted by the Senate during consideration of the ACA and included in the final version of the legislation. The Women's Health Amendment requires that health plans provide coverage for "additional preventive care and screenings" for women without imposing cost-sharing requirements. 42 U.S.C. § 300gg-13(a)(4). In urging support for the amendment, its lead sponsor argued that it was necessary to stop the "punitive practices of insurance companies" toward women. J.A. 2436.

In the Women's Health Amendment, Congress did not dictate which preventive services for women were to be covered, but delegated that task to the Health Resources and Services Administration (HRSA), a unit of the Department of Health and Human Services. HRSA "has as its goal to improve access to primary and preventive care services to uninsured and underinsured individuals" and "strives to develop 'best practices' and create uniform standards of care." J.A. 2422–23. While Congress did not dictate to HRSA the full list of "care and screenings" to be covered, the amendment's supporters made clear that they expected certain services would be

[2] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010) (ACA).

included. Among these were cancer screenings, well-women visits, domestic violence screenings, and family planning services. J.A. 2423.

I. The Institute of Medicine Report

Following passage of the ACA, HRSA commissioned the Institute of Medicine (IOM), a widely respected organization of medical professionals, to issue recommendations identifying the preventive services for women to be covered by the Women's Health Amendment. The IOM, in turn, convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. J.A. 317–18. After conducting an extensive study, the IOM committee issued a comprehensive report identifying eight evidence-based preventive health services that it recommended be included. J.A. 313–561.

Specifically, the IOM committee recommended that HRSA include "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education" as a required preventive services for women. J.A. 335. In making this recommendation, the IOM committee cited evidence that "contraception and contraceptive counseling are effective at reducing unintended pregnancies" and observed that "[n]umerous health professional associations and other organizations recommend the use of family planning services as part of preventive care for women." J.A. 335. It discussed in detail the health and other risks associated with unintended pregnancies, described studies showing that contraception was effective when used correctly, and explained that cost was a significant barrier to effective use of contraception. J.A. 427–34.

The IOM report was released July 19, 2011, and on August 1, 2011, HRSA adopted the recommendations of the report and issued its first "Women's Preventive Services Guidelines," as required by the Women's Health Amendment. J.A. 310–12. Consistent with the recommendations

of the IOM committee, the Guidelines required health plans to cover "All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." J.A. 311.[3]

II. The Agencies Work to Accommodate Religious Objections to Contraception

Shortly after the completion of the IOM report and the adoption of its recommendations by HRSA, the Agencies issued an interim final regulation that "provide[d] HRSA with the discretion" to exempt certain religious employers from the contraceptive mandate. J.A. 306. The exemption applied to any "organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986." J.A. 265. These two sections refer to "churches, their integrated auxiliaries, and conventions or associations of churches" and "the exclusively religious activities of any religious order." 26 U.S.C. § 6033(a)(3)(A)(i) & (iii).[4]

While they were working to finalize the exemption for churches and related entities, the Agencies announced on February 15, 2012, that they planned to further consider how to address organizations that did not qualify for the church exemption but nonetheless objected to providing contraception. Specifically, the Agencies said that they "plan[ned] to develop and propose changes … that would meet two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit organizations' religious objections to covering contraceptive services." J.A. 300. In order to facilitate this

[3] HRSA issued updated guidelines in 2016 and 2017, but continued to require coverage for contraception. J.A. 96–97; J.A. 180–82.

[4] The original definition of "religious employer" included additional criteria, J.A. 309, but it was subsequently simplified. J.A. 265.

process, they announced a temporary "safe harbor" from enforcement of the mandate for certain organizations. *Id.*

The Agencies subsequently issued an Advanced Notice of Proposed Rulemaking (ANPRM), a Notice of Proposed Rulemaking (NPRM), and ultimately a final rule. J.A 290–97; 269–89; 238–68. The final rule created an "accommodation" that was available to any nonprofit entity that "holds itself out as a religious organization" and that had religious objections to "providing coverage for some or all of any contraceptive services required" by the Women's Health Amendment. J.A. 243.

An organization that qualified for the accommodation could opt out of providing contraceptive coverage directly by submitting a standard form to its insurance company (if fully insured), or third-party administrator (if self-insured), informing it of its objections. An insurance company receiving such notification from an objecting fully insured organization was required to "[e]xpressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan," and instead "[p]rovide separate payments for any contraceptive services required to be covered … for plan participants and beneficiaries for so long as they remain enrolled in the plan." J.A. 262. The insurance company was further required to "segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services." *Id*. Finally, the insurer was required to provide written notice to plan participants and beneficiaries of the fact that "the eligible organization does not administer or fund contraceptive benefits" but that such benefits were available directly from the insurer. *Id*.

Under this system, fully insured objecting organizations could opt out of providing contraception directly, but their plan participants and beneficiaries would still receive the

benefits they were entitled to under the ACA. Shifting the burden to the insurer to provide the services directly was not expected to impose additional costs on the insurer, because "[c]overing contraceptives … yields significant cost savings," in the form of lower "direct medical costs of pregnancy" as well as lower "indirect costs, such as employee absence." J.A. 241. As a result, the insurance company would expect to see lower expenses from providing coverage to the organization's participants and beneficiaries for all other services.

Unlike fully insured employers, self-insured employers directly pay for the health expenses they elect to cover, typically with the administrative assistance of an outside organization known as a third-party administrator (TPA). Under the accommodation, self-insured objecting organizations could submit the standard form to their TPA, noting their objection to providing such coverage. J.A. 263–64. The TPA then assumed the obligation to provide contraceptive coverage to plan participants and beneficiaries, either by paying for contraceptive services directly or by contracting with another entity to do so. J.A. 264. And the TPA was obligated to provide the same notice that insurers were required to provide, stating that the organization did not provide contraceptive benefits, but that such benefits were available from the TPA. *Id.*

In these respects, the accommodation functioned in precisely the same manner for self-insured and fully-insured organizations. However, because TPAs for self-insured plans do not bear the costs for other benefits provided to plan participants and beneficiaries, they would not be expected to save money by providing contraceptive coverage. As a result, the regulations created a mechanism whereby these TPAs could obtain reimbursement from HHS for the cost of providing the coverage, as well as an allowance for administrative expenses and profit. The payment mechanism operated through the Federally-Facilitated Exchange (FFE) user fee paid by

companies that participate in federally-administered healthcare exchanges, and was referred to as the "FFE user fee adjustment." J.A. 251.

III. Litigation over the Contraceptive Mandate

Despite these efforts, several employers and colleges filed lawsuits challenging aspects of the mandate. Specifically, several closely held, for-profit corporations challenged the application of the mandate to them, arguing that being required to provide contraception violated their religious beliefs. Following the creation of the accommodation, many of these plaintiffs argued that the accommodation (for which for-profit corporations were not eligible) showed that the government could achieve the same benefits without requiring them to provide contraceptive services directly. Two of these challenges were consolidated before the Supreme Court in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). In *Hobby Lobby*, the Court held, 5-4, that the imposition of the mandate on for-profit closely held corporations violated the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb *et seq.*

Three days after its decision in *Hobby Lobby*, the Court issued an unsigned order in *Wheaton Coll. v. Burwell*, 573 U.S. 958 (2014), another challenge to the contraceptive mandate. Over the dissent of three justices, the Court ruled that Wheaton College could not be forced to comply with the mandate if it "inform[ed] the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services." *Id.* The Court stressed, however, that "[n]othing in [the] interim order affects the ability of the applicant's employees and students to obtain, without cost, the full range of FDA approved contraceptives" as the government could rely on the notice provided by Wheaton to "facilitate the provision of full contraceptive coverage under the Act." *Id.*

Shortly after these decisions, the Agencies initiated a formal rulemaking process using a NPRM to amend the eligibility criteria for the Accommodation in light of *Hobby Lobby*. Ex. 11. On the same day, the Agencies issued an interim final rule to address the Court's order in *Wheaton College*. Ex. 12. The interim rule created an alternate mechanism by which objecting entities could establish eligibility for the Accommodation by notifying HHS—rather than their third-party administrator—of their objection to providing contraception coverage. *Id*. Both sets of rules were finalized one year later. Ex. 10.

Several additional cases were filed by plaintiffs who were eligible for the accommodation but alleged that it violated their rights under RFRA. Many of these cases were ultimately consolidated before the Supreme Court in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016). Six days after argument in *Zubik*, the Court issued an order directing the parties to submit supplemental briefing to "address whether and how contraceptive coverage may be obtained by petitioners' employees through petitioners' insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees." *Zubik v. Burwell*, 194 L. Ed. 2d 599 (Mar. 29, 2016). The order proposed one such arrangement, but added that "[t]he parties may address other proposals along similar lines." *Id.* After the parties submitted supplemental briefing, the Court issued a short per curiam decision. *Zubik*, 136 S. Ct. 1557. Finding that the option it had proposed was "feasible," the Court decided that the parties should be "afforded an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'" *Id.* at 1560. The Court added:

> Nothing in this opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by petitioners' health plans "obtain, without cost, the full range of FDA approved contraceptives."

Id. at 1560–61 (citations omitted).

In early 2017, however, the Agencies announced that "no feasible approach has been identified . . . that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage," J.A. 172.

IV. The Interim Final Rules

On May 4, 2017, President Donald Trump issued an Executive Order directing the Agencies to "consider issuing amended regulations" to address "conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of Title 42, United States Code." J.A. 167–168. The order did not acknowledge the Court's instruction in *Zubik* that the Agencies ensure that women covered by health plans offered by objecting entities "receive full and equal health coverage, including contraceptive coverage." 136 S. Ct. at 1560 (citation omitted). Several months later, the Agencies issued the IFRs. They were issued without any prior notice, and became effective immediately—a full week before they were published in the *Federal Register*. Despite the lack of notice, the IFRs made several sweeping changes to the mandate, among them:

***Allowing Publicly Traded Corporations to Opt Out*:** The IFRs provided that publicly traded for-profit corporations could opt out of the mandate based on sincerely held religious views. The Religious IFR justified this expansion by arguing "in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some

publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character." J.A. 115.

***Allowing for Moral Objections*:** For the first time, the Agencies permitted entities with "sincerely held moral convictions" to opt out of providing contraceptive coverage. J.A. 142–166. The Moral IFR did not explain what type of belief would qualify as a "sincerely held moral conviction" that would allow an entity to avoid having to provide coverage. In most respects, the Moral IFR functioned in the same manner as the Religious IFR, with one exception: publicly traded companies were not eligible for the Moral IFR; instead, it was only available to nonprofit entities and closely held corporations.

***Making the Accommodation Optional*:** The two IFRs rendered the accommodation entirely optional. Any organization that claimed a religious or moral objection to providing contraceptive coverage could fully opt out. As a result, the organization's plan participants and beneficiaries would no longer receive the contraceptive coverage to which they were legally entitled. The IFRs did not create any mechanism for women who were denied coverage to obtain it from other sources, and it did not suggest that the Agencies would work to ensure that such women had coverage.

***Failing to Require Notice*:** The IFRs provided that "exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them." J.A. 114. Rather, the only notice plans were required to provide to participants was that already mandated by ERISA. So long as plans that did not provide contraception indicated that fact somewhere in their plan documents, they were in full compliance with the IFRs. J.A. 114.

V. This Action

On October 11, 2017, the Commonwealth of Pennsylvania filed suit in this matter alleging that the IFRs violated numerous statutory and constitutional provisions. Complaint, ECF No. 1. The Commonwealth moved for a preliminary injunction, ECF No. 9 (Nov. 2, 2017), which this Court granted on December 15, 2017. 281 F. Supp. 3d at 585. This Court concluded that the Commonwealth had satisfied all of the necessary requirements for the issuance of a preliminary injunction: it was likely to succeed on the merits of its claims that the IFRs violated the procedural and substantive requirements of the Administrative Procedure Act; it would suffer irreparable harm in the absence of an injunction; the balance of equities favored the issuance of an injunction; and an injunction was in the public interest. *Id.*

VI. The Final Rules

On November 7, 2018, while the appeal of the preliminary injunction was pending before the Third Circuit, the Agencies issued the Final Rules. J.A. 1–95. The Final Rules made few substantive changes to the IFRs: they continued to allow publicly traded companies to claim the religious exemption; they kept the moral exemption in essentially the same form; and they did not require objecting entities to utilize the accommodation. On December 14, 2018, Pennsylvania—joined by the State of New Jersey—filed an amended complaint challenging the Final Rules. *See* ECF No. 89. Three days later, the States filed a motion for a second preliminary injunction. *See* ECF No. 90 (Dec. 17, 2018). Following a hearing, this Court entered a nationwide preliminary injunction on January 14, 2019, the day the Final Rules were scheduled to go into effect. 351 F. Supp. 3d at 835. That decision is currently on appeal to the Third Circuit.

ARGUMENT

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(a). In a challenge brought under the Administrative Procedure Act (APA), as here, the Court must hold unlawful and set aside any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to constitutional right," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A)–(D). The Rules fail on all four counts and must be vacated.

I. The Rules Are Contrary to Law

A. The Rules Violate the Women's Health Amendment

Under the Women's Health Amendment, 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" preventive services for women identified by HRSA. § 300gg-13(a)(4). "This repeated use of 'shall' creates 'an obligation impervious to discretion.'" *Prometheus Radio Project v. FCC*, 824 F.3d 33, 50 (3d Cir. 2016) (cleaned up) (quoting *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)). The plain language of the statute does not provide HRSA with authority to create exemptions from the entities that "shall" provide such coverage.

Since 2011, the HRSA Guidelines have included "[c]ontraceptive methods and counseling" among the forms of preventive care that must be provided to women without cost sharing. J.A. 310–12 (2011 Guidelines); J.A. 180–82 (2016 Guidelines); J.A. 96–97 (2017 Guidelines). HRSA made the determination to include contraception based on the expert opinions of sixteen medical and health professionals commissioned by the IOM. J.A. 427–35. The decision was also fully consistent with the expectations of the supporters of the Women's Health Amendment, who repeatedly asserted that the amendment would provide coverage for "family planning."

