

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and
STATE OF NEW JERSEY,

Plaintiffs,

v.

No. 2:17-cv-04540-WB

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

Defendants,

and

LITTLE SISTERS OF THE POOR SAINTS PETER AND
PAUL HOME,

Intervenor-Defendant.

**STATES' OPPOSITION TO MOTIONS FOR SUMMARY JUDGMENT FILED BY
DEFENDANTS AND INTERVENOR-DEFENDANT AND REPLY MEMORANDUM OF
LAW IN SUPPORT OF STATES' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Plaintiffs the Commonwealth of Pennsylvania and the State of New Jersey (the “States”) respectfully submit this opposition to the motions for summary judgment filed by Defendants and Intervenor in the above matter, and reply in support of the States’ motion for summary judgment. Since its inception, this case has been about two sweeping rules that authorize virtually any employer, college or university, or other health plan sponsor to deny women access to necessary preventive care. These rules deny women access to the “full and equal” contraceptive care to which Supreme Court has recognized Congress entitled them, and instead allow employers to impose their own views on their employees. In so doing, they treat contraception—and women’s healthcare generally—as a second-class service.

Despite the best efforts of Defendants and Intervenor to focus on other matters, nothing in their motions changes these basic realities. The Rules were invalidly issued; they violate federal statutes; they are discriminatory; and they unlawfully impose the religious views of employers on their employees. For all these reasons, they should be struck down.

DISCUSSION

I. THE RULES ARE INCONSISTENT WITH THE ACA AND NOT AUTHORIZED BY RFRA

A. The Rules Violate the ACA

This Court has twice held that the Rules are inconsistent with the requirements of the Women’s Health Amendment. *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 821 (E.D. Pa. 2019); *Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 579 (E.D. Pa. 2017). Defendants and Intervenor offer no persuasive justification for disturbing those previous decisions, instead largely repeating the same arguments the Court previously rejected. The language of the Women’s Health Amendment is mandatory: groups health plans and health insurance issuers

“shall, at a minimum, provide coverage for and shall not impose any cost sharing requirements for” preventive services for women identified by HRSA. 42 U.S.C. § 300gg-13(a)(4). As the Court has recognized, the statute grants HRSA the discretion to identify *what* preventive services must be covered, but it does not allow it to determine *who* must provide those services.¹ 351 F. Supp. 3d at 817. The *who* is clear: any “group health plan and a health insurance issuer offering group or individual health insurance coverage.” And in case the use of “shall” was not clear enough, Congress added “at a minimum” to drive the point home.

Defendants fall back on their arguments that the phrases “for purposes of this paragraph” and “as provided for” confer upon the Agencies the discretion to go beyond the “what” and determine the “who.” Defs. Br. 11–12. They do not explain how they read such discretion into “for purposes of this paragraph”—particularly since the “paragraph” in question only addresses the “what,” while the “who” is set forth in the introductory language of 42 U.S.C. § 300gg-13(a) and applies equally to the four paragraphs that follow. Defendants and Intervenor do not dispute that the requirements of paragraphs (1) through (3) are mandatory, and offer no explanation of how the introductory language means different things applied to different provisions.

As to “as provided for,” this Court has previously determined that the language simply reflected an acknowledgement that the relevant guidelines did not exist at the time Congress enacted the Women’s Health Amendment, which explains why “as” was omitted from previous paragraphs in § 300gg-13(a), which referenced guidelines that *did* exist. 351 F. Supp. 3d at 820. And even if the Agencies’ reading of “as” were correct, it still does not support their ultimate

¹ Intervenor confuses this distinction, arguing that HRSA’s decision to require (for instance) coverage of mammograms only for women over 40 somehow suggests that HRSA’s discretion is broader than this Court previously recognized. Int. Br. 13. But “mammograms for women over 40” is an example of *what* must be covered; it does not change the *who* in any way.

conclusion that the paragraph grants them authority to dictate the *who* as well as the *what*. Paragraph (4) requires plans to cover “with respect to women, *such* additional preventive care and screenings not described in paragraph (1) *as provided for* in [HRSA guidelines]” § 300gg-13(a)(4) (emphasis added). Here, “such” means “of a kind or character to be indicated or suggested.”² The phrase “as provided for” and all that follows are doing the indicating—that is, they answer the question posed by “such” of what “additional preventive care and screenings not described in paragraph (1)” are required to be covered (i.e., those HRSA includes in guidelines). So under any interpretation, HRSA’s authority extends only to the *what*, not the *who*. And because the statute is clear, the Agencies’ reliance on *Chevron* is of no use to them. *Chevron v. NRDC*, 467 U.S. 837 (1984). *Chevron* applies to reasonable agency interpretation of ambiguous statutes; it is not a license to disregard the rules of grammar.

Finally, Intervenor repeats its arguments that the States’ rationale would threaten the legality of the preexisting church exemption and accommodation, and that this fact requires the Court to uphold the Rules. In *Real Alternatives*, the Third Circuit discussed the church exemption at length and found that it was consistent with the “longstanding governmental recognition of a particular sphere of autonomy for houses of worship,” *Real Alternatives, Inc. v. Sec’y HHS*, 867 F.3d 338, 350 (3d Cir. 2017) (quoting *J.A.* 195), relying on cases such as *Hosanna-Tabor Evangelical Lutheran Church and School v. EEOC*, 565 U.S. 171 (2012). Intervenor asserts that this doctrine (often referred to as the “ministerial exception”) is a “poor fit,” Int. Br. 16–17, but it never actually answers whether it believes that it provides authority for the church exemption. In its original lawsuit challenging the mandate, however, Intervenor argued that the doctrine *did* require exemptions for religious institutions—it just claimed that it

² *Such*, Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/such>.

required a broader exemption than the original church exemption. *See* Compl., *Little Sisters of the Poor Home for the Aged v. Sebelius*, No. 13-2611 Count VI (D. Colo. Sept. 24, 2013) (alleging “Interference in Matters of Internal Religious Governance”); *see also id.* ¶ 243 (“The Final Mandate’s narrow exemption for ‘religious employers’ but not others discriminates among religions on the basis of religious views or religious status.”); *id.* But it ultimately chose not to press these claims.

The States do not take a position on this question, because it is completely beside the point in this lawsuit. Rather, the above discussion simply confirms the correctness of this Court’s determination that “[w]hether a party could have brought a successful challenge to the procedures followed in the past is not before the Court.” 351 F. Supp. 3d at 815. The States here seek vacatur of the Rules because the agencies had no authority to issue them. These repeated attempts to make this case about everything but the legality of the Rules only highlight just how weak the legal justifications provided for them actually are.

B. The Federal Defendants Are Estopped from Arguing that the Rules Are Authorized by the ACA

Although the Court should reject Defendants’ argument on its merits, Defendants should also be estopped from continuing to defend the Rules on the ground that they are authorized by the Affordable Care Act. As the Third Circuit has long recognized, the equitable doctrine of judicial estoppel “prevents a party from assuming a position inconsistent with one which it took in a prior proceeding.” *McCarron v. F.D.I.C.*, 111 F.3d 1089, 1097 (3d Cir. 1997) (citation omitted). The doctrine exists “to prevent a party from playing ‘fast and loose’ with courts by asserting contradictory positions.” *Id.* (citing *United States v. Vastola*, 989 F.2d 1318, 1324 (3d Cir. 1993)). While asserting in this case that the ACA contains a “positive grant of authority” to

issue the Rules, Defendants have claimed elsewhere that the ACA “is invalid in its entirety.” Br. for the Fed. Defs., *Texas v. United States* at 18, No. 19-1011 (5th Cir. May 1, 2019).

To be clear, the States wholeheartedly disagree with the argument Defendants have advanced in *Texas*. The ACA is constitutional, period. But Defendants cannot have it both ways: while arguing in *Texas* that the ACA is invalid in its entirety, Defendants cannot simultaneously maintain the position in this case that the ACA provides them with a “positive grant of authority” to enact the Rules.

The States have consistently disagreed with the Agencies’ prior position that the ACA grants them authority for the Rules. Specifically, the States have argued, and the Court has agreed, that the plain terms of the ACA do not allow the Agencies to grant broad exemptions from Congress’s clear mandate. And the Agencies, at least according to their position in *Texas*, now apparently agree that the ACA does not grant them authority for the Rules. The fact that the Agencies arrive at this conclusion through different logic is irrelevant: if the ACA is perfectly valid but does not authorize the Rules (as the States contend), the Rules must be struck down; if it is not valid (as the Agencies contend), they must also be struck down. Either way, the States should prevail in this case.