Rather than confront the import of Congress's choice of words that impose a mandatory obligation, the Agencies ignore it altogether. Throughout the entirety of both Rules, the Agencies manage to avoid quoting or even acknowledging the use of the word "shall" in the Women's Health Amendment. By ignoring the mandatory language of the Women's Health Amendment, the Agencies are able to assert that the provision "demonstrate[s] that Congress intended HRSA to have the discretion the Agencies invoke." J.A. 6. The Agencies assert that the word "as" somehow conferred broad discretion on them to exempt entities from the requirements of the Women's Health Amendment. This Court has already rejected this argument: the word "as" simply indicates "that the HRSA guidelines would be *forthcoming*," because they did not exist at the time of the ACA's passage. 351 F. Supp. 3d at 820.[5]

In the Rules, the Agencies claim that the Women's Health Amendment to the ACA "provided a positive grant of authority for HSRA to develop those Guidelines." J.A. 5; *but see* Br. for the Fed. Defs., *State of Texas v. United States*, at 18, No. 19-1011 (5th Cir. May 1, 2019) (assertion by Defendants HHS, Azar, and United States that the ACA is "is invalid in its entirety"). But the Women's Health Amendment granted HRSA the authority to determine *what* women's preventive services would be covered; it did not grant it the authority to determine *who* must cover such services. Congress clearly spoke to the latter issue, defining the "who" in § 300gg-13(a), which applies to "[a] group health plan and a health insurance issuer offering group or individual health insurance coverage." That section requires insurers to cover four different categories of preventive services, including women's preventive services. *See* § 300gg-

[5] The Agencies argue that the statutory exclusion of so-called "grandfathered" plans implies that they have discretion to exempt any plan from the Women's Health Amendment. In reality, it implies the reverse: Congress knew how to exclude certain plans when it wished to, so the fact that it did not provide or authorize exclusions for objectors suggests that it did not wish to do so.

13(a)(1)–(4). So the Agencies' tortured reading of the statute would imply that the language of § 300gg-13(a) means different things in different contexts: for purposes of the other three requirements, it means exactly what it says, but for purposes of the obligation to cover women's preventive services, the definition is left up to HRSA's discretion.[6]

MCI Telecommunications Corp. v. American Telephone & Telegraph Co., 512 U.S. 218 (1994), further undermines the Agencies' claims. There, the Supreme Court rejected the FCC's contention that a provision allowing it to "modify any requirement" in a section of the Communications Act gave it the authority to exempt certain carriers from the requirement of that section that all common carriers "shall" file tariffs with the FCC. *Id.* at 227–34. If the word "modify" does not support such authority, it is hard to see how the word "as" (or the omission of phrases such as "evidence-based," J.A. 6), could possibly do so.

The ACA sought to facilitate access to healthcare, not limit it. The Women's Health Amendment sought to expand women's access to necessary preventive services, in recognition of the fact that "women often forgo those critical preventive screenings because they simply cannot afford it, or their insurance company won't pay for it unless it is mandated by State law." J.A. 2378. Congress mandated that HRSA identify what services were to be required, because it had the relevant expertise and was devoted to expanding access to health care.[7] To accept the

[6] As the Court previously discussed, *see* 351 F. Supp. 3d at 820, the subsection immediately preceding § 300gg-13(a)(4) uses very similar language, requiring health plans to cover "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." 42 U.S.C. § 300gg-13(a)(3). And the guidelines referenced in this subsection simply define the "what"; they "do not speak at all to *who* must provide that coverage," because the "who" is defined in § 300gg-13(a). 351 F. Supp. 3d at 820 (citing Ex. 153).

[7] Of course, HRSA has no particular expertise in creating religious or other exemptions to mandatory requirements; to the contrary, it has the stated goal of "Improv[ing] Access to Quality Health Care and Services." *See* Ex. 155.

Agencies' view of their authority would upend each of these fundamental understandings. The Agencies have offered no basis for doing so, and this Court should again reject their unsupported assertion of sweeping authority under the Women's Health Amendment.

B. RFRA Neither Permits Nor Requires the Religious Exemption Rule

The Agencies have also asserted that the Religious Exemption Rule—but not the Moral Exemption Rule—rests on authority derived from RFRA. Under RFRA, the federal government may not "substantially burden a person's exercise of religion" unless "application of the burden to that person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." *Id.* § 2000bb(a) & (b). This requirement applies "to all Federal law, and the implementation of that law." *Id.* § 2000bb-3(a). The statute further authorizes "[j]udicial relief" for violations of these requirement, providing: "A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." *Id.* § 2000bb(c).

This Court has correctly recognized that "the law is clear" that RFRA does not require the Religious Exemption Rule. 351 F. Supp. 3d at 823. As an initial matter, RFRA creates a judicial remedy; nowhere does it authorize agencies to create broad exemptions from otherwise mandatory obligations. 42 U.S.C. § 2000bb(c). As this Court previously held, "administrative agencies may not simply formulate a view of a law outside their particular area of expertise, issue regulations pursuant to that view, claim that the law requires those regulations, then seek to insulate their legal determination from judicial scrutiny." 351 F. Supp. 3d at 823. This decision was fully consistent with controlling precedent: "RFRA's demand for judicial review has been

recognized by the Supreme Court, by [the Third Circuit] in *Geneva*,[8] and by virtually all [other] circuits." *Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 357–58 (3d Cir. 2017).

As this Court previously noted, the proper analysis under RFRA can be found "through a close read of *Hobby Lobby*." 351 F. Supp. 3d at 824. In the course of arguing that there was little relevance to the fact that the Senate had rejected an effort to add a legislative conscience protection requirement to the ACA, the Supreme Court observed:

> [The Senate proposal] would not have subjected religious-based objections to the judicial scrutiny called for by RFRA, in which a court must consider not only the burden of a requirement on religious adherents, but also the government's interest and how narrowly tailored the requirement is.

Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 719 n.30 (2014). The Agencies' conclusion that RFRA justifies the Religious Exemption Rule cannot be squared with this description of how RFRA operates.

As this Court observed, *see* 351 F. Supp. 3d at 826 n. 23, the question of "whether RFRA grants agencies independent authority to issue regulations of general applicability" is a difficult one. But the Court need not resolve this question, because the Agencies' view of their authority under RFRA far exceeds any reasonable interpretation of that statute. According to their view, "agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden." J.A. 9. In other words, the Agencies contend that they can excuse religious objectors from a statutory obligation without even "attempt[ing]"

[8] *Geneva College v. Secretary United States Department of Health and Human Services,* 778 F.3d 422, 427 (3d Cir. 2015), *vacated and remanded sub nom. Zubik*, 136 S.Ct. at 1561.

to find an alternate means of achieving the goals of that statute. And they can do so without requiring objectors to so much as provide notice of their objection.

The Agencies' interpretation is particularly dangerous here, because their decision to exempt objectors from the mandate imposes a significant burden on third parties: women who will be denied access to legally mandated contraceptive coverage. Concerns about the impact of the exemptions on these women were discussed at length in numerous comments submitted by a broad spectrum of individuals and organizations. *See infra* Part VII.B. But according to the Agencies, such commenters were simply misinformed as to what the Rules actually do:

> If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits….
>
> The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to benefit other private parties, does not prevent the government from relieving some or all of the burden of its Mandate…. In the Religious [IFR] and these rules, the government has simply restored a zone of freedom where it once existed.

J.A. 14. In other words, whatever harm women may suffer as a result of the Rules is not the government's fault—and even if it were, the harm is unimportant, because the Rules are really about restoring a "zone of freedom."

Even on their own terms—that is, if the Agencies did have the authority to issue blanket exemptions under RFRA—the justifications offered by the Agencies fail. As an initial matter, the Agencies claim that the Exemption is a justifiable response "to the substantial burden identified by the Supreme Court in *Hobby Lobby*." J.A. 10. But *Hobby Lobby* held that the contraceptive mandate itself imposed a substantial burden on closely held, for-profit corporations with religious objections. *See* 573 U.S. at 719. It made clear that the case "[did] not involve publicly

traded corporations." *Id.* at 719. And it did not address whether the accommodation imposed a substantial burden on religious objectors; to the contrary, it identified the accommodation as a less restrictive means that served the compelling interest identified by the government. *Id.* at 730–31; *see also id.* at 738 (Kennedy, J., concurring) ("[The] accommodation equally furthers the Government's interest but does not impinge on the plaintiffs' religious beliefs."). So the Agencies cannot use *Hobby Lobby* to justify 1) extending the exemption to publicly traded corporations and 2) finding that the accommodation imposes a substantial burden on religious objectors.

With respect to the latter deficiency, the Agencies' actions are inconsistent with the Third Circuit's decision in *Real Alternatives*, which reaffirmed the view expressed in *Geneva College* that "the regulation at issue there [the accommodation] did not impose a substantial burden." 867 F.3d at 356 n.18. Nowhere in the Religious Exemption Rule do the Agencies acknowledge the Third Circuit's majority opinion in *Real Alternatives*; rather, the only mention of the case is a citation to the dissent. The omission of any discussion of the *Real Alternatives* majority opinion is all the more remarkable because *Real Alternatives* was one of only two published decisions by a court of appeals addressing a RFRA challenge to the contraceptive mandate following the remand in *Zubik* and prior to the issuance of the IFRs. *Cf. Ozinga v. Price*, 855 F.3d 730, 736 (7th Cir. 2017) (dismissing challenge to mandate as moot in light of *Hobby Lobby*).

Further compounding this error, the only authority other than *Hobby Lobby* that the Agencies *do* cite for their determination that the accommodation imposes a substantial burden is a decision of the Eighth Circuit—but the Agencies fail to mention that that decision was vacated by the Supreme Court following *Zubik*. *See* J.A. 11.[9] And because RFRA is not implicated in the

[9] The Agencies assert:

absence of a substantial burden, if the Agencies conclusion on this point is unsupported, their entire RFRA justification falls apart.

The same is true of the Agencies' assertion that the accommodation does not serve a compelling governmental interest. If this argument is wrong, their justification likewise collapses. In the Rule, they do not seriously grapple with the question of whether the accommodation is the "least restrictive means" of furthering the government's interest, and nothing in the Rule reflects that the Agencies have undertaken any additional, less restrictive efforts to see to it that women denied coverage are provided access to contraception.[10] So if the

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> To this extent, the Departments believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing substantial burden, to the burdens that an entity faces when it opposes, on the basis of its religious beliefs, complying with the Mandate or participating in the accommodation process, and is subject to penalties or disadvantages that would have applied in this context if it chose neither. *See also Sharpe Holdings*, 801 F.3d at 942.

J.A. 11. *But see Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015), *cert. granted, judgment vacated sub nom. U.S. Dep't of Health & Human Servs. v. CNS Ministries*, No. 15-775, 2016 WL 2842448, at *1 (May 16, 2016).

[10] The Religious Exemption Rule did mention one example of an action the government was considering that, it argued, would allow women denied coverage to obtain it elsewhere. The Rule discussed a separate, pending rulemaking issued by Defendant HHS relating to the Title X program. According to the Agencies, that proposed rule would allow women denied coverage to obtain it from a Title X clinic:

> The proposed regulation would amend the definition of "low income family"—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions.

J.A. 16. But in the final Title X rule (since enjoined by three courts, *see infra* Part I.C), HHS offered a different interpretation of the proposal:

> Some commenters are under the mistaken impression that the proposed rule requires project directors to consider women as being from a low income family if they have this insurance status, but the proposed rule said the project director "may" reach that conclusion, not that the director "must" do so.

accommodation serves a compelling governmental interest it would be permissible under RFRA, even if it were held to impose a substantial burden, and the Agencies' argument would again collapse. 42 U.S.C. § 2000bb-1(b). And for the reasons discussed below, *see infra* Part VII.B, the Agencies' conclusions as to the safety and efficacy of contraception cannot be justified based on the record, and therefore cannot support an about-face on the existence of a compelling interest.

For all these reasons, the Agencies' claim that the Religious Exemption Rule is justified by RFRA is erroneous and should be rejected.

C. The Rules Create an Unreasonable Barrier to the Availability of Appropriate Medical Care

Section 1554 of the ACA prohibits the Secretary of Health and Human Services from "promulgat[ing] any regulation that … creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care." 42 U.S.C. § 18114(1). By allowing employers to deny women access to legally-mandated contraceptive care, the Rules here do exactly that.

There can be no dispute that contraception is, for many women, "appropriate medical care." And since the Rules allow employers to deny women coverage for contraception, they "create[] . . . barriers" for women who wish to access such care. That some women denied coverage may be able to surmount these barriers and obtain contraception elsewhere (often at a significantly higher cost) does not change this fact: by allowing employers to deny coverage, they make it more difficult for women to access the care they need. Indeed, three separate district courts have recently issued decisions relying on Section 1554 to enjoin rules that would impose new requirements on Title X clinics, thus making it more difficult for women (and men) to access needed health care, including contraception. See *Oregon v. Azar*, No. 19-317, 2019 WL

Ex. 154 at J.A. 2592. The final Title X rule does not acknowledge that HHS itself, along with two other federal agencies, was under the same "mistaken impression."

1897475, at *12 (D. Or. Apr. 29, 2019); *California v. Azar*, No. 19-1184, 2019 WL 1877392, at *23–26 (N.D. Cal. Apr. 26, 2019); *Washington v. Azar*, No. 19-3040, 2019 WL 1868362, at *7 (E.D. Wash. Apr. 25, 2019).

The barriers created by the Rules are "unreasonable." The Rules will result in significant harm to women who lose coverage, and are not justified by their purported benefits—particularly because the Agencies made no effort to find a way to accommodate the concerns of religious objectors "while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'" *Zubik*, 136 S. Ct. at 1560–61. The unreasonableness of the Rules is only compounded by the Agencies' failure to address the many significant concerns raised by commenters, and their inexplicable about-face on fundamental questions such as the safety and efficacy of contraception. *See infra* Part II.A & B. As a result, the Rules create "unreasonable barriers to the ability of individuals to obtain appropriate medical care," and are therefore unlawful under the ACA and the APA. *See* 5 U.S.C. § 706(2)(C) (Agency action must be struck down if it is "in excess of statutory jurisdiction, authority, or limitations").

D. The Rules Violate Title VII of the Civil Rights Act and Section 1557 of the ACA (Count II)

Title VII of the Civil Rights Act prohibits employers from discriminating on the basis of sex. *See* 42 U.S.C. § 2000e-2(a). Similarly, section 1557 of the ACA provides that no individual shall "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). The Rules violate both of these provisions.

In 1978, Congress enacted the Pregnancy Discrimination Act (PDA), which amended Title VII to make clear that discrimination because of "pregnancy, childbirth, or related medical

conditions" is prohibited discrimination on the basis of sex. *See* 42 U.S.C. § 2000e(k). The PDA was intended to correct an erroneous interpretation of Title VII by the Supreme Court in *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976), and in enacting the statute Congress expressly embraced the logic of the dissenters in that case. *See* H. Rep. No. 95-948, at 2 (1978) ("It is the Committee's view that the dissenting justices correctly interpreted the [Civil Rights] Act."); *see also Newport News Shipbuilding and Dry Dock Co. v. EEOC*, 462 U.S. 669, 676–82 & n.17 (1983).

General Electric involved a challenge to a company rule that provided employees with disability benefits but specifically excluded disabilities related to pregnancy. *See* 429 U.S. at 125. Writing in dissent, Justice Stevens observed, "By definition, such a rule discriminates on account of sex; for it is the capacity to become pregnant which primarily differentiates the female from the male." *Id.* at 161–62. It is this principle that Congress embraced in enacting the PDA: discrimination on the basis of sex-based characteristics is discrimination on the basis of sex. *See* H. Rep. No. 95-948, at 2 (quoting Stevens dissent with approval); *see also Newport News*, 462 U.S. at 676 ("Accordingly, we shall consider whether Congress, by enacting the Pregnancy Discrimination Act, not only overturned the specific holding in *General Electric v. Gilbert*, *supra*, but also rejected the test of discrimination employed by the Court in that case. We believe it did.").

Relying on this principle, the Supreme Court subsequently struck down, in *U.A.W. v. Johnson Controls, Inc*., an employer's policy that excluded women, except those determined to be infertile, from jobs involving exposure to lead. *See* 499 U.S. 187, 199 (1991). By so targeting "women with childbearing capacity," the policy violated Title VII's prohibition on sex discrimination. *See id.* at 200. The Court noted that its conclusion was "bolstered by" the PDA,

finding that by using "the words 'capable of bearing children' … as the criterion for exclusion, [the employer] explicitly classifies on the basis of potential for pregnancy." *Id.* at 199. It concluded, "Under the PDA, such a classification must be regarded, for Title VII purposes, in the same light as explicit sex discrimination." *Id.*

The same logic prohibits employer policies that treat contraception differently from analogous categories of health care. For example, if an employer provides prescription drug coverage to its employers, it cannot exclude contraceptive prescriptions without running afoul of Title VII. *See Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1269 (W.D. Wash. 2001) ("In light of the fact that prescription contraceptives are used only by women, [defendant's] choice to exclude that particular benefit from its generally applicable benefit plan is discriminatory."); *but see In re Union Pac. R.R. Employment Practices Litigation*, 479 F.3d 936, 942 (8th Cir. 2007). As the *Erickson* court recognized, "when an employer decides to offer a prescription plan covering everything except a few specifically excluded drugs and devices, it has a legal obligation to make sure that the resulting plan does not discriminate based on sex-based characteristics and that it provides equally comprehensive coverage for both sexes." *See id.* at 1272.

The *Erickson* court's finding that differential treatment of contraceptive benefits is unlawful is grounded both in the principle that Title VII prohibits discrimination on the basis of "sex-based characteristics," *see id*., as well as Congress's expressed intent that the PDA's protections should "extend[] to the whole range of matters concerning the childbearing process." *See* H. Rep. No. 95-948, at 5. Since the capacity to become pregnant (and therefore the potential need for contraception) is a sex-based characteristic, such differential treatment is discrimination on the basis of sex. And even if that were not the case, contraceptive use is part of "the whole

range of matters concerning the childbearing process." Either way, differential treatment of contraceptive care violates Title VII. But differential treatment is precisely what the Rules authorize. An entity that refuses to provide contraceptive care will still have an obligation to provide other preventive care, *see* 42 U.S.C. § 300gg-13(a)(1); *id.* § 18022(b)(1)(F), and will similarly have an obligation to provide prescription benefits, *see id.* § 18022(b)(1)(I). But it will be permitted to exclude a category of coverage that is for the exclusive benefit of women. Such conduct is unlawful under Title VII, and by purporting to authorize such conduct, the Rules are unlawful under the APA. *See* 5 U.S.C. § 706(2)(A); *see also Farrington v. Johnson*, 206 F. Supp. 3d 634, 635, 644 (D.D.C. 2016) (refusing to dismiss APA claim arising under Title VII); *Pima Cty. Cmty. Coll. Dist. v. EEOC*, No. 75-210, 1976 WL 548, at *2 (D. Ariz. 1976) (observing that Title VII is "certainly a relevant statute within the contemplation" of the APA).

For the same reason, the Rules violate section 1557 of the ACA, 42 U.S.C. § 18116(a). That section prohibits "discrimination under[] any health program or activity, any part of which is receiving Federal financial assistance," on several grounds, including "the ground prohibited . . . under title IX of the Education Amendments of 1972." *Id.* Title IX prohibits discrimination "on the basis of sex" in education, 20 U.S.C. § 1681, and its implementing regulations make clear that it prohibits discrimination on the basis of pregnancy. *See* 34 C.F.R. § 106.40(b)(1) ("A recipient shall not discriminate against any student … on the basis of such student's pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom."). By authorizing employers and other plan sponsors to exclude contraception, the Rules authorize discrimination on the basis of sex, and are therefore unlawful under the APA.

E. The Rules Violate the Equal Protection Provisions of the Fifth Amendment (Count I)

The Rules violate the guarantee of equal protection, as applied to the Federal Government through the Fifth Amendment. Under the Fifth Amendment, classifications based on gender are subject to heightened scrutiny. *See Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1689–90 (2017); *see also Abdul-Akbar v. McKelvie*, 239 F.3d 307, 317 (3d Cir. 2001) ("Fifth Amendment equal protection claims are examined under the same principles that apply to such claims under the Fourteenth Amendment."). Successful defense of such a classification "requires an 'exceedingly persuasive justification'"—the government must demonstrate "at least that the challenged classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives." *Morales-Santana*, 137 S. Ct. at 1690 (citations and internal quotation marked omitted). This burden is a demanding one. *United States v. Virginia*, 518 U.S. 515, 533 (1996).

The Rules at issue here unquestionably target women for uniquely unfavorable treatment. Although the ACA requires coverage for many different types of preventative services, the Rules single out care for women's reproductive health for different treatment and lesser protection. While the President's Executive Order purported to be concerned with conscience issues generally, in fact the only regulatory provision explicitly mentioned in the Executive order, and then in the Final Rules, is 42 U.S.C. § 300gg-13(a)(4), which governs preventative care and services for women.

The Government has failed to provide an "exceedingly persuasive justification" for allowing conscience protections to override what Congress determined to be essential healthcare benefits for women, while leaving undisturbed all other essential healthcare benefits. As Congress and the courts have recognized, women's health, education, and livelihoods depend on their ability to control their reproductive choices, without which they cannot participate as full and equal

members of society. *See generally*, *United States v. Virginia*, 518 U.S. at 532 (women cannot be denied an "equal opportunity to aspire, achieve, participate in and contribute to society"); *Int'l Union v. Johnson Controls*, 499 U.S. 187, 211 (1991) (a woman's reproductive and economic roles are her own choice, not that of the government or her employer). And certainly the protection afforded an employer's mere moral objections to the provision of contraceptive services cannot provide an "exceedingly persuasive justification" for overriding Congress' decision to provide essential healthcare benefits to women.

Moreover, even if this Court were to consider "conscience protections" to be an important governmental objective in the provision of healthcare generally, the Government cannot demonstrate that the *discriminatory* means employed here are "substantially related to the achievement of those objectives." The Government has failed to provide any justification for targeting only women's health care when purportedly protecting religious and moral conscience decisions.

> [C]ontraceptive care is by no means the sole form of health care that implicates religious concerns. To cite a few examples: artificial insemination and other reproductive technologies; genetic screening, counseling, and gene therapy; preventative and remedial treatment for sexually-transmitted diseases; sex reassignment; vaccination; organ transplantation from deceased donors; blood transfusions; stem cell therapies; end-of-life care, including the initiation and termination of life support; and, for some religions, virtually all conventional medical treatments.

Grote v. Sebelius, 708 F.3d 850, 866 (7th Cir. 2013). Of course, an insurance system in which each individual or employer can demand an insurance policy that conforms to his or her religious beliefs is unworkable. But that limitation cannot justify the Government's decision to allow employers to opt out of providing essential healthcare benefits for *women only.*

In sum, the Women's Health Amendment was intended to ensure that women receive essential healthcare coverage on an equal basis with men, and the Government violated women's

equal protection rights when it chose to target the essential healthcare benefits that the ACA afforded women while leaving all other essential health benefits intact.

F. The Religious Exemption Rule Violates the Establishment Clause (Count V)

The Establishment Clause of the First Amendment provides that "Congress shall make no law respecting an establishment of religion." U.S. Const. amend. I. There is no single test that courts consistently apply to determine when an Establishment Clause violation has occurred, but it is clear, at a minimum, that the Government violates the Clause when its actions have a purpose or primary effect of advancing religion. *See Lemon v. Kurtzman*, 403 U.S. 602, 612–13 (1971); *Doe v. Indian River School Dist.*, 653 F.3d 256, 283–84 (3d Cir. 2011). And while the Government is permitted to seek to accommodate religious views, "accommodation is not a principle without limits." *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 706 (1994). The Religious Exemption Rule violates the Establishment Clause because it favors a broadly defined group of religious employers and plan sponsors by granting them absolute and unqualified power to impose substantial burdens on employees who do not share their employers' religious beliefs.

Courts most frequently begin their Establishment Clause analysis by looking to the well-established three-part test *Lemon* test, which holds that "a state law or governmental action violates the Establishment Clause if (1) it lacks a secular purpose, (2) its principal or primary effect advances or inhibits religion, or (3) it fosters an excessive government entanglement with religion." *Stratechuk v. Board of Education*, 587 F.3d 597, 604 (3d Cir. 2009) (cleaned up). Although courts in recent years have not universally applied the *Lemon* test, it remains a touchstone of Establishment Clause analysis. *See Stratechuk*, 587 F.3d at 604 (applying *Lemon* while also discussing the "coercion test" and the "endorsement test').

In this case, the context, history, and plain language of the Religious Exemption Rule demonstrates that, in contravention of the *Lemon* test, its principal purpose and effect is to advance

the religious views of employers and plan sponsors to the detriment of their employees who do not share their religious beliefs and without due consideration of the employees' countervailing interests. This purpose is clear from the language of the Executive Order, which states that it is the policy of the Executive Branch to "vigorously enforce Federal law's robust protections for religious freedom." *See* Ex 6 (Executive Order). Similarly, the stated purpose of the Religious Exemption Rule is to protect "religious beliefs[] in the context of health care and human services," J.A. 3 (final Rule), and "provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts," J.A. 99 (IFR). The Rule does not even bother to feign a non-religious purpose, such as health or economic concerns. If allowed to be put into effect, the Rule's only effect will be to favor the religious views of employers over the health needs of their employees.

To be sure, the Government may, under certain circumstances, alleviate a burden on religious exercise without running afoul of the Establishment Clause. *See Cutter v. Wilkinson*, 544 U.S. 709, 719–20 (2005). But "[a]t some point, accommodation may devolve into 'an unlawful fostering of religion.'" *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334–35 (1987) (quoting *Hobbie v. Unemployment Appeals Com'n of Florida*, 480 U.S. 136, 145 (1987)). This is such a case. Here, the Government has elevated the religious beliefs of employers over the health needs of their employees, in an absolute and unqualified way, without giving due weight to the employees' interests. The Rule fails to require employers or their health plans to provide contraceptive coverage for employees even when contraceptives are necessary to preserve a women's health. And this dramatic expansion favoring the religious beliefs of employers over women's health has been done despite the existence of a much less burdensome pre-existing alternative, i.e., the accommodation that required health care

providers, rather than employers, to provide employees with ready access to the contraceptive coverage mandated by the ACA.

The most directly analogous case is *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985), in which a department store challenged a Connecticut statute that provided all employees with the right not to work on their chosen Sabbath day. *Id*. at 708. The Supreme Court held that the Connecticut statute, by providing "Sabbath observers with an absolute and unqualified right not to work on whatever day they designate as their Sabbath" violates the Establishment Clause. *Id*. at 709. The Court noted that the State impermissibly "commands that Sabbath religious concerns automatically control over all secular interests at the workplace; the statute takes no account of the convenience or interests of the employer or those of other employees who do not observe a Sabbath." *Id*. The Court further noted that the statute provided no exception for "when the employer's compliance would require the imposition of significant burdens on other employees required to work in place of the Sabbath observers," and the statute "allows for no consideration as to whether the employer has made reasonable accommodation proposals." *Id*. at 710.