C. The Religious Exemption Rule Is Not Authorized by RFRA

In defending the Rules as a legitimate exercise of the Agencies’ authority under the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.* Defendants and Intervenor disregard the fact that the mandate derives from an act of Congress, which make the provision of preventive services to women mandatory for covered health plans. Whatever authority agencies

may derive from RFRA, it does not give them the power to create wholesale exemptions from federal law based upon their own unsupported views about what RFRA requires.³

1. The Accommodation Does Not Impose a Substantial Burden

The Agencies' assertion that the Religious Exemption Rule is required by RFRA is premised on their conclusion that the accommodation imposed a substantial burden on religious exercise. *See* Defs. Br. 16. Their analysis on this point was extremely brief—occupying slightly more than one column in the *Federal Register*, J.A. 11—and cited only two cases: *Hobby Lobby* (which took pains not to address this question), and a decision of the Eighth Circuit that the Agencies fail to mention was vacated by the Supreme Court. *See Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927 (8th Cir. 2015), *cert. granted, judgment vacated sub nom. HHS v. CNS Ministries*, No. 15-775, 2016 WL 2842448, at *1 (May 16, 2016).

Defendants attempt to shore up the conclusions of the Rule by suggesting that little analysis on this point was required. They assert it is “not for the courts to question the determination by certain entities that the accommodation requires them to violate the tenets of their faith by making them complicit in the provision of contraceptive coverage.” Defs. Br. 17. But the Third Circuit has reached the opposite conclusion: It has held that the existence of a substantial burden is “the threshold inquiry posed to any individual attempting to bring a successful RFRA claim, and it is undoubtedly for the court to answer whether it has been satisfied.” *Real Alternatives*, 867 F.3d at 358. And in assessing whether government action imposes a substantial burden, “the connection between the conduct and the religious belief

³ Even Defendants do not go so far as to advance the argument made by Intervenor that the Agencies' conclusions in the Rules can be justified based on the Agencies' own decision, following the issuance of the IFRs, not to contest RFRA challenges to the mandate, leading to unopposed injunctions entered in those cases. *See* Int. Br. 26–29.

matters, for the law distinguishes between direct participation and remote facilitation, treating the former as compelling and the latter as negligible.” *Id.* at 361 (cleaned up). Thus, while plaintiffs in *Real Alternatives* alleged that their “sincerely held religious beliefs prohibit them from using, supporting, or otherwise advocating the use of abortifacients, or participating in a health insurance plan that covers such items for themselves or their families,” *id.* at 346, the court nevertheless concluded that such assertions did not establish a substantial burden, *id.* at 363.

Thus, while courts may not question the reasonableness of a person’s religious beliefs, they are required to assess whether the government action at issue imposes a substantial burden on those beliefs. And here, eight of nine circuits to address the issue before *Zubik* held that the accommodation did *not* impose a substantial burden.⁴ They did so because, as the Third Circuit recognized in *Geneva College*, [f]ederal law, rather than any involvement by the appellees in filling out or submitting the self-certification form, creates the obligation of the insurance issuers and third-party administrators to provide coverage for contraceptive services.” 778 F.3d at 437.⁵

⁴ *Geneva Coll. v. Sec’y HHS*, 778 F.3d 422 (3d Cir. 2015); *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151 (10th Cir. 2015); *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207 (2d Cir. 2015); *E. Texas Baptist Univ. v. Burwell*, 793 F.3d 449, 452 (5th Cir. 2015); *Michigan Catholic Conference & Catholic Family Servs. v. Burwell*, 807 F.3d 738 (6th Cir. 2015); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 618 (7th Cir. 2015); *Eternal Word Television Network, Inc. v. Sec’y HHS*, 818 F.3d 1122 (11th Cir. 2016); *Priests For Life v. HHS*, 772 F.3d 229 (D.C. Cir. 2014). All of these decisions were vacated by the Supreme Court in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

⁵ Intervenor repeats the claim that *Geneva College* “was procured on incorrect facts, which the government later admitted.” Int. Br. 21. It appears to base this assertion largely on a sentence from the government’s brief in *Zubik*, which is contained in a longer description of the mechanics of the accommodation. That sentence addresses—with respect to self-insured plans only—the legal status under ERISA of the contraceptive coverage administered by the plan’s third-party administrator. The longer passage reads as follows, with the language quoted by Intervenor underlined:

Nor does the government, in fact, provide contraceptive coverage using any “plan infrastructure” belonging to petitioners. If an objecting employer has an insured plan, the regulations provide that the insurer must “[e]xpressly exclude

It quoted approvingly Judge Posner’s conclusion in *Notre Dame* that “[f]ederal law, not the religious organization’s signing and mailing the form, requires health-care insurers, along with third-party administrators of self-insured plans, to cover contraceptive services.” 743 F.3d at 554.

While *Zubik* vacated these decisions, it did nothing to call into question their logical underpinnings. If the substantial burden analysis were as Defendants suggest—and essentially

contraceptive coverage from the group health insurance coverage provided in connection with the group health plan” and must instead “[p]rovide separate payments” for contraceptive services. If an objecting employer has a self-insured plan subject to ERISA, the Departments’ authority to require the TPA to provide contraceptive coverage derives from ERISA. As a result, the coverage provided by the TPA is, as a formal ERISA matter, part of the same “plan” as the coverage provided by the employer. But an ERISA plan in this sense is simply “a set of rules that define the rights of a beneficiary and provide for their enforcement.” The rules governing contraceptive coverage are established by the government, not the employer, and the employer does not fund, control, or have any other involvement in that separate coverage—instead, the TPA alone does so.

Br. for the Resp’ts, *Zubik*, 136 S. Ct. 1557. at 38-39 (footnotes and citations omitted) (cited in Int. Br. 21). It is not clear how the underlined language (or any of the other passages cited by Intervenor) can be fairly read as an admission by the government that it had “procured” an earlier judicial decision on “incorrect facts,” particularly since Intervenor has not pointed to any specific earlier statements from the government contradicting the above assertion. Nor does Intervenor explain why the status of contraceptive coverage “as a formal ERISA matter” is relevant to the substantial burden analysis, particularly given the subsequent statement that “[t]he rules governing contraceptive coverage are established by the government, not the employer, and the employer does not fund, control, or have any other involvement in that separate coverage—instead, the TPA alone does so” (as well as the fact that it does not apply to self-insured plans at all). And, finally, if the government’s concession was so fatal to its case (and contradicted its earlier claims to the Third Circuit), it is surprising that the Supreme Court did not even mention that fact in *Zubik*, much less rely on it to rule against the government. (Referring to this “concession,” Intervenor falsely asserts, “The Supreme Court itself recognized the government’s ‘substantial clarification and refinement’ in its position . . . ” Int. Br. at 23 (quoting *Zubik*, 136 S. Ct. at 1560). But the quoted language actually referred to “the substantial clarification and refinement in the positions of *the parties*” (emphasis added), *which included Intervenor*, and it did so in reference to their responses to the Court’s request for post-argument supplemental briefing and not based on any prior “concession” from the government.)

As a result, it is difficult to see how this argument is relevant to this case, which is about the legality of the Rules issued by Defendants. Regardless, Intervenor recently made the same argument to a panel of the Third Circuit, which included a member of the *Geneva College* panel. So presumably if that court agrees that it was misled by the government, it will so state.

required courts to accept plaintiffs' assertions—it is hard to see why eight circuits got the question so wrong, and why the Supreme Court in *Zubik* did not at least point out that the decisions were so off-base.

2. The Agencies Wrongly Concluded that the Mandate Does Not Serve a Compelling Interest

Even if the accommodation were found to impose a substantial burden, it would still be permissible under RFRA because the government has a compelling interest in providing women with “full and equal” access to contraceptive coverage, and the accommodation is the least restrictive means of doing so. Defendants offer little basis for challenging the latter conclusion, and the arguments they offer with respect to the former amount to a recitation of what they argued in the Rules. But as discussed below, *see infra* Part VI.A, the Agencies' conclusions with respect to the safety and efficacy of contraception are deeply flawed and certainly cannot justify an about-face on such a critical issue as to whether the mandate does serve a compelling interest.

In fact, prior to the IFRs, the existence of a compelling interest went largely unquestioned. The *Hobby Lobby* majority assumed without deciding that such an interest exists. *Burwell v. Hobby Lobby*, 573 U.S. 682, 728 (2014). Justice Kennedy and the four dissenters both emphasized this point. *Id.* at 737 (Kennedy, J., concurring) (“It is important to confirm that a premise of the Court’s opinion is its assumption that the HHS regulation here at issue furthers a legitimate and compelling interest in the health of female employees.”); *id.* at 761 (Ginsburg, J., dissenting); *see also Priests for Life v. HHS*, 808 F.3d 1, 23 (D.C. Cir. 2015) (Kavanaugh, J.) (“In light of the numerous benefits that would follow from reducing the number of unintended pregnancies, it comes as no surprise that Justice Kennedy’s opinion expressly referred to a ‘compelling’ governmental interest in facilitating women’s access to contraception.”). Given this

precedent—and the lack of sufficient scientific evidence in the Rules to overturn the Agencies’ prior consensus—the Agencies’ conclusion cannot be justified.

II. THE RULES CREATE UNREASONABLE BARRIERS TO MEDICAL CARE

Section 1554 of the ACA bars the Secretary of HHS from issuing any regulation that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care.” 42 U.S.C. § 18114(1).⁶ As the States explained, the Rules do just that, by making it more difficult for women to obtain care to which they are legally entitled. Pls. Br. 20–21. In response, Defendants do not try to dispute that the Rules will make it more difficult for some women to obtain contraceptive care. Rather, they argue that the Rules reflect a ““decision not to impose a governmental mandate,”” and therefore do not violate this provision. Defs. Br. 19 (quoting J.A. 17).⁷ Intervenor makes virtually the same argument, asserting that the Agencies merely “fail[ed] to extend a mandate.” Int. Br. 29.