The Religious Exemption Rule violates the Establishment Clause for the same reasons that the Connecticut statute did in *Caldor*. Here, the new rule provides employers with an absolute and unqualified right to deny contraceptive coverage to their employees based solely on the employer's self-professed religious beliefs. This exemption takes no account of the hardships imposed on the non-believing employees who lose this vital health care coverage. And this absolute right is conferred on religious employers despite the existence of a much less intrusive potential remedy, which previously required health care providers, but not the employers themselves, to ensure that their employees have access to ACA-mandated health benefits. Just as in *Caldor*, the religious beliefs of one party in an employer-employee relationship trump everything else, with no

consideration for the hardships imposed on those who do not share those religious beliefs and no consideration given to less restrictive alternatives. *See also Cutter*, 544 U.S. at 710 ("An accommodation must be measured so that it does not override other significant interests."); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (plurality op.) (religious accommodations are permissible when they do not "impose substantial burdens on non-beneficiaries").

In sum, the Religious Exemption Rule impermissibly favors religious employers over their employees who do not share their religious beliefs, and it does so in a manner that goes well beyond mere accommodation. The Religious Exemption Rule grants an unqualified right to religious employers that imposes significant hardships on their employees in violation of the Establishment Clause.

II. The Rules Are Arbitrary and Capricious (Count IV)

Not only are the Rules contrary to law, but they are also arbitrary and capricious in contravention of the APA. 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if it fails to "'examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.'" *Prometheus Radio Project v. FCC*, 652 F.3d 431, 469 (3d Cir. 2011) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983)). Agency action is also arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. "[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Id.* at 50.

In reaching its conclusions, a federal agency has an independent "obligation to remain open-minded about the issues raised and engage with the substantive responses submitted."

Prometheus Radio Project, 652 F.3d at 453 (cleaned up). The agency "must respond in a reasoned manner" to all public comments "that raise significant problems." *Am. Coll. of Emergency Physicians v. Price*, 264 F. Supp. 3d 89, 94 (D.D.C. 2017) (quoting *City of Waukesha v. EPA*, 320 F.3d 228, 257 (D.C. Cir. 2003)); *see United States v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). These responses "enable the Court to see what major issues of policy were ventilated and why the agency reacted to them as it did." *Price*, 264 F. Supp. 3d at 94 (cleaned up) (quoting *Auto. Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968)). "[F]ailure to address these comments, or at best its attempt to address them in a conclusory manner, is fatal to its defense." *Ass'n of Private Sector Colleges & Universities v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012) (cleaned up).

Three examples demonstrate the agencies' faulty reasoning: First, the Agencies failed to justify their abrupt about-face on the safety, efficacy, and benefits of contraception. Second, the Agencies failed to respond to significant comments. And third, the Agencies failed to adequately account for the economic impact the Rules will have on women.

A. The Agencies Failed to Provide a Reasoned Explanation for Their Reversal on the Safety, Efficacy, and Benefits of Contraception.

Prior to October 2017, the Agencies consistently recognized that contraception and contraceptive counseling are safe, effective, and beneficial preventive services for women. Facts ¶¶ 37–47. Because women face the unique health needs associated with the ability to become pregnant, and because unintended pregnancy poses health risks, the Agencies determined that contraception is a preventive service. *Id.* And because cost sharing is a barrier to effective contraception use, the Agencies concluded that the contraceptive mandate is necessary to remedy a critical gender disparity that prevents women from achieving equal health outcomes with men. *Id.*

In the Final Rules, the Agencies assert the opposite. J.A. 17–21. Faced with some comments asserting that contraception poses health risks to women, that some forms of contraception are actually abortion, and that contraception has not reduced teen pregnancy,[11] they now decline to "take a position on the[se] empirical question[s]." J.A. 20. They likewise conclude that "it is not clear" that the Rules "will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate"—even though the Rules will deprive non-objecting female employees of access to cost-free contraceptive services. J.A. 20–21.[12]

Agencies are "free to change their existing policies," *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016), but they must provide a "reasoned explanation" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Simply demonstrating awareness of their change in policy is insufficient if the agencies provide a poorly reasoned explanation for "why [they] deemed it necessary to overrule its previous position." *Navarro*, 136 S. Ct. at 2126. And when—as here—the "new policy rests upon factual findings that contradict those which underlay its prior policy" and "its prior policy has engendered serious reliance interests," the agency must provide "a more detailed justification." *Fox Television Stations, Inc.*, 556 U.S. at 515. Whether contraception is safe, effective, and beneficial is a factual question that was previously answered in the affirmative by

[11] Only some of the 27 comments supporting the Rules raised these concerns with any specificity. *See* Exs. 111–113, 115–117, 119.

[12] The Agencies had previously explained that the church exemption would likely not negatively impact women because houses of worship "are more likely than other employers to employ people of the same faith who share the same objection." J.A. 243. But the Agencies had rejected expanding the exemption to other employers precisely because female employees of non-religious employers are "less likely than individuals in plans of religious employers to share their employer's (or institution of higher education's) faith and objection to contraceptive coverage on religious grounds." J.A. 256. The Agencies do not reverse this conclusion here.

Defendant HHS, the agency charged with "fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." Ex. 150. The contraceptive mandate has also generated significant reliance interests: the Agencies acknowledge that between 55.6 million and 62.4 million women covered by private insurance currently have cost-free contraceptive coverage, J.A. 43, and concede that at least 70,515 women will lose coverage, J.A. 43, 91.

The Agencies have failed to provide a reasoned explanation, much less a detailed justification, for reversing course here. To the contrary, their conclusions "run[] counter to the evidence before the agency." *State Farm*, 463 U.S. at 43. The Agencies cannot manufacture a scientific controversy and then use the existence of that false controversy to justify sweeping regulatory changes.

For one, the Agencies claim that the existence of side effects associated with some forms of contraception indicates that "significantly more uncertainty and ambiguity exists on these issues." J.A. 20. But in doing so, the Agencies arbitrarily treat all 18 forms of contraception categorically. *Cf.* J.A. 2344 ("No one product is best for everyone. Some methods are more effective than others at preventing pregnancy."). They misrepresent the fact that any medication will have side effects and any medication can be contraindicated for patients with certain medical conditions. This is exactly why the Agencies had previously concluded that "[i]t is for a woman and her health care provider in each particular case to weigh any risks against the benefits in deciding whether to use contraceptive services in general or any particular contraceptive service." J.A. 242. The Agencies point to no new evidence suggesting that all 18 forms of contraception are all *categorically* unsafe for women, nor any evidence countermanding their prior conclusion that unintended pregnancy is a health risk for women. They ignore the FDA's undisputed determinations that the 18 approved methods of contraception are "proven safe and

effective," Ex. 148, even though all methods of contraception, like all medical services, must be individually prescribed. J.A. 2344 ("No one product is best for everyone. . . . This page lists FDA-approved and cleared methods for birth control. Talk to your healthcare provider about the best method for you."). And they ignore the overwhelming consensus of the medical community in support of contraception's safety and efficacy. *E.g.* J.A. 628, 631–32, 641, 643, 647–48, 650–51, 659. The Agencies' newfound "uncertainty and ambiguity," J.A. 20, therefore, is flatly unreasonable and arbitrary.

The Agencies also use the assertion by some commenters that certain forms of contraception are "abortifacients" to justify their conclusions on the "health effects of contraception and pregnancy." J.A. 19. But while such personal religious beliefs are relevant to a claim under RFRA, they do not provide a basis for the Agencies to make new factual findings about the "health effects" of contraception, particularly where those findings contradict the Agencies' earlier assertions. J.A. 257 ("FDA-approved contraceptive methods, including Plan B, Ella, and IUDs, are not abortifacients within the meaning of federal law."). Indeed, Defendant HHS defines pregnancy as "the period of time from implantation until delivery," 45 C.F.R. § 46.202(f)—a definition shared by the medical community. *E.g.*, J.A. 712 (noting that since 1965, ACOG has recognized that "the establishment of a pregnancy takes several days and is not completed until a fertilized ovum is implanted in the lining of the woman's uterus." (citations omitted)). As ACOG and many other commenters stated, "[e]very FDA-approved contraceptive method acts before implantation, does not interfere with an existing pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus." J.A. 647 (citations omitted); *see, e.g.*, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997) (conclusion by the FDA that "[e]mergency contraceptive pills are not effective if the woman is pregnant" and have no

"adverse effect on the fetus" if taken when a women is pregnant). The Agencies have presented no evidence to support a redefinition of pregnancy, rendering this analysis arbitrary and capricious.[13]

In addition, the Agencies decline to "take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy," yet use purported ambiguity over this empirical question to conclude that "it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general." J.A. 19. But Defendant HHS ignores its own conclusion that the 63 percent decline in teen pregnancy between 1990 and 2013 "is due to the combination of an increased percentage of adolescents who are waiting to have sexual intercourse and the increased use of effective contraceptives by teens." Ex. 152 (citations omitted). The studies cited by the Agencies do not suggest otherwise: that other factors have influenced the undisputed decline in teen pregnancy does not obviate the role of increased access to contraception, and that many women who had abortions were using contraception when they got pregnant only reinforces the problem of inconsistent use of less effective methods. *Cf.* J.A. 19–20. The Agencies' lack of evidence indicates that any "uncertainty and ambiguity" over the effectiveness of contraception is manufactured.

Finally, the Agencies summarily conclude that the Rules "are not likely to have negative effects on the health or equality of women nationwide," after again declining to take a position on "those evidentiary issues." J.A. 21. But the Agencies fail to provide any evidence

[13] The Agencies also misrepresent how the FDA itself describes several methods of contraception. J.A. 19 n.39. The FDA notes that several forms of contraception "may also work . . . by preventing attachment (implantation) to the womb (uterus)." J.A. 2363. The Agencies insert the words "of a human embryo after fertilization," which the FDA did not use. *See id.*

contradicting their earlier conclusions that contraception "improves the social and economic status of women" and that contraceptive coverage without cost sharing is necessary to eliminate the "financial barriers that prevented women from achieving health outcomes on an equal basis with men." Facts ¶¶ 37–47. Moreover, the Agencies provide no source supporting any ambiguity over the impact of contraception or the mandate on unintended pregnancy, and their only source for claiming that state mandates "have not necessarily lowered rates of unintended pregnancy (or abortion) overall" is a law review article, not a research study. J.A. 20 & n.53. The Agencies ignore several comments proving that Colorado's contraceptive mandate reduced the unintended pregnancy and abortion rate, J.A. 799–800, 807, 1330—claiming instead that no commenter provided empirical data about state contraceptive equality mandates, J.A. 20. They also ignore comments showing that the contraceptive mandate has allowed women to choose longer-term and more effective forms of contraception, which decreases the risk of unintended pregnancies. *E.g.*, J.A. 1033, 1125; 1151–52, 1329–30.

* * *

The Agencies have failed to provide a reasoned explanation—much less a detailed justification—for their newfound suppositions that contraception is not safe, effective, and beneficial for women. *See Fox Television Stations, Inc.*, 556 U.S. at 515. The Rules, which rest on these shifting sands, are therefore arbitrary and capricious.

B. The Agencies Failed to Consider Other Significant Comments.

Of the 110,000 comments recognized by the Agencies, only 27 comments (representing 17 unique individuals or organizations) supported the religious and moral exemptions. Facts ¶¶ 48–54, Exs. 106–120. Put differently, only 0.025% of comments supported the Rules; 99.96% opposed them. Yet the Agencies nowhere acknowledge this significant disparity, nor do they modify the exemptions in any way to increase contraceptive coverage for women. Instead, the

Agencies treat these 27 comments as bearing equivalent weight to the more than 109,950 comments opposing the Rules.

The Agencies also ignore several other comments of significance:

- The American medical community—including the American Academy of Family Physicians (Ex. 23), the American Academy of Nursing (Ex. 24), the American College of Nurse-Midwives (Ex. 25), the American College of Physicians (Ex. 26), the American Congress of Obstetricians and Gynecologists (ACOG) (Ex. 27), the American Academy of Pediatrics (Ex. 27), the Society for Adolescent Health and Medicine (Ex. 27), and the American Public Health Association (Ex. 28)[14]—unequivocally opposed the Rules as anti-science and harmful to women. But the Agencies nowhere acknowledge the elevated importance of comments by medical professionals in Rules impacting the medical needs of women.

- Many commenters explained that other state- and federal-funded programs cannot meet an increased need for contraceptive coverage. *E.g.*, J.A. 600–02, 634–37, 653, 660–61, 1065–66, 1184–86, 1337–39, 1355–56, 1463–65. In particular, commenters stated that Title X is insufficiently funded to meet existing needs, much less absorb an increase from women who lose access due to objecting employers. *E.g.*, J.A. 600–02, 634–37, 653, 660–61, 1065–66, 1184–86, 1337–39, 1355–56, 1463–65. But the Agencies ignored these concerns, insisting only that then-proposed changes to Title X "could further reduce any potential effect of these final rules on women's access to contraceptives." J.A. 16.[15]

- The contraceptive mandate required coverage not just for contraceptive methods but for contraceptive counseling. A number of commenters noted the specific importance of contraceptive counseling, "during which an individual could discuss her specific health history and contraceptive needs in private with a healthcare provider." J.A. 1184; *see, e.g.*, J.A. 1222, 1167. As the IOM Report adopted by the Agencies recognized, "[e]ducation and counseling are important components of family planning services because they provide information about the availability of contraceptive options, elucidate method-specific risks and benefits for the individual woman, and provide instruction in effective use of the chosen method." J.A. 432. In the Rules, the Agencies note only that "[s]ome commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling," J.A. 21. They focus only on the financial cost of losing coverage for contraceptive *methods*, failing entirely to examine how the inability to even discuss contraception will impact women.

[14] *See supra.*

[15] The final Title X rules ultimately eschewed these proposed changes. *See supra* note 10.

Failure to address significant comments, as the Agencies did here, is fatal to an agency's defense. *Duncan*, 681 F.3d at 449.

C. The Agencies' Regulatory Impact Analysis is Arbitrary and Capricious.

The Agencies estimated that at least 70,515 and at most 126,400 women will lose contraceptive coverage when their employers claim exemptions under the Rules. Facts ¶¶ 61–96. Although nominally used to calculate the annual financial impact of the final Rules, the Agencies also use these figures to support their narrative that the Rules will have only a minimal impact. *E.g.*, J.A. 16 n.26. But the Agencies reached their estimates by relying on a series of unsupported assumptions and omissions. This failure to articulate "a rational connection between the facts found and the choice made" renders their analysis arbitrary and capricious. *See Prometheus Radio Project*, 652 F.3d at 469 (quoting *State Farm*, 463 U.S. at 43).

First, the Agencies ignore that an individual who objects to contraceptive coverage—whether under the individual exemption; because he or she shares a moral objection with his or her employer, J.A. 90; or because he or she is self-employed, Facts ¶ 89—will cause his or her female dependents to also lose coverage. Ex. 149 ¶ 17. Yet the Agencies explicitly assume that each individual policyholder has at least one dependent, J.A. 41, and acknowledge that the individual exemption extends "to family coverage covering the participant and his or her beneficiaries enrolled under the plan," J.A. 33. If the Agencies could estimate that 15 women would lose coverage due to the moral exemption, J.A. 92, there is no reason to ignore the impact on female dependents of objecting individuals.

Second, the Agencies continue to assume that only 209 employers are using the accommodation—despite admitting that the number of persons covered by accommodated plans more than doubled from 2015 to 2017. In the Religious Exemption IFR, the Agencies used 2015 numbers to estimate that 1,027,000 employees and beneficiaries were covered by insurance plans

from 209 accommodated entities. J.A. 124–126. In the final Rules, however, the Agencies used 2017 numbers to estimate that 2,907,000 employees and beneficiaries were covered by accommodated insurance plans. Yet the Agencies continued to use an estimate of 209 accommodated entities, J.A. 41–42—as if each entity more than doubled their staff in just two years. Assuming that each policyholder has only one dependent (as the Agencies do, J.A. 41), these 209 accommodated entities employed 1,453,500 employees in 2017—an average of nearly 7,000 employees each. Basic math reveals the irrationality of the Agencies' assumption.

Third, the Agencies assume without basis that the majority of persons currently working for an accommodated employer will not lose contraceptive coverage. They speculate that 100 of the 209 entities using the accommodation will continue to do so in spite of the new exemptions, and that these 100 entities represent 75 percent of all persons covered by accommodated plans. J.A. 41–42. Both assumptions rest on the thin reed that religious hospitals will continue to use the accommodation. J.A. 42. But the Agencies cite only a handful of statements made prior to October 2017; they point to no employer who commented or otherwise committed to continue using the accommodation in spite of the new exemptions. Given the Agencies' impassioned articulation of the religious liberty interests at state, there is no reason not to think all accommodated employers will adopt the new exemptions, which would impact at least 256,025 women.[16]

Finally, the Agencies arbitrarily cut the purported upper bound of women effected by the Religious Rule by two thirds. The Agencies first painstakingly marched through sourced statistics in order to estimate that 379,000 women of childbearing age who use contraception

[16] 2,907,000 covered persons * 20.2% women of childbearing age * 43.6% of women using contraception covered by the Guidelines. *See* Facts ¶ 67.

work for private, non-publicly traded employers that did not cover contraception pre-ACA, are not self-insured church plans, and are not exempt under the Church Exemption. Facts ¶¶ 88–95. But the Agencies then concluded, without any reasonable explanation, that only one third of these women work for employers who would actually qualify for the new religious exemption. J.A. 45. This speculation is especially arbitrary because the Agencies had already incorporated the 6% of employers who knew they did not offer contraception coverage pre-ACA—compared to the 31% who did not know whether they did or not—precisely because they felt this knowledge suggested a sincerely held religious objection to contraception. J.A. 44 & n.103. The Agencies also entirely neglect to conduct this analysis for the final Moral Exemption Rule, apparently assuming (without saying so) that no employer pre-ACA declined to offer contraceptive coverage for moral reasons. J.A. 92.

In sum, the Agencies' assumptions, omissions, and arbitrary speculations render their economic assessment of the Rules arbitrary and capricious.

III. The Agencies Violated the APA's Procedural Requirements (Count III)

The APA sets forth clear procedural requirements that an agency must follow in issuing a new rule. *See* 5 U.S.C. § 553(b)–(d). Among other requirements, the agency must publish a "[g]eneral notice of proposed rule making" in the Federal Register, which "shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* § 553(b). Only after accepting and considering comments on the proposal may the agency publish a final rule, which must contain a "concise general statement of [the rule's] basis and purpose." *Id.* § 553(c).

It is undisputed that the Agencies did not follow these requirements prior to issuing the IFRs. In fact, the IFRs became effective as soon as they were posted on the internet, which was a

full week before they were even published in the *Federal Register*. At the time, the Agencies argued that they were granted specific statutory authority to disregard notice-and-comment rulemaking, or, in the alternative, that they had "good cause" to do so. J.A. 119–20. In the final Rules, they repeat the first argument and briefly mention the second, but provide no support for it. J.A. 17. And they claim that, in addition, the fact that the Agencies accepted comments between the issuance of the IFRs and the issuance of the final Rules excuses any earlier procedural failures. J.A. 17. None of these arguments is valid. *See* 281 F. Supp. 3d at 571–76 (rejecting first two arguments); 351 F. Supp. 3d at 812–16 (rejecting third).

First, the Agencies claim express statutory authority from a provision of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104–191 (1996), which was codified in the Internal Revenue Code, ERISA, and the PHSA, as was the Women's Health Amendment fourteen years later. *See* 29 U.S.C. § 1191c; 26 U.S.C. § 9833; 42 U.S.C. § 300gg-92. In each case, the relevant language provides that the respective Secretary "may promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter." 42 U.S.C. § 300gg-92; 29 U.S.C. § 1191c; 26 U.S.C. § 9833.[17] But the APA provides that a "[s]ubsequent statute may not be held to supersede or modify this subchapter . . . except to the extent that it does so expressly." 5 U.S.C. § 559. The language in HIPAA relied on by the Agencies says nothing about notice-and-comment procedures, and the reference to "interim final rules" falls well short of the "express[]" modification of the APA's procedural requirements required by section 559. *See Asiana Airlines v. F.A.A.*, 134 F.3d 393, 397 (D.C. Cir. 1998) (Section 559 is satisfied only in "Congress has established procedures so clearly

[17] "Subchapter" is replaced with "chapter" and "part" in ERISA and the Internal Revenue Code, respectively.

different from those required by the APA that it must have intended to displace the norm."). The Agencies made precisely the same argument in *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18 (D.D.C. 2010), and that court correctly rejected it, as did this Court in granting the States' first motion for a preliminary injunction, 281 F. Supp. 3d at 571-72.

Second, the Agencies asserted in the IFRs that they satisfied the "good cause" exception under the APA, which allows an agency to bypass notice and comment when it "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." 5 U.S.C.A. § 553. That exception, however, "is to be 'narrowly construed and only reluctantly countenanced.'" *Util. Solid Waste Activities Grp. v. E.P.A.,* 236 F.3d 749, 754 (D.C. Cir. 2001) (citation omitted). It is not an "'escape clause[]' that may be arbitrarily utilized at the agency's whim," but instead "should be limited to emergency situations." *Am. Fed'n of Gov't Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981) (citing S. Rep. No. 79-752 (1945)). In the final Rules, the Agencies fail to offer any explanation for *why* they had good cause. And, regardless, the justifications offered in the IFRs—which include the existence of "extensive litigation" over the mandate and the need to resolve "uncertainty"—do not represent the type of "emergency situation[]" under which the exception applies. *See* 281 F. Supp. 3d at 572–76 (rejecting good cause argument); *United States v. Reynolds*, 710 F.3d 498, 510 (3d Cir. 2013) ("The desire to eliminate uncertainty, by itself, cannot constitute good cause [under the APA]. To hold otherwise would have the effect of writing the notice and comment requirements out of the statute.").

Finally, the Agencies argue that the Rules "comply with the APA's notice and comment requirements" because they were issued "after receiving and thoroughly considering public

comments" following the IFRs. J.A. 17. But the Third Circuit has rejected this argument, holding that the "provision of post-promulgation notice and comment procedures cannot cure the failure to provide such procedures prior to the promulgation of the rule at issue." *NRDC v. EPA*, 683 F.2d 752, 768 (3d Cir. 1982).[18]

NRDC involved a challenge to a decision by EPA, announced in March 1981 without a prior opportunity for comment, to indefinitely postpone the effective date of several duly promulgated regulatory amendments. 683 F.2d at 756. Several months later, EPA announced that it would be terminating the indefinite postponement, effective January 31, 1982, while it simultaneously initiated a rulemaking proceeding and solicited comments on whether to extend the postponement beyond that date. *Id.* at 757. After receiving and reviewing comments, EPA announced that all but four of the amendments would go into effect January 31, 1982, while the remaining four would be further postponed. *Id.*

The *NRDC* court reviewed EPA's justifications for foregoing notice-and-comment rulemaking with respect to the initial postponement—including that the agency had "good cause," *id.* at 764—and found that they were lacking. It then turned to the question of remedy, addressing EPA's argument that its acceptance of post-promulgation comments cured its original failure to follow the APA. *Id.* at 767. The court rejected this argument and, as a result, elected to invalidate not only the original indefinite postponement, but, relevant here, the subsequent postponement of the four amendments that was issued after notice and comment. *Id.* (ruling that "the further postponement of the four amendments as of January 31, 1982, was ineffective").

[18] The Courts of Appeals have taken different approaches to this question. *See* Kristin E. Hickman & Mark Thomson, *Open Minds and Harmless Errors: Judicial Review of Postpromulgation Notice and Comment*, 101 Cornell L. Rev. 261 (2016).

NRDC relied on the Third Circuit's decision in *Sharon Steel Corp. v. E.P.A.*, which explained: "Provision of prior notice and comment allows effective participation in the rulemaking process while the decisionmaker is still receptive to information and argument." 597 F.2d 377, 381 (3d Cir. 1979). The logic applies with equal force here. By foregoing notice and comment prior to issuing the IFRs, the Agencies forced commenters to "come hat-in-hand and run the risk that the decisionmaker is likely to resist change." *Id.* Here, the record demonstrates that the Agencies did, in fact, "resist change." Despite the fact that only 27 of the comments received supported the Rules and that numerous medical organizations and other experts submitted comments identifying serious problems with them, *see supra* Part II.B, the Agencies made almost no substantive changes following the comment period.

The concerns expressed in *NRDC* and *Sharon Steel* were particularly acute in this case, because the Agencies were simultaneously defending the IFRs in litigation while purporting to "thoroughly consider[]" comments on the same IFRs. Thus, they were challenging in court specific arguments about legality of the IFRs, while simultaneously claiming to consider with an open mind comments raising many of the same arguments. *Compare* 281 F. Supp. 3d at 579 (discussing the Agencies' argument that "the textual structure of the ACA permits HHS to proscribe the 'manner or reach of the coverage'"); *with* J.A. 5 (rejecting argument that the language of the ACA does not grant the Agencies such authority); *compare* 281 F. Supp. 3d at 553 (discussing the Agencies' claims that RFRA authorized the exemptions); *with* J.A. 9–10 (rejecting argument that RFRA did not grant the Agencies discretion to create additional exemptions). The situation the Agencies found themselves in—making certain arguments in court, while simultaneously claiming to keep an open mind about the validity of those same arguments—is entirely a result of their decision to forego notice and comment before issuing the

IFRs, and underscores the seriousness of the concerns expressed by the Third Circuit in *NRDC* and *Sharon Steel*.

Accepting the Agencies' arguments would authorize federal agencies "to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued," which "would allow agencies "to circumvent *Sharon Steel* and the APA." *NRDC*, 683 F.2d at 768. For good reason, the Third Circuit concluded, "We cannot countenance such a result." *Id.*; *see also* Hickman & Thomson, *supra*, at 286 ("[G]iving effect to postpromulgation rulemaking would undoubtedly provide a powerful disincentive for agencies to comply with § 553's prepromulgation notice and comment requirements when they seek to bind the actions of regulated parties.").

IV. The Rules Must be Vacated

A reviewing court shall "hold unlawful and set aside" agency action that is "contrary to law" or otherwise violates the requirements of the APA. 5 U.S.C. § 706(2).[19] This section requires that the Rules here be vacated. Although some courts have recognized circumstances under which rules that violate the APA should be remanded without vacatur, "neither the Supreme Court nor the Third Circuit has held that the APA permits a court to remand an invalid

[19] Relevant here, this requirement applies to agency action that is:

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
> (B) contrary to constitutional right, power, privilege, or immunity;
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or]
> (D) without observance of procedure required by law….

5 U.S.C. § 706(2). The Rules are invalid under each of these criteria.

regulation without first vacating the regulation." *Comite de Apoyo a los Trabajadores Agricolas v. Solis*, 933 F. Supp. 2d 700, 714 (E.D. Pa. 2013); *see also Council Tree Commc'ns, Inc. v. F.C.C.*, 619 F.3d 235, 258 n.13 (3d Cir. 2010) ("express[ing] no view as to whether [the court is] authorized to order" remand without vacatur).[20] Rather, "Section 706(2)'s seemingly mandatory language" requires vacatur if the agency action violates the requirements of that section. *Comite de Apoyo*, 933 F. Supp. 2d at 714.