But that is not what happened at all. Congress enacted the Women’s Health Amendment, which required health plans to cover preventive services for women, and it directed HRSA to

⁶ In their opening brief, the States discussed three recent decisions relying on Section 1554 to enjoin regulations governing Title X clinics. Pls. Br. 20-21 (citing *Oregon v. Azar*, No. 19-317, 2019 WL 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)). Those injunctions were stayed by the Ninth Circuit after the States filed their brief. *California v. Azar*, No. 19-15974, 2019 WL 2529259 (9th Cir. June 20, 2019). Plaintiffs-Appellees in those cases have petitioned for *en banc* review of the decision staying the injunctions.

⁷ Defendants attempt to write this provision out of the law entirely by arguing that claims under section 1554 are “not reviewable under the APA at all.” Defs. Br. 19. But the exception to the APA’s presumption of justiciability they cite is “very narrow” and applies only when decisions are ““committed to agency discretion by law.”” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (quoting 5 U.S.C. § 701). It makes no sense to suggest that compliance with the requirements of section 1554—all of which are limits on the agency’s authority—is nonetheless “committed to agency discretion by law.”

determine which preventive services plans must cover. HRSA concluded that contraception was one such service. So the Rules reflect the Agencies' choice to allow certain plan sponsors to *deny* women the benefits of the Mandate—rather than a decision “not to impose” a mandate in the first place.

III. THE RULES VIOLATE TITLE VII AND SECTION 1557 OF THE ACA

The Rules violate Title VII of the Civil Rights Act as well as section 1557 of the ACA, both of which prohibit discrimination on the basis of sex.⁸ Because discrimination on the basis of sex includes “pregnancy, childbirth, or related medical conditions,” 42 U.S.C. § 2000e(k), if 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.” *Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1272 (W.D. Wash. 2001). But here, the Rules specifically authorize employers to exclude from coverage drugs and devices for women—and only women.

⁸ Intervenor argues that section 1557 should be read to incorporate the exemption for religious organizations set forth in Title IX, relying on *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016). The district judge in that case held that section 1557's prohibition of discrimination “on the ground prohibited under . . . title IX of the Education Amendments of 1972” must incorporate the exceptions set forth in Title IX, because Congress used the phrase “et seq.” in a parenthetical citation to the U.S. Code. *Id.* Notwithstanding Congress's clear reference to “the ground prohibited under . . . title IX” (i.e., “on the basis of sex,” 18 U.S.C § 1681(a)), the *Franciscan Alliance* court held that the use of “et seq.” in the parenthetical “can only mean Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions.” 227 F. Supp. 3d at 690–91. (There are several other exceptions in Title IX, including those for “fraternities and sororities,” “father-son or mother-daughter activities,” and “scholarship awards in ‘beauty’ pageants.” § 1681(a)(6), (a)(8), (a)(9).) The States submit that the better reading of this provision is that Congress intended to incorporate only the “ground prohibited under” Title IX, which is why it used those precise words.

Defendants simply miss the point of the States' Title VII claim. Because the Rules allow employers to engage in such discrimination by denying women access to required preventive services, they must be invalidated under the APA. Defendants' argument to the contrary implies that they are free to issue regulations permitting employers to discriminate on the basis of sex, without being subject to legal challenge. But the APA requires courts to strike down agency action that is "not in accordance with law." 5 U.S.C. § 706(2)(A). The fact that Title VII provides a separate right of action for employees who have suffered discrimination does not preclude actions under the APA alleging that an agency has undertaken action "not in accordance" with that provision.⁹ *Pima County Community College District v. EEOC*, No. 75-210, 1976 WL 548 (D. Ariz. Apr. 7, 1976), demonstrates that claims alleging violations of Title VII can be brought under the APA. In that case, the court allowed an employer to pursue an APA claim against the EEOC, arguing that the agency had not followed the requirements of Title VII in the way it handled discrimination claims brought by several of its employees. *Id.* at *2. Here, the States allege that the Rules are "not in accordance" with Title VII and therefore must be struck down under the APA.

The Women's Health Amendment was enacted to address the "fundamental inequity in the current system" and to stop the "punitive practices of insurance companies" toward women. J.A. 2437, 2378. The Institute of Medicine entitled its report "Closing the Gaps," precisely because then-existing guidelines for preventive services were not written with women in mind and therefore left out certain essential services for women. J.A 313–561. The Rules, however, deny some women the equal treatment the Amendment sought to require. In fact, the President's

⁹ For the same reason, Defendants' claim that the States have an adequate remedy at law under Title VII itself has no merit. *See* Defs. Br. 22.

Executive Order specifically directed the Agencies to consider issuing regulations that address objections to those services provided under the Women’s Health Amendment, but said nothing about any other services mandated by the ACA or any other law. J.A. 167. So Defendants’ claims that the Rules do not authorize discrimination on the basis of sex ring hollow. As a result, they violate the prohibitions on such discrimination in Title VII and section 1557 of the ACA.

IV. THE RULES VIOLATE THE EQUAL PROTECTION GUARANTEE OF THE FIFTH AMENDMENT

Equal protection jurisprudence has consistently held that all gender-based classifications require “an exceedingly persuasive justification” in order to survive heightened judicial scrutiny. *J.E.B. v. Alabama ex rel. T.B.*, 511 U.S. 127, 137 (1994) (citing *Administrator of Mass. v. Feeney*, 442 U.S. 256, 273 (1979)). The government must demonstrate that “the [challenged] classification serves important governmental objectives” and that its discriminatory means are “substantially related to the achievement of those objectives.” *United States v. Virginia*, 518 U.S. 515, 533 (1996). Rather than trying to meet that burden, however, the Agencies ignore the clear discriminatory means employed by the Rules and twist the States’ equal protection claim into what they deem a “disparate impact” argument. Defs. Br. 24.

The Rules clearly single out women with a laser-like focus that is readily apparent in the record. By explicitly referencing *only* preventive care and services for women in § 300gg-13(a)(4), the Rules noticeably leave untouched male-specific and gender-neutral healthcare services. *See Harris v. McCrae*, 448 U.S. 297, 323 n. 26, 326 (1980) (holding that the equal protection component of the Fifth Amendment prohibits “purposeful discrimination”). Despite their insistence that the Rules “do not discriminate against women on the basis of sex” (Defs. Br. 24), even now the Agencies fail to provide any meaningful justification for their targeting of women’s health care to the exclusion of other services—let alone an “exceedingly persuasive”

justification. *See J.E.B.*, 511 U.S. at 137; *see also Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1689–90 (2017) (same).

V. THE RELIGIOUS EXEMPTION RULE VIOLATES THE ESTABLISHMENT CLAUSE

The First Amendment’s Establishment Clause provides that “Congress shall make no law respecting an establishment of religion.” U.S. Const. amend. I. The Religious Exemption Rule violates the Establishment Clause because it favors the religious convictions of a vast group of employers and plan sponsors by granting them absolute power to impose substantial burdens on employees who do not share their religious beliefs. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985) (recognizing as “a fundamental principle of the Religious Clauses” that “[t]he First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities”); *Real Alternatives*, 867 F.3d at 364.

The Agencies readily emphasize the religious focus of the Religious Exemption Rule in arguing against the States’ equal protection claim; yet they retreat from that position when addressing the Establishment Clause claim. Defs. Br. 26. By its own terms, the Religious Exemption Rule aims to protect “religious beliefs[] in the context of health care and human services,” J.A. 3 (final Rule), and “individuals and entities with sincerely held religious beliefs in certain health care contexts.” J.A. 99 (IFR). The Executive Order similarly signaled its commitment to “vigorously enforce Federal law’s robust protections for religious freedom.” J.A. 167. And as is clear from the record evidence, the Rules are not grounded in either evidence or science. *See* Pls. Br. 33–35. Thus, the Agencies cannot now argue that the Rules do not “promote religion in general.” Defs. Br. at 26.

The Agencies suggest that there is no Establishment Clause violation resulting in an undue burden on women because the government was not obligated to impose a mandate for contraceptive coverage. *See* Defs. Br. 27. But they cite no case which suggests that a Rule permitting women to be denied necessary preventive services mandated by Congress is not a “burden” on those women who lose that coverage.¹⁰ And the Intervenor’s contention that “dozens of courts have held” that the Final Rule “lifts a significant state-imposed burden on religious exercise,” Defs. Br. 35, ignores the eight of nine Circuit Courts that had found to the contrary, *see supra note 4*, and instead relies on cases that the government failed to defend.