Even if this court were authorized to consider other remedies upon a finding of an APA violation, vacatur is appropriate here. The deficiencies of the Rules are "serious," and could not be easily corrected on remand. *See Council Tree*, 619 F.3d at 258 (relying on "seriousness" of APA violations in concluding "even assuming we have the authority to remand the matter without vacatur, we would decline to do so here."). Moreover, because the Rules are already enjoined, the "disruptive consequences" of vacatur would be limited. *See id.* This Court has on two previous occasions concluded that the harms from the Rules were serious enough to warrant the "extraordinary remedy," *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008), of a preliminary injunction. *See* 351 F. Supp. 3d at 827–30; 281 F. Supp. 3d at 581–85. Those findings remain valid today. *Cf. City of Philadelphia v. Sessions*, 309 F. Supp. 3d 289, 340 (E.D. Pa. 2018), *aff'd in part, vacated in part sub nom. City of Philadelphia v. Attorney Gen. of United States of Am.*, 916 F.3d 276 (3d Cir. 2019) ("The Court's finding of irreparable injury from the preliminary injunction stage remains equally applicable at the permanent injunction stage.") (cleaned up).

[20] *Council Tree* did note that the agency defendant had "cite[d] to a case in which [the Third Circuit] remanded without vacatur, albeit without commenting on the issue." 619 F.3d 235, 258 n.13 (citing *Am. Iron & Steel Inst. v. EPA*, 568 F.2d 284, 310 (3d Cir. 1977)).

CONCLUSION

For the reasons set forth above, the States' Motion for Summary Judgment should be granted and the Rules vacated.

May 15, 2019

Respectfully submitted,

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

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

O R D E R

AND NOW, this day of , 2019, upon consideration of the Motion for Summary Judgment filed by Plaintiffs Commonwealth of Pennsylvania and State of New Jersey, any response thereto, and for good cause shown, it is hereby **ORDERED** that the Motion is **GRANTED**.

It is further **ORDERED** that the following Rules issued by Defendants are **VACATED**:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018); and

2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (issued in interim form Oct. 6, 2017, and in final form Nov. 7, 2018).

BY THE COURT:

_____

WENDY BEETLESTONE, J.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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

PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS

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May 15, 2019

In support of their Motion for Summary Judgment, the Commonwealth of Pennsylvania and the State of New Jersey (the "States") respectfully submit the following Statement of Undisputed Material Facts:

I. The Women's Health Amendment

1. During consideration of the Patient Protection and Affordable Care Act, the Senate passed the "Women's Health Amendment," sponsored by Senator Barbara Mikulski of Maryland. S. Amdt. 2791, 111th Congress (2009–2010).

2. In offering the amendment, Senator Mikulski stated, "Women are often faced with the punitive practices of insurance companies. No. 1 is gender discrimination. Women often pay more and get less. For many insurance companies, simply being a woman is a preexisting condition. Let me repeat that. For many insurance companies, simply being a woman is a preexisting condition." J.A. 2378.

3. Speaking in support of the Women's Health Amendment, Senator Kirstin Gillibrand stated, "In America today, too many women are delaying or skipping preventive care because of the costs of copays and limited access. In fact, more than half of women delay or avoid preventive care because of its cost. This fundamental inequity in the current system is dangerous and discriminatory and we must act." J.A. 2437.

4. During consideration of the Women's Health Amendment, at least six different senators mentioned "family planning" as a service that the amendment would cover or potentially cover. J.A. 2435 (Sen. Boxer); J.A. 2437 (Sen. Gillibrand); J.A. 2438 (Sen. Mikulski); J.A. 2423 (Sen. Cardin); J.A. 2423 (Sen. Feinstein); J.A. 2526 (Sen. Murray).

5. The Women's Health Amendment was included in the final version of the ACA, which became law on March 23, 2010.

II. The Institute of Medicine Report

6. Following passage of the ACA, HRSA commissioned the Institute of Medicine (IOM), to issue recommendations identifying the preventive services for women to be covered by the Women's Health Amendment.

7. The IOM convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations to develop these recommendations.

8. On July 19, 2011, the IOM Committee issue its report, entitled *Clinical Preventive Services for Women: Closing the Gaps*.

9. The IOM Report recommended that HRSA include "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education" as a required preventive service for women. J.A. 335.

10. The IOM Report cited evidence that "contraception and contraceptive counseling are effective at reducing unintended pregnancies." J.A. 335.

In recommending the inclusion of contraceptive methods and education in the HRSA Guidelines, the IOM Report made the following assertions:

11. "Numerous health care professional associations and other organizations recommend the use of family planning services as part of preventive care for women, including ACOG [American College of Obstetricians and Gynecologists], AAFP [American Academy of Family Physicians], the American Academy of Pediatrics (AAP), the Society of Adolescent Medicine, the AMA [American Medical Association], the American Public Health Association, the Association of Women's Health, Obstetric and Neonatal Nurses, and the

March of Dimes. In addition, the CDC recommends family planning services as part of preventive visits for preconception health (Johnson et al., 2006).” J.A. 429.

12. “Unintended pregnancy is highly prevalent in the United States. In 2001, an estimated 49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception—according to the National Survey of Family Growth (Finer and Henshaw, 2006).” J.A. 427.

13. “Although certain subgroups of women are at greater risk for unintended pregnancy than others (e.g., women aged 18 to 24 years, unmarried women, women with low incomes, women who are not high school graduates, and women who are members of a racial or ethnic minority group), all sexually active women with reproductive capacity are at risk for unintended pregnancy.” J.A. 428.

14. “[W]omen with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy.” J.A. 428.

15. Babies born as a result of unintended pregnancies face “significantly increased odds of preterm birth and low birth weight” and are “less likely to be breastfed or are breastfed for a shorter duration.” J.A. 428.

16. “Pregnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy). Short interpregnancy intervals in particular have

been associated with low birth weight, prematurity, and small for gestational age births (Conde-Agudelo et al., 2006; Fuentes-Afflick and Hessol, 2000; Zhu, 2005). In addition, women with certain chronic medical conditions (e.g., diabetes and obesity) may need to postpone pregnancy until appropriate weight loss or glycemic control has been achieved (ADA, 2004; Johnson et al., 2006)." J.A. 428.

17. Pregnancy "may be contraindicated for women with serious medical conditions," including pulmonary hypertension, cyanotic heart disease, and Marfan Syndrome." J.A. 428.

18. "[E]vidence exists that "greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally." J.A. 430.

19. "It is thought that greater use of long-acting, reversible contraceptive methods-including intrauterine devices and contraceptive implants that require less action by the woman and therefore have lower use failure rates-might help further reduce unintended pregnancy rates (Blumenthal et al., 2011)." J.A. 433.

20. "Studies show that as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined (Boonstra et al., 2006)." J.A. 430.

21. "Other studies show that increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are

associated with lower rates of contraceptive use (Santelli and Melnikas, 2010)." J.A. 430.

22. "For example, the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain. (ACOG, 2010a)." J.A. 432.

23. "Long-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases." J.A. 432.

24. "Despite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years." J.A. 434.

25. "In fact, a review of the research on the impact of cost sharing on the use of health cue services found that cost-sharing requirements, such as deductibles and copayments, can pose barriers to care and result in reduced use of preventive and primary care services, particularly for low-income populations." J.A. 434.

26. "Cost barriers to the use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods [LARCs] and sterilization have high up-front costs (Trussell et al., 2009)." J.A. 433.

27. "A recent study conducted by Kaiser Permanente found that when out-of-pocket costs for contraceptives were eliminated or reduced, women were

more likely to rely on more effective long-acting contraceptive methods (Postlethwaite et al., 2007)." J.A. 434.

28. The IOM Report included statistics on the "Percentage of U.S. Women Experiencing an Unintended Pregnancy During First Year of Typical Use and First Year of Perfect Use, by Contraceptive Method." It defined "typical use" as use "[a]mong typical couples" and "perfect use" as using a method "both consistently and correctly." J.A. 431.

29. The Report found that the failure rates for three long-acting, reversible contraceptive methods (Intrauterine Devices ParaGard (copper T) and Mirena (LNG-IUS), and Implanon) were all below one percent. J.A. 431.

30. The Report found that the failure rate for birth control pills (both "[c]ombined pill and progestin-only pill") was eight percent under "typical use" and 0.3 percent under "perfect use." J.A. 431.

31. The Report found that the failure rate for male condoms without spermicides was fifteen percent under "typical use" and two percent under "perfect use." J.A. 431.

III. The Contraceptive Mandate and its Implementing Regulations

32. In July 2010, prior to the issuance of the IOM report, the Departments of Health and Human Services, Labor, and the Treasury issued interim final rules on the Women's Health Amendment and other provisions of the ACA relating to preventive medicine. These interim rules noted the ACA's requirement that plans cover preventive services for women pursuant to guidelines issued by HRSA and stated that HHS was "developing these guidelines and expects to issue them no later than August 1, 2011." J.A. 564.

A. HRSA Guidelines

33. On August 1, 2011, HRSA adopted the recommendations of the report and issued its first "Women's Preventive Services Guidelines," consistent with the Women's Health Amendment. J.A. 310–12.

34. Consistent with the recommendations of the IOM committee, the guidelines required health plans to cover "All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." J.A. 311.

35. In 2016, HRSA updated the Guidelines but retained the requirement that plans cover contraception methods and counseling. J.A. 180–82.

36. In 2017, HRSA updated the Guidelines but retained the requirement that plans cover contraception methods and counseling. J.A. 96–97.

B. The Government's Compelling Interest in Enforcing the Contraceptive Mandate

37. Prior to October 2017, Defendants consistently recognized that they had a compelling government interest in enforcing the contraceptive mandate because contraception and contraceptive counseling are safe, effective, and beneficial preventive services for women.

38. The FDA—a component of Defendant HHS—has approved and cleared 18 methods of contraception for women. Ex. 147.

39. The FDA does not approve a method of contraception unless it is proven safe and effective. Ex. 148 ("New drugs and certain biologics must be proven safe and effective to FDA's satisfaction before companies can market them in interstate commerce. . . . If FDA grants an approval, it means the agency has determined that the benefits of the product outweigh the known risks for the intended use.").

40. The Women's Health Amendment reflected Congress's determination "that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women." J.A. 301.

41. As a result, costs borne disproportionally by women "imposed financial barriers that prevented women from achieving health outcomes on an equal basis with men." J.A. 256 (citing Ex. 19); *accord* J.A. 300.

42. One of these unique health care needs arises from women's ability to become pregnant. J.A. 241 (citing Exs. 19, 134); J.A. 300 (same).

43. Defendants adopted the IOM Report and other studies demonstrating that unintended pregnancy poses health risks for women and fetuses. *E.g.*, J.A. 300 (citing Ex. 19); J.A. 241 (citing Exs. 19, 128, 129, 130, 136); J.A. 256.

44. Contraceptive coverage, the Departments concluded, prevents these health risks by "reducing the number of unintended and potentially unhealthy pregnancies." J.A. 301.

45. Contraception also "improves the social and economic status of women." J.A. 301 (citing Exs. 127, 131, 132, 135); *accord* J.A. 242 (same).

46. Because "cost sharing can be a significant barrier to access to contraception," "eliminating cost sharing is particularly critical to addressing the gender disparity" that motivated Congress to pass the Women's Health Amendment in the first place. J.A. 242 (citing Exs. 19, 133); *accord* J.A. 301 (same).

47. As recently as January 2017, Defendants asserting "the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage." J.A. 173.

IV. Comments on the Interim Final Rules

48. In the Final Rules, Defendants stated that they received approximately 110,000 comments posted to Regulations.gov. J.A. 5, 60.

49. The Administrative Record, as produced, contained many duplicate or near-duplicate comments from the same individual or organization. It appears that many identical or similar comments were submitted by the same individual or organization to both the docket for the Religious Exemption IFR and the Moral Exemption IFR. Defendants did not distinguish between the two dockets in the Administrative Record.

50. The actual number of comments was significantly greater due to thousands of form comments, all of which opposed the Rules. For example, one PDF in the Administrative Record contains 29,139 pages, each page with approximately a dozen form comments opposing the Rules. CD 12, Bates 715547.

51. Almost all of the comments opposed the Rules.[1]

52. Only 27 comments (representing 17 unique individuals or organizations) supported the Rules. Exs. 106–120.[2]

53. Thirteen comments (representing nine unique individuals or organizations) did not clearly take a position for or against the Rules. Exs. 121–126.[3]

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[1] The Joint Appendix contains selected comments opposing the Rules. Most organizations filed similar or identical comments to both dockets. Generally, the Joint Appendix contains the comment filed to the docket for the Religious Exemption IFR.

[2] Where an identical comment supporting the Rules was produced multiple times in the Administrative Record, the Joint Appendix contains only one copy of that comment. The number 27 refers to the number of total comments, including duplicates, located in the Administrative Record.

[3] Where the same comment neither supporting nor opposing the Rules was produced multiple times in the Administrative Record, the Joint Appendix contains only one copy of that

54. Of the 110,000 comments counted by Defendants, 0.025% supported the Rules and 99.96% opposed the Rules.

55. Many commenters stated that contraception is a vital preventive service for women:[4]

a. "Contraceptive efficacy at preventing unintended pregnancy is supported by decades of rigorous evidence and by the government itself.[5] . . . In truth, contraception enables women, including teens, to prevent

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comment. The number 13 refers to the number of total comments, including duplicates, located in the Administrative Record.

[4] Excerpted quotes are not intended to be comprehensive of all commenters. Footnotes included within quotes are lifted directly from the comment.

[5] *See, e.g.*, Institute of Medicine, (2011), Clinical Preventive Services for Women: Closing the Gaps, Washington, DC: The National Academies Press; American College of Obstetricians and Gynecologists. (2016, December), Women's Preventive Services Initiative: Recommendations for Preventive Services for Women Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration (p. 82-91), Retrieved 27 November 2017, from https://www.womenspreventivehealth.org/final-report/; Trussell, J. (2011, May), Contraceptive failure in the United States, Contraception, 83(5), 397-404; Hatcher, R.A., Trussell, J., Nelson, AL., Cates, W., Kowal, D., & Policar, M.S. (Eds.). (2011). Contraceptive Technology (20th ed.), Atlanta, GA: Bridging the Gap Communications; Declaration of Dr. Lawrence Finer in Support of Plaintiffs' Motion for Preliminary injunction at 4-5, California v. Wright, No. 4:17-cv-05783-HSG (Nov. 9, 2017) ("Sexually active couples using no method of contraception have a roughly 85% chance of experiencing a pregnancy in a one-year period, while the risk for those using a contraceptive method ranges from 0.05% to 28%.") (citing Sundaram, A., Vaughan, B., Bankole, A., Finer, L., Singh, S., & Trussell, J. (2017, March), Contraceptive failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth, Perspectives on Sexual and Reproductive Health, 49(1), 7-16); Peipert, J.F., Madden, T., Allsworth, J.E., & Secura, G.M. (2012, December), Preventing unintended pregnancies by providing no-cost contraception, Obstetrics & Gynecology, 120(6), 1291-1297; Finer, L.B., & Zolna, M.R. (2016, March), Declines in unintended pregnancy in the United States, 2008-2011, New England Journal of Medicine, 374(9), 843-852; Harper, C.C., Rocca, C.H., Thompson, K.M., Morfesis, J., Goodman, S., Darney, P.B., . . . Speidel, J.J. (2015, June), Reductions in pregnancy rates in the USA with long-acting reversible contraception: A cluster randomized trial, The Lancet, 386(9993), 562-568; Speidel, JJ., Harper, C.C., & Shields, W.C. (2008, September), The potential of long-acting reversible contraception to decrease unintended pregnancy, Contraception, 78(3), 197-200.

unintended pregnancy and control the timing of a desired pregnancy.[6] The Centers for Disease Control and Prevention named family planning one of the ten great public health achievements of the past century,[7] and family planning is widely credited for contributing to women's societal, educational, and economic gains.[8]" *E.g.*, J.A. 632 (American Academy of Nursing Comments).

56. Many commenters stated that contraception does not pose serious health risks:

a. "As with any medication, certain types of contraception may be contraindicated for patients with certain medical conditions, including high blood pressure, lupus, or a history of breast cancer.[9,10] Specifically, the IFR suggests an increased risk of venous thromboembolism (VTE). In fact, VTE among oral contraceptive users is very low and much lower than the risk of VTE during pregnancy or in the immediate postpartum

[6] *See, e.g.*, Boonstra, H.D. (2014, September 3). What is behind the declines in teen pregnancy rates? *Guttmacher Policy Review*, 17(3), 15-21; Lindberg, L., Santelli, J., & Desai, S. (2016, November), Understanding the decline in adolescent fertility in the United States, 2007-2012, *Journal of Adolescent Health*, 59(5), 577-583.

[7] Centers for Disease Control and Prevention. (2013, April 26). *Ten Great Public Health Achievements in the 20th Century*, Retrieved 27 November 2017, from https://www.cdc.gov/about/history/tengpha.htm.

[8] *See, e.g.*, Sonfield, A., Hasstedt, K., Kavanaugh, M.L., & Anderson, R. (2013, March). *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children*, Retrieved 30 November 2017, from the Guttmacher Institute website: https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.

[9] Progestin-only hormonal birth control: pill and injection. FAQ No. 86. American College of Obstetricians and Gynecologists. July 2014.

[10] Combined hormonal birth control: pill, patch, and ring. FAQ No. 185. American College of Obstetricians and Gynecologists. July 2014.

period.[11] The IFR also suggests contraception increases the risk of breast cancer, but there is no proven increased risk of breast cancer among contraceptive users, particularly those under 40.[12]" J.A. 1064 (NARAL ProChoice America Comments); *see also* J.A. 605 (AccessNow Comments), J.A. 622 (ACLU Comments); J.A. 651 (American Congress of Obstetricians and Gynecologists, American Academy of Pediatrics, & Society for Adolescent Health and Medicine Comments); J.A. 659 (American Public Health Association Comments); J.A. 665 (American Society for Emergency Contraception Comments); J.A. 684 (Asian & Pacific Islander American Health Forum Comments); J.A. 789 (Center for Inquiry & Secular Coalition for America Comments); J.A. 803 (Colorado Consumer Health Initiative Comments); J.A. 878 (Family Planning Councils of America Comments); J.A. 946 (Ibis Reproductive Health Comments); J.A. 1025 (Lift Louisiana Comments); J.A. 1088 (National Asian Pacific American Women's Forum); J.A. 1138 (National Family Planning & Reproductive Health Association Comments); J.A. 1173 (National Institute for Reproductive Health Comments); J.A. 1193 (National Latina Institute of Reproductive Health Comments); J.A. 1295–95 (Physicians for Reproductive Health Comments); J.A. 1306 (Power to

[11] Risk of venous thromboembolism among users of drospirenone-containing oral contraceptive pills. Committee Opinion No. 540. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:1239-42.

[12] Curtis KM, Jatlauoui TC, Tepper NK, et al. US Selected Practice Recommendations for Contraceptive Use, 2016. MMWR Recomm Rep 2016;65(No. RR-4):1-66. DOI: http://dx.doi.org/10.15585/mmwr.rr6504a1.

Decide Comments); J.A. 1341 (Public Health Solutions Comments); J.A. 1354 (Raising Women's Voices for the Health Care We Need Comments); J.A. 1371 (Reproductive Rights and Justice Practicum at Yale Law School Comments); J.A. 1454 (Wisconsin Alliance for Women's Health Comments); J.A. 1468 (Women's Health and Family Planning Alliance of Texas Comments); J.A. 1481 (Women's Law Project Comments t); J.A. 1496 (Yale Students for Reproductive Justice Comments).

b. "The Departments go further, selectively interpreting data in order to overstate 'negative health effects' associated with contraceptives. This includes misleading assertions of an association between contraceptive use, breast cancer, and cervical cancer, as well as vascular events and 'risky sexual behavior.' The Departments ignore substantial evidence to the contrary, and ignore the balance of significant non-contraceptive health benefits associated with contraceptive use." J.A. 1072 (NARAL Pro-Choice Maryland Comments); *see also* J.A. 1215 (National Partnership for Women & Families, Jacobs Institute of Women's Health, Union of Concerned Scientists Comments); J.A. 1323 (Professor James Trussell, Princeton University Comments).

c. "It is especially irresponsible to misrepresent the risks of breast and cervical cancer without accurately reporting the substantial evidence of contraceptives' association with cancer prevention, since any evaluation of preventative health care should fully weigh the risks and benefits.

Contraceptives are associated with a reduced risk of colorectal cancer;[13] endometrial cancer is 50 percent less likely among women who use oral hormonal contraceptives for at least one year compared to women who have never used oral hormonal contraceptives;[14] oral hormonal contraceptives can reduce the risk of ovarian cancer by 27 percent, and 20 percent for every five years of additional use;[15] oral hormonal contraceptives can lower the risk of hereditary ovarian cancer in women with BRCA1 or BRCA2 gene mutations;[16] and oral hormonal contraceptive use for more than 10 years can lower the risk of ovarian cancer among women with endometriosis, who are typically at higher risk of developing ovarian cancer.[17]" J.A. 1027 (NARAL Pro-Choice Maryland Comments); *see also* J.A. 665 (American Society for Emergency Contraception Comments); J.A. 1194–95 (National Latina Institute of Reproductive Health Comments; J.A. 1314 (Planned Parenthood Federation of American & Planned Parenthood Action Fund Comments); J.A. 1323 (Professor James Trussell, Princeton University Comments).

[13] Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. *International Journal of Endocrinology and Metabolism, 11*(1), 41-47.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

57. Many commenters stated that contraception does not terminate pregnancy and therefore is not an abortifacient:

a. "FDA-approved contraceptive methods are not abortifacients. Every FDA-approved contraceptive acts before implantation, does not interfere with a pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus, which is when pregnancy begins.[18]" J.A. 1063 (NARAL Pro-Choice America); *see also* J.A. 605 (AccessMatter Comments); J.A. 647 (American Congress of Obstetricians and Gynecologists, American Academy of Pediatrics, & Society for Adolescent Health and Medicine Comments); J.A. 684 (Asian & Pacific Islander American Health Forum Comments); J.A. 803 (Colorado Consumer Health Initiative Comments); J.A. 947 (Ibis Reproductive Health Comments); J.A. 1073–74 (NARAL ProChoice Maryland Comments); J.A. 1087 (National Asian Pacific American Women's Forum Comments); J.A. 1193 (National Latina Institute of Reproductive Health Comments); J.A. 1230 (National Partnership for Women and Families Comments);J.A. 1276 (National Women's Law Center Comments); J.A. 1295 (Physicians for Reproductive Health Comments); J.A. 1306 (Power to Decide); J.A. 1341 (Public Health Solutions Comments); J.A. 1353–54 (Raising Women's Voices for the Health Care We Need Comments); J.A.

[18] Brief for Physicians for Reproductive Health, American College of Obstetricians and Gynecologists et al. as Amici Curiae Supporting Respondents, Sebelius v. Hobby Lobby, 573 U.S. XXX (2014) (No. 13-354). Available at acog.org/~/media/Departments/Government%20Relations%20and%29Outreach/20131021AmicusHobby.pdf?.

1370–71 (Reproductive Rights and Justice Practicum at Yale Law School Comments); J.A. 1454 (Wisconsin Alliance for Women's Health Comments), J.A. 1468 (Women's Health and Family Planning Alliance of Texas Comments); J.A. 1481 (Women's Law Project Comments); J.A. 1495–96 (Yale Students for Reproductive Justice Comments).

58. Many commenters stated that increased access to contraception is not associated with increased sexual activity. To the contrary, increased access to contraception is associated with lower teen pregnancy rates:

a. "Increased access to contraception is not associated with increased unsafe sexual behavior or increased sexual activity.[19,20] In fact, research has shown school-based health centers that provide access to contraceptives are proven to increase use of contraceptives by already sexually active students, not to increase onset of sexual activity.[21,22] On the other hand, young females who did not use birth control at first sexual intercourse were twice as likely to become pregnant.[23] Overall, increased access to

[19] Kirby D. Emerging answers 2007: Research findings on programs to reduce teen pregnancy and sexually transmitted diseases. Washington, DC: The National Campaign to Prevent Teen and Unplanned Pregancy. 2009.

[20] Meyer JL, Gold MA, Haggerty CL. Advance provision of emergency contraception among adolescent and young adult women: a systematic review of literature. J Pediatr Adolesc Gynecol. 2011;24(1);2-9).

[21] Minguez M, Santelli JS, Gibson E, Orr M, & Samant, S. Reproductive health impact of a school health center. Journal of Adolescent health, 2015;56(3), 338-344.

[22] Knopf JA, Finnie RKC, Peng Y, et al. Community Preventative Services Task Force. School-based health centers to advance health equity: a Community Guide systematic review. American Journal of Preventative Medicine 2016;51(1):114-26.

[23] *Id.*

and use of contraception has contributed to a dramatic decline in rates of adolescent pregnancy.[24] More females are using contraception the first time they have sex.[25]" J.A. 1064 (NARAL Pro-Choice America Comments).

b. "Unintended pregnancies account for nearly half of the 6.1 million pregnancies annually in the U.S. and 75% of teenage pregnancies. All taxpayers carry the burden of these costs as two-thirds (68%) of the 1.5 million unplanned births that occurred in 2010 were paid for by public insurance programs, primarily Medicaid." J.A. 1033 (Commonwealth of Massachusetts Executive Office of Health and Human Services Comments)

c. "Teen pregnancy is also at the lowest point in at least 80 years.[26]" J.A. 1072 (NARAL Pro-Choice Maryland).

d. "The supplemental information also fails to consider important research on the impact of positive outcomes associated with reducing barriers to

[24] Lindberg L, Santelli J, Desai S. Understanding the Decline in Adolescent Fertility in the United States, 2007-2012. J Adolesc health. 2016;59(5):577-583. DOI: 10.1016/j.jadohealth.2016.06.024.

[25] *Id.*

[26] Declaration of Dr. Lawrence Finer in Support of Plaintiffs' Motion for Preliminary Injunction at 8, California v. Wright, No. 4:17-cv-05783-HAS (Nov. 9, 2017) ("In 2013, the U.S. pregnancy rate among 15-19 year olds was at its lowest point in at least 80 years and had dropped to about one-third of a recent peak in 1990.") (citing Kost, K, Maddow-Zimet, I., & Arpaia, A. (2017, August). *Pregnancies, Births and Abortions Among Adolescents and Young Women in the United States, 2013: National and State Trends by Age, Race and Ethnicity*. Retrieved 27 November 2017, from the Guttmacher Institute website: https://www.guttmacher.org/sites/default/files/report_pdf/us-adolescent-pregnancy-trends-2013.pdf).

contraceptive access. One study not cited in the register, where over 9,000 women were provided the contraceptive method of their choice at no cost, found that eliminating barriers to contraception can significantly decrease the rates of teen birth, abortion rates, and repeat abortions, and may also reduce the rate of unintended pregnancies.[27] At the same time, the Centers for Disease Control and Prevention's High School Youth Risk Behavior Survey Data shows declines in teens who have ever had sex, are currently sexually active, or have had sex with four or more partners between 2011 and 2015.[28] These findings weaken the Administration's claim that expanded access to contraception will lead to more risk-taking among women." J.A. 1283 (New York City Comments).

e. "Contraception for all girls and women should be voluntary and free. Research shows that making it so leads to dramatic declines in the teen pregnancy rate. Take the state of Colorado. Between 2009 and 2013, when the state provided free long acting reversible contraception, the teen birth rate, abortion rate, and pregnancy rate among unmarried women under 25 who do not have a high school degree fell by 40 plus percent. . . . Access to birth control has particularly important consequences for educational attainment because of the timing of high school and college degrees. The bottom line is access to free contraception can mean the difference

[27] Peipert, J., Madden T., Allsworth, J., & Secura G. (2012). Preventing Unintended Pregnancies by Providing No-Cost Contraception. *Obstetrics & Gynecology*, 120(6), 1291-1297.