In sum, the Religious Exemption Rule impermissibly favors religious employers and plan sponsors over employees who do not share their religious beliefs, and does so in a manner that exceeds any reasonable accommodation. *See Cutter v. Wilkinson*, 544 U.S. 709, 710 (2005) (“An accommodation must be measured so that it does not override other significant interests.”); *Estate of Thornton*, 472 U.S. at 709 (holding that a State statute violated the Establishment Clause where “religious concerns automatically control[led] over all secular interests a the workplace” and the statute took no account of the interest of employees who did not share that religious view). Accordingly, the Religious Exemption Rule violates the Establishment Clause, and the States’ are entitled to summary judgment on this claim.

¹⁰ The Agencies’ reliance on *Corp. of Presiding Bishop v. Amos*, 483 U.S. 327 (1987), is misplaced. *Amos* upheld the grant of a religious exemption to Title VII’s prohibition on religious discrimination in employment. In doing so, the Court noted that the first prong of the *Lemon* test was satisfied because the exemption alleviated “significant governmental interference with the ability of religious organizations to define and carry out their religious missions.” *Id.* at 335. Unlike some decisions by certain religious organizations about who to hire and fire as an employee, the exemption here is not necessary to prevent significant government interference with a religious institution’s ability to carry out its religious mission.

VI. THE RULES ARE ARBITRARY AND CAPRICIOUS

Defendants do not dispute that they have reversed their prior conclusion that contraception is safe, effective, and beneficial for women. Defs. Br. 29–34. They do not dispute that their prior position rested on factual findings contradicting their current conclusions, nor that their prior position engendered serious reliance interests. *Id.* They do not dispute that the overwhelming majority of comments, including all comments from leading medical organizations, opposed the Rules as harmful to women’s health and in contravention of science. *Id.* 34–35. And they concede that their estimate of impacted women was “highly speculative,” *id.* 36, even as they continue to defend the Rules as reasonable because they impact only “a very small percentage of entities,” *id.* 30, 33 n.13; *see also* J.A. 13–17 & n.26 (arguing that Rules will impact “less than 0.1%” of all women in the United States and therefore will not unduly burden third parties).¹¹

Arbitrary and capricious review, though deferential, is not toothless. *See State Farm*, 463 U.S. at 43. When agencies reverse position on policies that rested on factual findings and engendered serious reliance interests—as the Agencies did here—they must provide “a more detailed justification,” including a “reasoned explanation” for “disregarding facts and circumstances that underlay or were engendered by the prior policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).¹² The Agencies must also “respond in a reasoned manner” to all public comments “that raise significant problems.” *Am. Coll. of Emergency*

¹¹ Intervenor likewise does not dispute these points, nor any of the States’ specific arguments, Pls. Br. 31–40, as to why the Rules are arbitrary and capricious. *See* Int. Br. 30–32. The Intervenor’s affirmative arguments as to why the Rules are not arbitrary and capricious, *id.*, are meritless. *See supra* Part I.C & n.5.

¹² The Agencies dispute that this standard even applies, Defs. Br. 29, though they do not refute that the necessary preconditions exist.

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)). The Agencies must also explain why they have “exercised [their] discretion in a given manner,” and their explanation must enable this Court “to conclude that the agenc[ies]’ action was the product of reasoned decisionmaking.” *Owner-Operator Indep. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 203 (D.C. Cir. 2007) (cleaned up). The Rules fail to satisfy all three requirements.

A. The Agencies Fail to Provide Reasoned Explanations for Reversing Position on the Safety, Efficacy, and Benefits of Contraception.

Defendants’ defense of their decisionmaking, Defs. Br. 29–31, epitomizes their arbitrary and capricious reasoning. First, Defendants rely on that a 2017 study they claim found no evidence that the mandate led “to an increased use of more effective methods from less effective methods.” Defs. Br. 30, 34; J.A. 20 & n.51. But the study actually showed the opposite: an increase in the use of the most effective methods from 6 percent in 2008, to 12 percent in 2012, to 14 percent in 2014. J.A. 2650, 2652. Although the study noted that the role of the mandate in these early years “remain[ed] unclear,” the study concluded that contraceptive use is shifting towards the most effective methods, which “underscore the importance of ensuring full access to the broad range of methods available.” J.A. 2654, 2650. The Agencies did the opposite. Second, Defendants justify the Rules because they are only “exempting a very small percentage of entities” and therefore not negatively impacting many women. Defs. Br. 30; *see also id.* 33 n.13¹³; J.A. 13–17 & n.26. But only six pages later, Defendants rebuff these estimates as grounded on “inadequate data” and using “highly speculative” assumptions. Defs. Br. 36.

¹³ Contrary to the Agencies’ statement, Defs. Br. 33 n.13, the States dispute both that the Final Rule impacts only a small number of women and that denying even a small number of women contraceptive coverage will not have negative health or equity effects.

Defendants cannot have it both ways. Finally, Defendants justify a broad, categorical moral exemption by pointing to just two nonprofit litigating employers. Defs. Br. 30–31. But the existence of two nonprofit objectors does not explain the need for a categorical moral exemption for all closely held for-profits, institutes of higher education, health insurance issuers, individuals, and nonprofits. Nor does it follow that because these two nonprofits hired employees with similar views, all potential moral objectors will likewise employ people who would, “by definition, not want contraceptive coverage.” Defs. Br. 31. Even Defendants’ strongest examples of reasoned decisionmaking fall flat.

In responding to the States’ specific criticisms, Defendants attempt a sleight of hand: they are not actually concluding anything about the safety, efficacy, or benefits of contraception, but instead simply explaining the importance of providing conscience-based exemptions. Defs. Br. 31–33. The Court should not be fooled. In a section titled “Health Effects of Contraception and Pregnancy,” the Agencies declined to “take a position on the variety of empirical questions discussed above”—empirical questions such as, are contraceptives safe, are contraceptives abortifacients, and has access to contraception helped lower teen pregnancy. J.A. 17–20, 73–75. All of these are questions on which Agencies *had previously* taken a position. Pls. Br. 31–36 (yes, no, yes). The Agencies’ sudden disinterest in addressing fundamental facts about a women’s preventive healthcare—and indeed, their assertion that these facts are even in dispute—is a clear divergence that requires a reasoned explanation. Federal agencies cannot manufacture a scientific debate where none existed, then used that manufactured debate to justify a policy reversal.

Defendants’ more specific arguments fare no better. First, Defendants do not dispute that each method of contraception—like every medication—must be prescribed individually. *See*,

e.g., J.A. 651, 2344–45. But they justify the Rules by treating all methods of contraception categorically: “the benefits of [all] contraceptives are more uncertain than previously recognized.” Defs. Br. 31, 33. The fallacy of this categorical assessment is borne out by the Agencies’ own citations: almost three-quarters of the cited articles address the side effects of oral contraception, which represents only three of the sixteen FDA-approved contraceptive methods. *Compare* J.A. 17–18 nn.28–34, *with* Ex. 147. The rest address hormonal contraception more broadly, which still does not cover the spectrum of contraception covered by the mandate. *Id.* Second, Defendants’ post hoc claim to have considered comments about Colorado’s contraceptive equity law, Defs. Br. 34, cannot supersede the Rules themselves, which justified the exemptions in part because “public commenters did not point to studies showing those state mandates reduced unintended pregnancies.” J.A. 20. As the States noted, Pls. Br. 36, several commenters provided just that data. Finally, Defendants do not dispute they are contradicting their earlier conclusions that cost-free access to contraception improves the social and economic status of women. Pls. Br. 35–36. That they assume only a small number of women will lose this access, Defs. Br. 33 n.13, has no bearing on whether contraception benefits women overall.

B. The Agencies Did Not Respond to Significant Comments.

At the outset, the Court should reject Defendants’ argument that this Court already determined they adequately responded to all significant comments. But this Court’s prior finding found the States were not likely to succeed in arguing that the Agencies failed to address the several comments the States proffered in their preliminary injunction motion—which was filed well before the Agencies provided the administrative record. *See* 351 F. Supp. 3d at 811–12. The States are not precluded from challenging, at the summary judgment stage and with the benefit of the full record, the Agencies’ responses to other significant comments. *See Berrigan v. Sigler*, 499 F.2d 514, 518 (D.C. Cir. 1974).

Defendants also attempt to sidestep the more than 99 percent of public comments opposing the Rules. But although an agency need not move in lockstep with the weight of comments, the “[p]resence in the record of substantial quantities of adverse comment may signal clear error of agency judgment.” *Telocator Network of Am. v. F.C.C.*, 691 F.2d 525, 538 n.106 (D.C. Cir. 1982). The ratio of comments is particularly relevant here because the Agencies relied on the existence of conscience-objecting commenters to justify the Rules. *E.g.*, J.A. 11 (“Various entities sincerely contended . . . in public comments, that complying with either the Mandate or the accommodation was inconsistent with their religious observance or practice. The Departments have concluded that withholding an exemption from those entities has imposed a substantial burden on their exercise of religion[.]”); J.A. 59 & n.5 (noting that commenters had supported a moral exemption prior to 2017). That the Agencies finalized the exemptions even though only 17 individuals or organizations supported them more than “signal[s] clear error of agency judgment.”¹⁴ The error is particularly stark for the Final Moral Exemption Rule because the Agencies have not pointed to a single commenter who expressed a non-religious moral objection to contraception.¹⁵

Defendants’ reliance on *NRDC v. E.P.A.*, 822 F.2d 104, 122 n.17 (D.C. Cir. 1987), is inapt. That case addressed whether the number of comments, “without more,” was relevant to a substantial evidence challenge under 5 U.S.C. § 706(2)(E), which applies only when agency factfinding takes place “on the record of an agency hearing.” *Id.* The States instead argue that the Agencies were arbitrary and capricious in violation of § 706(2)(A) because they failed to respond

¹⁴ Neither the Agencies nor Intervenor have pointed to any supportive comments beyond the 27 comments (representing 17 unique individuals or organizations) identified by the States.