[28] Centers for Disease Control and Prevention (CDC), *1991-2015 High School Youth Risk Behavior Survey Data*.

between completing high school and college and not." J.A. 1360 (Representatives of Education and Youth Development Communities Comments).

59. Many commenters stated that contraception is important to women's health and equality:

a. "Women face a unique set of health care challenges because they access more health services than men, yet earn less on average than men.[29]" J.A. 598 (AccessMatters Comments).

b. "Unintended pregnancies have higher rates of long-term health complications for women and their infants. Women with unintended pregnancies are more likely to delay prenatal care, leaving their health complications unaddressed and increasing risk of infant mortality, birth defects, low birth weight, and preterm birth. Women with unintended pregnancies are also at higher risk for maternal morbidity and mortality, maternal depression, and experiencing physical violence during pregnancy.[30]" J.A. 599 (AccessMatters Comments).

c. "Birth control is also vital in furthering equal opportunity for women, enabling women to be equal participants in the social, political, and economic life of the nation. By enabling women to decide if and when to

[29] U.S. Census Bureau. Income, Poverty, and Health Insurance Coverage in the United States: 2008, Table A-2. 2009

[30] Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. JAMA 2006;295:1809-23; 19 Tsui AO, McDonald-Mosley R, Burke AE. Family Planning and the Burden of Unintended Pregnancies. Epidemiologic Reviews. 2010;32(1):152-174. doh 1 0.1093 /epirev/mxg012

become parents, birth control allows women to access more professional and educational opportunities. . . . Studies show that access to contraception has increased women's wages and lifetime earnings.[31] In fact, the availability of the oral contraceptive pill alone is associated with roughly one-third of the total wage gains for women born from the mid-1940s to early 1950s.[32] Access to oral contraceptives may also account for up to one-third of the increase in college enrollment by women in the 1970s,[33] which was followed by large increases in women's presence in law, medicine, and other professions.[34]" J.A. 1057 (NARAL Pro-Choice America Comments).

d. "The Department of Health and Human Services has previously acknowledged that the contraceptive coverage benefit enables "women to achieve equal status as health and productive members of the job force." (77 Fed. Reg. 8725, 8728). Lower education, career level, and earnings are

[31] See, Jennifer J. Frost & Laura Duberstein Lindberg, Reasons for Using Contraception: Perspectives of US Women Seeking Care at Specialized Family Planning Clinics, 87 CONTRACEPTION 465, 467 (2013); Adam Sonfield, et al., Guttmacher Ist., The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children (2013), available at http://

[32] See Martha J. Bailey et al., The Opt-in Revolution? Contraception and the Gender Gap in Wages, 19, 26 (Nat'l Bureau of Econ. Research Working Paper o. 17922, 2012), http://www.nber.org/papers/wl 7922 (last visited Feb. 9, 2016); Claudia Goldin & Lawrence F. Katz, The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions, 110 J. Pol. Econ. 730, 749 (2002).

[33] Heinrich H. Hock, The Pill and the College Attainment of American Women and Men 19 (Fla. State Univ., Working Paper 2007).

[34] Claudia Goldin & Lawrence F. Katz, The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions, 110 J. Pol. Econ. 730, 749 (2002), https://dash.harvard.edu/handle/1/2624453.

important social determinants of health, and can be considered social risk factors for poor health outcomes. Access to birth control enables women to be more financially secure, which mitigate [sic] social risk and improve health." J.A. 1095 (National Center for Health Research).

e. "By improving women's social and economic status, access to contraception promotes equal opportunities far beyond the health care realm. Contraception allows women to decide if and when to become parents, creating more professional and educational opportunities. Indeed, the U.S. Supreme Court found that "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives."[35] Increased control over reproductive decisions in turn, provides women with educational and professional opportunities that have increased gender equality over the decades since birth control was introduced." J.A. 1147 (National Health Law Program Comments).

f. "[R]esearch links women's access to contraception with increases in the pursuit of professional degrees and career paths with higher pay and prestige, which leads to women's increased earning power and the narrowing of the gender pay gap. Expanding opportunities for employers to deny providing contraceptive coverage will reverse the positive trends

[35] *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 856 (1992); *see also Erickson v. Bartell Drug Co.*, 141 F. Supp. Ed 1266, 1273 (W.D. Wash. 2001) ("[T]he adverse economic and social consequences of unintended pregnancies fall most harshly on women and interfere with their choice to participate fully and equally in the marketplace.") (internal quotations omitted).

toward achieving gender parity, and have a tremendous adverse effect on women's health and well-being." J.A. 1249 (New York State Department of Financial Services Comments).

g. "Significantly, access to contraceptive coverage has given women the option to delay childbearing and pursue additional education, spend additional time in their careers, and increase earning power over the long-term. One-third of the wage gains women have made since the 1960s have been attributed to access to oral contraceptives.[36] Access to birth control has helped narrow the wage gap between women and men. The decrease in the wage gap among 25 to 49-year-olds between men's and women's annual incomes would have been 10 percent smaller in the 1980s and 30 percent smaller in the 1990s in the absence of widespread legal birth control access for women.[37]" J.A. 1386 (State Attorneys General Comments).

V. The Final Religious and Moral Exemption Rules

60. On November 7, 2018, the Agencies issued two new rules that "finalize" the IFRs "with changes based on public comments." J.A. 1–55 (Final Religious Exemption Rule); J.A. 56–95 (Final Moral Exemption Rule).

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[36] *Birth Control Has Expanded Opportunity for Women – in Economic Advancement, Educational Attainment, and Health Outcomes*, Planned Parenthood 1,1 (June 2015, http://www.plannedparenthood.org/files/1614/3275/8659/BC_factsheet_may2015_updated_1.pdf.

[37] *See* Martha J. Bailey et al., *The Opt-In Revolution? Contraception and the Gender Gap in Wages* 27 (Nat'l Bureau of Econ. Research, Working Paper No. 17322, 2012), http://www-personal.umich.edu/~baileymj/Opt_In_Revolution.pdf.

61. Defendants estimated that at least 70,515 and at most 126,400 women will lose contraceptive coverage when their employers claim exemptions under the Rules. J.A. 40–47; 89–92.

62. The first number, 70,515, represented the Defendants' estimate based on the number of employers that have litigated against the contraceptive mandate or who took advantage of the accommodation.

63. Defendants estimated the number of women affected by currently litigating employers who will use the new religious exemption as follows:

64. Defendants began with an estimate that the employers still litigating over the mandate employ 49,000 persons. J.A. 40–41; *see* Ex. 140.

65. Because 60% of employees, on average, are covered by their employer's health benefits, Defendants estimated that the litigating employers employ 29,000 persons. J.A. 41. Sixty percent of 49,000 is actually 29,400.

66. Defendants estimated that each employer policyholder has one dependent, resulting in 58,000 covered persons. J.A. 41. (Should be 58,800.)

67. Because women of childbearing age (15-44) constitute 20.2% of the U.S. population, and because 43.6% of women use contraception covered by the Guidelines, Defendants estimated that 5,200 women would be affected by the loss of contraceptive coverage. J.A. 41.

68. Defendants also estimated that educational institutions litigating over the mandate provide student plans that cover 2,600 students. J.A. 41. Assuming that half of those students are women and that each has a dependent of

childbearing age, Defendants estimated that 1,150 female students would be affected by the loss of contraceptive coverage. J.A. 41.

69. This results in a total of 6,400 women who work for a litigating employer or study at a litigating school and who would lose contraceptive coverage. J.A. 41.

70. Defendants estimated the number of women affected by currently accommodated employers who will use the new religious exemption as follows:

71. Defendants began by noting that in 2017, there were 1,823,000 employees and beneficiaries covered by plans offered by self-insured employers who took advantage of the accommodation and whose Third Party Administrators (TPAs) sought reimbursement under the fee adjustment provision, 45 C.F.R. § 156.50(d)(3)(iii). J.A. 41.

72. Defendants assumed that all TPAs for self-insured plans using the accommodation sought user fee adjustments in 2017. J.A. 42.

73. The Department of Labor estimates that, among persons covered by employer-sponsored insurance in the private sector, 37.3 percent were covered by fully insured plans. J.A. 42. Extrapolating from the number of persons covered by plans offered by self-insured employers using the accommodation, Defendants estimated that 1,084,000 000 employees and beneficiaries were covered by fully-insured plans using the accommodation. J.A. 42.

74. This resulted in a total of 2,907,000 employees and beneficiaries covered by plans taking advantage of the accommodation. J.A. 42.

75. Defendants then assumed that these 2,907,000 employees and beneficiaries are associated with only 209 entities are using the accommodation. J.A. 41.

76. Defendants assumed that 100 entities would continue to use the accommodation. J.A. 42.

77. Defendants then assumed that these 100 entities would account for 75% of all persons covered by accommodated plans. J.A. 42.

78. Correspondingly, the 109 entities that will use the new exemptions represent only 25% of all persons currently covered by accommodated plans. J.A. 42. Defendants calculated this figure to be 797,000 persons. J.A. 43.

79. Applying the percentage of women of childbearing age (20.2%) and percentage of women who use contraception covered by the Guidelines (43.6%), Defendants calculated that 64,000 woman who are covered by currently accommodated entities would lose coverage. J.A. 43.

80. Combining the number of women affected by litigating entities claiming the new religious exemption with the number of women affected by accommodated entities claiming the new religious exemption, Defendants estimated that 70,500 women would lose contraceptive coverage due to the Final Religious Exemption Rule. J.A. 43.

81. Defendants estimated that 15 women would lose contraceptive coverage due to the Final Moral Exemption Rule, as follows:

82. In the absence of any data, Defendants estimated that nine nonprofit entities will use the moral exemption. J.A. 89–90. Defendants then

assumed that these entities would only hire persons who share their moral convictions, just as churches generally only hire persons who share their religious convictions. J.A. 90. Therefore, they estimated that no woman working for a nonprofit that uses the moral exemption would be affected. J.A. 90.

83. Defendants also assumed that no institute of higher education would use the moral exemption. J.A. 90

84. In the absence of any data, Defendants estimated that nine for-profit entities would use the moral exemption. J.A. 91.

85. Defendants then assumed that these nine entities would employ fewer than 100 employees and an average of 9 policyholders. J.A. 91.

86. Assuming that each policyholder has one dependent, Defendants calculated that 162 covered persons could work for for-profit employers using the moral exemption. J.A. 91.

87. Applying the same percentage of women of childbearing age (20.2%), but a different percentage of women who use contraception covered by the Guidelines (44.3%), Defendants calculated that 15 woman would lose coverage due to the Final Moral Exemption Rule. J.A. 91.

88. The second number, 126,400, estimates the number of women currently working for employers who did not provide contraceptive coverage prior to the ACA:

89. Defendants began by calculating that 64.2 million women under age 65 were covered by private sector employer-sponsored insurance in 2017. J.A. 43–44. Defendants then eliminated the 5% of women who are covered by employer-sponsored plans but do not use their employer-sponsored plan as their

primary source of health insurance. J.A. 44. This resulted in 61 million women. J.A. 44. Defendants further eliminated the 3.8% of women who are self-employed, resulting in 58.7 million women. J.A. 44.

90. Using data about grandfathered plans, Defendants then estimated that 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based non-grandfathered plans. J.A. 44.

91. Because 46.7% of women under age 65 are of childbearing age, Defendants calculated that 22.9 million of childbearing age received primary health insurance coverage from private sector, third party employment-based non-grandfathered plans. J.A. 44.

92. Data shows that prior to the ACA, 6% of employers did not offer contraception and 31% did not know whether they offered contraceptive coverage. J.A. Using the 6% figure only, as well as percentage of women who use contraception covered by the Guidelines (43.6%), Defendants estimated that 599,000 women of childbearing age who use contraception were covered by plans that omitted contraceptive coverage prior to the ACA. J.A. 44.

93. Defendants then assumed that no publicly traded company would use the new religious exemption. This eliminated the 31.3% of employees in the private sector who work for publicly traded companies, leaving 411,000 women. J.A. 44.

94. Next, Defendants attempted to calculate how many women work for employers already exempt under the Church Exemption. Defendants estimated

that there are approximately 24,200 Catholic churches and integrated auxiliaries in the United States. J.A. 45. They noted that Guidestone, a self-insured church plan organized by the Southern Baptist Convention, covers 38,000 employers. J.A. 45. They also noted that Christian Brothers, a self-insured church plan covering Catholic organizations, covers the 24,000 Catholic churches and auxiliaries listed above as well as 500 additional entities not exempt as churches. J.A. 45. In total, Defendants estimated 62,000 church and church plan employers. J.A. 45. Using the number of persons covered by Guidestone (220,000) as transferable ratio, Defendants calculated that 32,100 women of childbearing age who use contraceptive work for already-exempted employers. J.A. 45.

95. In sum, Defendants estimated that 379,000 women of childbearing age who use contraception work for private, non-publicly traded employers that did not cover contraception pre-ACA and are not exempt under the Church Exemption. J.A. 45.

96. Defendants then assumed that only one third of these employers would be able to claim the new religious exemption. J.A. 45. Therefore, only 126,400 women would be impacted. J.A. 45.

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