¹⁵ Only ten comments even supported the moral exemptions. Exs. 106, 111–113, 116–120.

to the significant fact that more than 99 percent of comments opposed the Rules, treated comments in favor and in opposition as commensurate,¹⁶ and finalized exemptions that only 17 individuals or organizations favored but hundreds of thousands opposed. *See Ass'n of Data Processing Serv. Organizations, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683 (D.C. Cir. 1984) (noting that agency action supported by substantial evidence can still be arbitrary and capricious).

Defendants further dispute the significance of comments from leading American medical organizations in a rulemaking affecting women's access to preventive healthcare. Defs. Br. 35. But as the case cited by Defendants notes, “[s]ignificant comments are those which, if true, raise points relevant to the agency’s decision *and which, if adopted, would require a change in an agency’s proposed rule.*” *City of Portland, Oregon v. E.P.A.*, 507 F.3d 706, 715 (D.C. Cir. 2007) (cleaned up). The American medical community¹⁷—with expertise in healthcare, the subject of these exemptions—unequivocally opposed the Rules and presented detailed evidence that, if adopted, would have required the Agencies to rescind the Rules. *See* Pls. Br. 37. The Agencies have not reasonably explained why they chose to run counter to medical consensus and instead rely on law review articles. *See* J.A. 19 & n.42, 20 & n.53,

Defendants do not materially dispute the States’ other contentions. They do not dispute that they failed to address comments on the importance of contraceptive counseling. Pls. Br. 37. Nor do they dispute that they failed to address comments explaining that state- and federal-

¹⁶ For example, only a handful of comments challenged the safety, efficacy, and benefits of contraception. Exs. 111–113, 115–117, 119. Many more comments defended contraception. *E.g.*, Exs. 21–22, 27–29, 31, 34, 39, 41, 44, 49, 54, 61, 65, 66–68, 73–76, 78–81, 85, 86–92, 94, 102–105. Yet the Rules imply the existence of a genuine debate by repeatedly stating that “some commenters” said one thing while “other commenters” disagreed.

¹⁷ The Agencies do not point to any comment by a medical association or health professional that supported the Rules.

funded programs have insufficient capacity to meet existing needs, must less absorb any increase due to women denied contraceptive coverage by their employers. *Id.*

C. The Regulatory Impact Analysis is Arbitrary and Capricious.

Defendants' attempts to explain the unsupported assumptions and omissions in their regulatory impact analysis, Defs. Br. 35–38, should also be rejected. First, Defendants admit their estimate of 209 accommodated entities was arbitrary—indeed, any number would have done. Defs. Br. 37 (stating that the number “provides added color or context” but ultimately served no purpose). But Defendants cannot so easily dismiss this figure. They explicitly reaffirmed 209 as “the best estimate available” for accommodated entities, J.A. 41, despite the more than doubling of employees and beneficiaries covered by accommodated insurance plans from 2015 to 2017, Pls. Br. 38–39. The Agencies also used this number when explaining why the Rules would not pose additional costs on third party administrators and issuers. J.A. 39. More fundamentally, the Agencies reached this estimate by adding the number of nonprofits challenging the accommodation with the number of closely held for-profit entities challenging the mandate. J.A. 40. Extrapolating the impact on woman using the number of litigating entities is a core part of the Agencies' impact analysis. J.A. 40–43. If this number is simply “color,” then Defendants have called into question their entire methodology.

Second, Defendants provide no basis for assuming that *only one third* of private, non-publicly traded employers who did not cover contraception pre-ACA, were not self-insured church plans, and could not claim the church exemption would have a religious objection to contraception. Their calculation of 379,000 women of childbearing age who use contraception and work for these employers already incorporated the six percent of employers who knew they provided no contraceptive coverage. The Agencies explained that these six percent “may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31

percent . . . who did not know whether the coverage was offered.” J.A. 44 & n.103. The Agencies declined to account for this 31 percent precisely because “these employers’ lack of knowledge . . . suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage.” *Id.* Having already tilted the calculation in favor of religious objectors, the Agencies’ final elimination of two-thirds of these women is arbitrary.

Third, Defendants do not dispute that they lack evidence of any accommodated entity publicly committing to continue using the accommodation in spite of the new exemptions, rendering this assumption “highly speculative,” Defs. Br. 36. *Compare* Defs. Br. 37–38, with Pls. Br. 39. And finally, contrary to Defendants’ assertion in their brief, the Rules did not determine that the economic impact from the individual exemption “would be minimal because spouses and dependents would likely share the faith of the policy holder.”¹⁸ Defs. Br. 36 (citing J.A. 33–34).

VII. THE RULES ARE PROCEDURALLY INVALID

This Court has previously held that the Agencies were not granted express statutory authority to forego the procedures set forth in the APA; that they lacked good cause to do so; and that the subsequent acceptance of post-promulgation comments did not cure their procedural failings. *See* 281 F. Supp. 3d at 571–76; 351 F. Supp. 3d at 812–16. These decisions were correct, and Defendants and Intervenor have provided no basis for reconsidering them.

A. The Acceptance of Post-Promulgation Comments Does Not Render the Rules Procedurally Valid

While they do not challenge the first two conclusions in any meaningful way, Defendants continue to argue that their acceptance of post-promulgation comments justifies their failure to

¹⁸ The States did challenge the individual exemption. If an individual claims an exemption, his or her female dependents will lose coverage. Ex. 149 ¶ 17. Some of these women will turn to state-funded programs and some will forgo contraception altogether, leading to an increased risk of unintended pregnancy. Am. Compl. ¶¶ 124–25, 146–53.

follow the APA's procedural requirements. Defendants are trying to have it both ways: After two courts enjoined the IFRs, they nevertheless continued to litigate their validity, with the goal of having the injunctions overturned and the IFRs reinstated immediately. At the same time, they took comments on the IFRs, so that they could turn around and assert that they had complied with the APA regardless of how those cases turned out. But that is not what the APA requires. Rather, the Agency must issue a Notice of Proposed Rulemaking, accept and consider comments on the NPRM, and then issue a final rule accompanied by an explanation—all *before* the final rule may go into effect. 5 U.S.C. § 553(b)–(d). But here, the IFRs went into effect on October 6, 2017, and were never withdrawn, and the Rules made only minor changes to them.

The Third Circuit's decisions in *Sharon Steel Corp. v. E.P.A.*, 597 F.2d 377 (3d Cir. 1979), and *NRDC v. EPA*, 683 F.2d 752 (3d Cir. 1982), make clear that this procedure does not satisfy the APA. Under similar facts, the *NRDC* court invalidated *both* the initial rule and the final rule at issue in that case, notwithstanding the agency's acceptance of post-promulgation comment. 683 F.2d at 767. It did not do so because of any circumstances that were unique to that case, but rather because a contrary determination “would allow [an agency] 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.” *Id.* at 768. Such a result “would allow EPA to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued,” which “would allow agencies to circumvent *Sharon Steel* and the APA.” *Id.*

Here, the process the Agencies chose to follow forced commenters to “come hat-in-hand and run the risk that the decisionmaker is likely to resist change.” *Sharon Steel*, 597 F.2d at 381. As a result, they denied the States the opportunity for “effective participation in the rulemaking process while the decisionmaker is still receptive to information and argument.” *Id.* Defendants rely on cases from other circuits in urging this Court to revisit its previous conclusion, but even those decisions recognize the risks inherent in such an approach. For instance, in *Levesque v. Block*, the First Circuit observed, “There is, of course, a difference between, on the one hand, mandating a post-promulgation comment period when exigent circumstances foreclose prior public comment ... and, on the other hand, allowing post-promulgation comment to suffice when good cause did not exist, as in our case. When pre-promulgation comment is impossible, comment after the fact is better than none at all. When pre-promulgation comment is possible, however, *one does not want to encourage the circumvention of section 553 by accepting post-promulgation procedures.*” 723 F.2d 175, 177 (1st Cir. 1983). If the process utilized in this case were held to be procedurally valid, there would be no reason for an agency to ever seek comments before issuing a rule.¹⁹

Defendants and Intervenor ignore this Court’s earlier determination that the States would likely prevail on this claim “even under the more lenient open mind standard.” 351 F. Supp. 3d at 816 n.19. Despite the overwhelming opposition to the Rules expressed by commenters, the Agencies made only a few “non-substantive technical revisions,” *id.* (quoting J.A. 32), and

¹⁹ Defendants and Intervenor both suggest that the Agencies’ failure to comply with the APA should be excused because the IFRs were enjoined. *E.g.*, Defs. Br. 40. As discussed above, however, the Agencies continued to litigate the validity of the IFRs while they were purportedly reviewing comments on them. And it would be a perverse rule that justifies an agency’s failure to comply with the APA specifically because a court has determined that the agency’s actions were likely illegal.

nothing in the Rules demonstrates that they kept an open mind. *See id.*; *see also Levesque*, 723 F.2d at 188 (holding that post-promulgation comments are insufficient unless the agency puts forward “evidence of a level of public participation and a degree of agency receptivity that demonstrate that a real ‘public reconsideration of the issued rule’ has taken place”). Regardless of what standard is applied, the Agencies’ procedures here fall short.

B. The Agencies Lacked “Good Cause” to Disregard the APA’s Requirements

Intervenor continues to argue that the Agencies had “good cause” to bypass the APA’s requirements. But its argument rests largely on claims this Court has already rejected as well as inaccurate claims about the legal landscape at the time the IFRs were issued.²⁰

The “good cause” exception 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) (cleaned up), and its use “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 IFRs, the Agencies themselves claimed that the need to eliminate “uncertainty caused by years of litigation and regulatory changes” established “good cause” that allowed them to dispense with notice and comment. J.A. 121.²¹ But as this Court previously recognized, 281 F.

²⁰ For instance, Intervenor again argues that the Agencies’ previous use of IFRs (or the use of IFRs by agencies more generally) renders the process the Agencies followed here per se legitimate. Int. Br. at 37, 42; *see also* 351 F. Supp. 3d at 815 (rejecting arguments). These issues were not before the Court at that time, and they are not before the Court now.

²¹ Intervenor seems to take issue with the Agencies’ characterization, claiming that the legal state of affairs prior to the issuance of the IFRs reflected “certainty, not uncertainty.” Int. Br. 39. But as discussed above, prior to *Zubik*, eight of the nine circuits to address the issue had rejected the RFRA argument upon which the Agencies relied in the IFRs. Although the Supreme Court vacated these decisions, it did nothing to disturb their reasoning. Notwithstanding the nearly unanimous consensus of the courts of appeal prior to *Zubik*, Intervenor claims that “a cascade of injunctions” justified the Agencies’ not only rejecting the logic of those eight courts of appeals but also dispensing entirely with the procedural requirements of the APA. Int. Br. 38.

Supp. 3d at 573, the Third Circuit has rejected this argument, finding, “The desire to eliminate uncertainty, by itself, cannot constitute good cause. To hold otherwise would have the effect of writing the notice and comment requirements out of the statute.” *United States v. Reynolds*, 710 F.3d 498, 510 (3d Cir. 2013).

Intervenor nonetheless claims, relying on *Reynolds*, that the Agencies were justified in arguing that the need to resolve “outstanding issues” in pending litigation allowed them to dispense with notice and comment. Int. Br. 37 (quoting 82 Fed. Reg. at 47,814 & *Zubik*, 136 S. Ct. at 1560). But the statement in *Reynolds* on which they rely was instead an acknowledgement that the Third Circuit had “recognized urgency alone as sufficient [to establish good cause] *only* when a deadline imposed by Congress, the executive, or the judiciary requires agency action in a timespan that is too short to provide a notice and comment period.” 710 F.3d at 511 (emphasis added). Here, there was no “deadline . . . requir[ing] agency action” to be completed before the Agencies could complete notice and comment rulemaking. In fact, the only “deadline” the Agencies cited in the IFRs as justification for disregarding the APA was a moving deadline to file a *status report* with the Seventh Circuit, J.A. 120, which is surely not what the *Reynolds* court had in mind.²²

While its brief includes several string cites listing various injunctions, it does not explain which specific injunctions it contends provided justification for the Agencies’ actions. Nor does it explain how many of the injunctions it relies on raised arguments that were fully resolved by the Supreme Court in *Hobby Lobby* (and thus irrelevant to the Agencies’ decision to issue the IFRs); how many were pending on appeal at the time of the IFRs; and how many were previously reversed by decisions that were subsequently vacated by *Zubik*.

²² Intervenor repeats the argument previously made by Defendants that the possibility that some objectors might wish to switch from “grandfathered” plans established good cause. Int. Br. 38 & n.20. The Court previously questioned Defendants about this assertion, and they could point to no support in the record for it. 281 F. Supp. 3d at 574 n.9. Under normal circumstances, the Court is not obligated to accept at face value agency assertions that are without evidentiary support. In this context—where the Agencies carry the heavy burden of showing that they satisfy the APA’s stringent “good cause” requirement—there is even less reason to do so.

C. The Agencies' Errors Were Not Harmless

Finally, the Agencies' errors were in no way "harmless." The Agencies' failure to comply with the APA's requirements prejudiced the States and all potential commenters because the Agencies approached the acceptance of comments with anything but an "open mind." By their own admission, they made "largely 'non-substantial technical revisions,' [to the IFRs] that Defendants concede 'do not alter the fundamental substance of the exemptions set forth in the IFRs.'" 351 F. Supp. 3d at 816 n.19 (citation omitted). By issuing binding regulations before taking comments on them, the Agencies forced concerned parties to "come hat-in-hand and run the risk that the decisionmaker is likely to resist change"—a concern borne out here by the very limited nature of the changes made in the Rules in the wake of overwhelming opposition to them. *Sharon Steel*, 597 F.2d at 381.

VIII. THE STATES HAVE STANDING

On two occasions, this Court has examined the evidence in the record and concluded that the States have standing because the "Rules inflict a direct injury upon the States by imposing substantial financial burdens on their coffers." 351 F. Supp. 3d at 807. The Rules will lead women to lose contraceptive coverage, requiring them to seek such coverage from state-funded programs and thus imposing a direct financial cost on the States.²³ Defendants and Intervenor have also both moved to dismiss for lack of standing, and those motions are currently pending. Defendants do not raise standing in their current motion, except in a passing reference to their motion to dismiss. Defs. Br. 10 n.5. Intervenor briefly discusses standing, but it largely repeats arguments this Court has previously rejected. Int. Br. 10–11.

²³ See Exs. 178–181; 184–189 (declarations setting forth bases for States' standing).

Intervenor does contend, however, that a recent class action decision by a court in the Northern District of Texas in *DeOtte v. Azar*, No. 18-825 (N.D. Tex. June 5, 2019), “has made it impossible for this Court to redress any injury” the States face. Int. Br. 11. *DeOtte* was only issued this month and remains subject to appeal. As with other cases challenging the Mandate, the government did not put up any substantive defense. Even so, the decision raises several serious questions. For instance, there are serious questions as to whether the court had jurisdiction at all or whether the claims are barred by the statute of limitations. The class definitions are arguably vague and overbroad, and would seem to encompass many plaintiffs whose claims are barred by *re judicata*—including some of the plaintiffs in *Real Alternatives*. The decision also relies on the same factually flawed argument Intervenor have made here regarding the government’s statements in *Zubik*, *see supra* 5, which the government apparently made no effort to contest.

But even if the decision were unquestionably correct and not subject to attack on appeal or in any other forum, it still would sweep far less broadly than the Rules. For one thing, Defendants in *DeOtte* are the federal agencies, but in Pennsylvania, New Jersey and most other states, state officials enforce the mandate with respect to insurance providers. Moreover, the decision does not apply to health plans provided by colleges and universities to students, whereas the Rules do, and it does not apply to the Moral Exemption at all. And the decision at least purports to subject claims of objections to the Mandate to some degree of judicial scrutiny; nothing in the Rules does the same, however. Therefore, the *DeOtte* decision does not undermine this Court’s standing analysis.

IX. THE RULES SHOULD BE VACATED

The APA requires a court to “set aside” agency action it deems unlawful. 5 U.S.C. § 706(2). Here, this requirement dictates that the Rules be vacated. *See Council Tree Comms.*,

Inc. v. F.C.C., 619 F.3d 235, 258 (3d Cir. 2010). But Defendants nonetheless repeat the arguments they made earlier in these proceedings against the issuance of a nationwide injunction. Defs. Br. 41-42 (discussing alleged harms from nationwide injunctions and “nonparty injunctions”). This Court rightly rejected these arguments then, and they simply have no relevance at this stage of the litigation. Defendants cite no authority for limiting the States’ remedy upon a final determination that the Rules are unlawful, nor do they explain how such a result can be squared with “Section 706(2)’s seemingly mandatory language.” *Comite de Apoyo a los Trabajadores Agricolas v. Solis*, 933 F. Supp. 2d 700, 714 (E.D. Pa. 2013).²⁴

The APA and Third Circuit precedent require that the Rules be vacated. And even if the Court had the authority to issue some sort of lesser relief, it would be inappropriate here. *See* Pls. Br. 46. The Rules violate multiple provisions of law and were issued in a procedurally invalid manner. It is not this Court’s responsibility to clean up the Agencies’ mess and re-fashion the Rules in a manner that somehow excises their most egregious provisions. Because the Rules are unlawful, they must be vacated.

CONCLUSION

For the reasons set forth above, Defendants’ and Intervenor’s motions for summary judgment should be denied; the States’ summary judgment motion should be granted; and the Rules should be vacated.

²⁴ Defendants’ arguments for limiting the States’ relief are factually flawed as well. For instance, they assert “the individual exemption is not challenged by Plaintiffs.” Defs. Br. 42. This claim is false. *See supra* note 18. And Defendants’ legal justification for the individual exemption is plainly foreclosed by *Real Alternatives*, 867 F.3d at 366.

Respectfully Submitted,

June 28, 2019

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

COMMONWEALTH OF PENNSYLVANIA and
STATE OF NEW JERSEY,

Plaintiffs,

v.

No. 2:17-cv-04540-WB

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

Defendants.

**PLAINTIFFS' RESPONSE TO INTERVENOR- DEFENDANT'S
STATEMENT OF UNDISPUTED MATERIAL FACTS**

Plaintiffs the Commonwealth of Pennsylvania and the State of New Jersey (the "States") respectfully respond to "Defendant-Intervenor the Little Sisters of the Poor Saints Peter and Paul Home Statement of Undisputed Material Facts" (ECF No. 206-2).

The States object generally to Intervenor's own characterizations of the statutes and regulations to the extent that these characterizations differ from the text of these documents. The statutes and regulations speak for themselves. The States also object generally to Intervenor's use of the words "abortion," "abortion-inducing," and "abortifacients" when referring to methods of contraception covered by the HRSA Guidelines. "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.” *E.g.*, J.A. 647.

The States also dispute the following specific assertions by Intervenor:

I. The Federal Mandate and Its Regulatory History

1. Congress has never enacted a federal statute listing contraceptives as part of required health insurance. J.A. 99.

Response: Paragraph 1 states a legal conclusion to which no response is required.

2. Congress does not require that cost-free access to all FDA-approved contraceptives be provided by small employers. 26 U.S.C. § 4980H(c)(2)(A).

Response: Paragraph 2 states a legal conclusion to which no response is required.

3. Congress does not require that cost-free access to all FDA-approved contraceptives be provided in grandfathered health plans. J.A. 306, 2176.

Response: Paragraph 3 states a legal conclusion to which no response is required.

4. Congress does not require cost-free access to all FDA-approved contraceptives in public-sector plans such as Medicare, Medicaid, and Tricare. J.A. 383 (“preventive services requirements . . . affect only private plans”).

Response: Paragraph 4 states a legal conclusion to which no response is required.

5. The Affordable Care Act requires certain employers to offer “health insurance coverage”

that includes “preventive care and screenings” for women without “any cost sharing requirements.” 42 U.S.C. § 300gg-13(a)(4); 26 U.S.C. § 9815; 29 U.S.C. § 1185d.

Response: Paragraph 5 states a legal conclusion to which no response is required.

6. Under the Affordable Care Act, the penalty for offering a plan that excludes coverage for even one of the FDA-approved contraceptive methods is \$100 per day for each affected individual. 26 U.S.C. § 4980D(a)-(b).

Response: Paragraph 6 states a legal conclusion to which no response is required.

7. If an employer larger than 50 employees fails to offer a plan at all, the employer owes \$2,000 per year for each of its full-time employees. 26 U.S.C. § 4980H(a), (c)(1).

Response: Paragraph 7 states a legal conclusion to which no response is required.

8. “Family planning” was mentioned only in passing during Senate floor debates concerning the Women’s Health Amendment, while many senators went into considerable detail about cost and access to mammograms, pap smears, post-partum depression, domestic violence, heart disease, and diabetes. J.A. 2377-79, 2422-26, 2435-38.

Response: Disputed. In fact, multiples Senators discussed the need to include family planning in coverage of preventive services during debate on the Women’s Health Amendment. Ex. 151.

9. The preventive services mandate was first implemented in an interim-final rule on July 19, 2010 (“First IFR”), which stated that the Health Resources and Services Administration (“HRSA”) would produce “comprehensive guidelines” for women’s preventive services.

J.A. 564.

Response: Disputed that the referenced interim final rules “implemented” the preventive services mandate, which was enacted by Congress. The regulation otherwise speaks for itself.

10. Nothing in the Affordable Care Act requires HRSA to include contraceptives in its comprehensive guidelines. J.A. 306.

Response: Paragraph 10 states a legal conclusion to which no response is required.

11. This First IFR was enacted without prior notice of rulemaking or opportunity for prior comment as it came into effect on the day that comments were due. J.A. 562, 566.

Response: Disputed. The regulation referenced was published July 19, 2010, and went into effect September 17, 2010.

12. The First IFR did not mention family planning as a “preventive service,” instead listing “immunizations . . . blood pressure and cholesterol screening, diabetes screening for hypertensive patients, various cancer and sexually transmitted infection screenings, genetic testing for the BRCA gene, adolescent depression screening, lead testing, autism testing, and oral health screening and counseling related to aspirin use, tobacco cessation, and obesity.” J.A. 567.

Response: Undisputed that the quoted language appears in the regulation. J.A. 567. The regulation further stated, “The Department of HHS is developing these guidelines [for preventive services for women] and expects to issue them no later than August 1, 2011.”

J.A. 564.

13. HRSA commissioned the Institute of Medicine (“IOM”) to “review what preventive services are necessary for women’s health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women.” The charge to the IOM does not include any discussion of coverage issues. J.A. 326-27.

Response: Undisputed that the cited page contains the quoted text. The further characterization of the IOM report is disputed. The report speaks for itself. *Id.*

14. The IOM Report argues that greater *use* of contraception will lower rates of unintended pregnancy, but the Mandate is about increasing *access* to contraception. Studies have shown that there are “many and varied reasons why women choose not to use contraception, most of which have nothing to do with cost.” J.A. 2220, 2249-51.

Response: Disputed. Paragraph 14 cites a single law review article, not a research study. To the extent a further response is required, the States dispute Intervenor’s contention that the mandate does not facilitate greater use of contraception. The States also dispute that the IOM report focused on use at the exclusion of access. Women can have different and multiple reasons for not using contraception, and “cost sharing can be a significant barrier to access to contraception.” J.A. 242 (citation omitted). This is particularly true for the most effective forms of contraception, where effectiveness is measured “by studying the rate of failure (i.e., having an unintended pregnancy) in the first year of use.” J.A. 430–31. “Cost barriers to use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods and sterilization have high up-front costs (Trussell et al., 2009).” J.A. 433. “[M]ultiple studies have

demonstrated that when financial and logistical barriers are removed, women overwhelmingly select the most effective forms of contraception.” J.A. 648 (citations omitted).

15. In reports by the CDC, Guttmacher, and other organizations, the cost of birth control did not appear as an explanation for low rates of contraceptive use. Instead, the studies found that factors such as mistaken assumptions about infertility, worries about the side effects of birth control, and indifference or ambivalence to pregnancy were the main drivers behind women not using contraceptives. J.A. 2249.

Response: Disputed. Paragraph 15 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately summarizes the underlying studies, and therefore dispute that the underlying studies demonstrate that cost is not an explanation for low rates of contraceptive use. To the extent a further response is required, the States dispute that cost is not a barrier to the use of contraception. *See* Response 14.

16. Some studies show that the overall proportion of unintended pregnancies does not correlate to changes in contraceptive use. J.A. 2227.

Response: Disputed. Paragraph 16 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately summarizes the underlying studies, and therefore dispute that the underlying studies demonstrate that there is no correlation between changes in contraceptive use and unintended pregnancies. To the extent a further response is required, the States dispute that contraception does not

prevent unintended pregnancy. *E.g.*, J.A. 649 (citations omitted), 799–800, 807, 1329–30 (citation omitted).

17. The CDC reports that 12% of women using contraception will become pregnant in a given year. This figure essentially stayed the same between 1995 and 2010. J.A. 2220.

Response: Disputed. Paragraph 17 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately summarizes the underlying CDC report, and therefore dispute that the underlying report supports the inference that contraception has no impact on unintended pregnancies. To the extent a further response is required, the States dispute the relevance of Paragraph 17. No method of contraception is 100 percent effective, some methods of contraception are less effective than others, and all methods of contraception must be used both consistently and correctly to maximize effectiveness. J.A. 431.

18. Other studies have shown that the increase in contraception access and use is possibly connected to increasing rates of STIs, as access to contraception generally leads to more sex with more partners. J.A. 2236-38.

Response: Disputed. Paragraph 18 cites a single law review article, not a research study. In addition, the States lack information about whether the law review article accurately summarizes the underlying studies, and therefore dispute that the underlying studies demonstrate that an increase in contraception access and use is causally connected to an increasing rate of STIs or to more sex with more partners.

19. Studies have shown that there are a variety of potential harms to women’s health from the use of contraceptives, including ties to cancer. J.A. 2238-40.

Response: Disputed. Paragraph 19 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately summarizes the underlying studies, and therefore dispute that the underlying studies demonstrate a variety of potential harms to women’s health from the use of contraceptives. To the extent a further response is required, the States dispute the categorical treatment of all contraceptive methods. All methods of contraception—like all medications—have side effects and can pose risks to some users. *E.g.*, J.A. 651. But all methods of contraception also have benefits that must be weighed against these risks. *Id.* This is why “patients and physicians, not politicians, should determine the right contraceptive for a patients’ health care needs.” *Id.*

20. The World Health Organization has classified oral contraceptives as carcinogens. JA 17-18, 2240.

Response: Disputed. Paragraph 20 cites a single law review article, not a research study. The States lack information as to whether the law review article and the Final Religious Exemption Rule accurately summarize the underlying WHO Report. To the extent a further response is required, the States dispute the implication that oral contraceptives are categorically unsafe. The American Cancer Society recognizes that oral contraceptives “confer[s] a protective effect against cancer in the endometrium and ovary.” J.A. 3392. The FDA has also approved oral contraceptives as safe and effective. J.A. 2352–53. That oral contraceptives may pose risks to some women reinforces the importance of women

making individualized decisions in consultation with their doctors, not their employers.

21. FDA-approved contraceptive methods required by the Mandate include “emergency contraception.” The FDA’s Birth Control Guide notes that some emergency contraceptives may work by preventing implantation of a fertilized egg in the uterus. J.A. 2361-63.

Response: Disputed to the extent it inaccurately summarizes the cited document. The FDA’s Birth Control Guide states that emergency contraception “works mainly by stopping the release of an egg from the ovary.” J.A. 2362.

22. The list of FDA-approved contraceptive methods endorsed by the IOM Report includes methods that can interfere with a human embryo before implantation. J.A. 2362-63.

Response: Disputed. The FDA does not use the words “human embryo.” *Id.*

23. According to the FDA’s own publication, each of the 18 methods it has approved can have side effects and other health risks. At least forty potential side effects are mentioned throughout the document, ranging from irritation and tiredness all the way to “severe infection[s]” or ectopic pregnancies, as well as some “Less Common Risks” such as heart attack or stroke. J.A. Ex. 147.

Response: Disputed to the extent it inaccurately summarizes the cited document. The States dispute the implication that the existence of side effects categorically renders all methods of contraception unsafe for all women. *See also* Response 19.

- a. 16 of the 18 approved methods provide no protection against STIs. Two provide a “reduced risk” of STIs. J.A. Ex. 147.

Response: Paragraph 23.a is not material to this litigation. The States also the implication that contraception is not safe or beneficial. *See* Response 19.

- b. The FDA's publication claims that one method of emergency contraception it has approved has an 87.5% chance of preventing a pregnancy but admits that "other studies have resulted in lower pregnancy prevention rates." J.A. 2362.

Response: Disputed to the extent Paragraph 23.b suggests that access to emergency contraception has no benefit for women. Not all methods of contraception are equally effective. *See* Response 17.

- c. The FDA states the other method of emergency contraception it has approved has only a 60-66% chance of preventing a pregnancy. J.A. 2363.

Response: Disputed to the extent Paragraph 23.c suggests that access to emergency contraception has no benefit for women. Not all methods of contraception are equally effective. *See* Response 17.

24. Thirteen days after the IOM recommendations were issued, the HRSA issued guidelines on its website. The HRSA guidelines included "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures." J.A. 310-11.

Response: Undisputed.

25. HRSA's inclusion of contraceptive coverage in the preventive services guidelines is posted on its website and has never been subject to notice-and-comment rulemaking. J.A. 101.

Response: Undisputed that the HRSA Guidelines are posted on the agencies' website.

The remainder of the paragraph states a legal conclusion to which no response is required.

26. The same day that the HRSA guidelines were posted on its website, HHS promulgated its Second IFR, effective immediately, once again without prior notice or opportunity for public comment. J.A. 304.

Response: Undisputed.

27. The Second IFR stated that it "contain[ed] amendments" to the First IFR, in particular recognizing that Congress's grant of authority to HRSA to develop "guidelines" included the authority to consider the impact of the Mandate on religious objectors. J.A. 304, 306.

Response: Disputed that Congress granted HRSA authority to consider the impact of the contraceptive mandate on religious objectors. 42 U.S.C. § 300gg-13(a)(4).

28. The Mandate has many gaps, including that employers with fewer than 50 employees need not provide insurance coverage at all. 26 U.S.C. § 4980H(c)(2)(A).

Response: Paragraph 28 states a legal conclusion to which no response is required.

29. Approximately a fifth of large employers are exempt through ACA's exception for "grandfathered health plans." J.A. 306, 2176.

Response: Disputed. Paragraph 29 mischaracterizes the record. J.A. 2176 states that in 2017, "23% of firms offering health benefits offer at least one grandfathered health plan."

This does not mean that a fifth of large employers are exempt.

30. The Second IFR acknowledged HRSA's discretion to exempt certain religious employers from the guidelines, but it defined religious employer narrowly, ultimately excluding non-profits like the Little Sisters of the Poor, who serve people of all faiths. J.A. 306.

Response: Disputed to the extent Paragraph 30 asserts that HRSA has authority to exempt certain religious employers from the Guidelines.

31. The Agencies received "over 200,000" comments, including many comments that explained the need for broader religious exemptions, but the Second IFR was finalized "without change." J.A. 299-300, 298.

Response: Disputed to the extent Paragraph 31 implies that the Agencies did not adequately respond to these comments.

32. The Agencies then published an Advance Notice of Proposed Rulemaking and a Notice of Proposed Rulemaking, which were later adopted into a final rule making further changes to the Mandate. J.A. 290, 269-70, 239.

Response: Disputed. The ANPRM, NPRM, and final rule addressed how the contraceptive mandate would be implemented through changes to the church exemption and creation of the accommodation. They did not make changes to the conclusion that contraceptive methods and counseling are preventive services for women and therefore must be provided by covered plans without cost-sharing, pursuant to the Women's Health Amendment. *E.g.*, J.A. 241.

33. The Agencies received over 600,000 comments in response to the ANPRM and NPRM.

J.A. 240, 272.

Response: Undisputed.

34. The Agencies amended the definition of a religious employer, but continued to limit that definition to churches and the “exclusively religious” activities of religious orders. J.A. 243.

Response: Paragraph 34 states a legal conclusion to which no response is required.

35. The Agencies also adopted a mechanism—termed an “accommodation”—by which religious employers could offer the objected-to coverage on their health plans by executing a self-certification and delivering it to the organization’s insurer or third-party administrator (TPA). Self-certification would trigger the insurer’s or TPA’s obligation to provide payments for contraceptive services. J.A. 243.

Response: Disputed to the extent Paragraph 35 implies that the accommodation does not accommodate the objections of certain religious employers for the purposes of the Religious Freedom Restoration Act. Paragraph 35 otherwise states a legal conclusion to which no response is required.

36. The regulations stated that: “plan participants and beneficiaries (and their health care providers) do not have to have two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy).” J.A. 245.

Response: Paragraph 36 states a legal conclusion to which no response is required. The regulations speak for themselves. To the extent a response is required, the States note that the prior two sentences provide necessary context: “As the payments at issue derive solely from a federal regulatory requirement, not a health insurance policy, they do not implicate issues such as issuer licensing and product approval requirements under state law, and they minimize cost and administrative complexity for issuers. At the same time, because the payments for contraceptive services are not a group health plan benefit under this approach, this policy ensures that eligible organizations and their plans do not contract, arrange, pay, or refer for contraceptive coverage, and that such coverage is expressly excluded from their group health insurance policies.” J.A. 245.

37. On EBSA Form 700, the self-certification form, there is a “Notice to Third Party Administrators of Self-Insured Health Plans,” which states that the form “constitutes notice to the third party administrator that . . . [t]he obligations of the third party administrator are set forth in 26 C.F.R. § 54.9815-2713A, 29 C.F.R. § 2510.3-16, and 29 C.F.R. § 2590.715-2713A,” and that “[t]his certification is an instrument under which the plan is operated.” J.A. 1971. It is these regulations that require that “the third party administrator will provide or arrange payments for” the abortifacient drugs and devices. 26 C.F.R. § 54.9815-2713A; 29 C.F.R. § 2510.3-16; 29 C.F.R. § 2590.715-2713A. J.A. 1971-72.

Response: Undisputed that EBSA Form 700 contains the quoted language. Disputed that third party administrators will provide or arrangement payment for abortifacient drugs and devices. The second sentence of Paragraph 37 is a conclusion of law to which no response is required.

38. The first two IFRs did not address the concerns of many religious organizations and many filed lawsuits under the Religious Freedom Restoration Act seeking relief. J.A. Ex. 138.

Response: Disputed to the extent that Paragraph 38 suggests the contraceptive mandate, as implemented with a church exemption and accommodation, violated the Religious Freedom Restoration Act.

39. In July 2013, one of the organizations that had sued for relief, Wheaton College, received an emergency injunction from the Supreme Court that protected it from the penalties in the Mandate. J.A. 221; *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014).

Response: Disputed. The Supreme Court's injunction protected Wheaton College only if it "informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services." *Wheaton Coll. v. Burwell*, 134 S. Ct. 2806, 2807 (2014).

40. Following that injunction and "in light of the Supreme Court's interim order" in the Wheaton case, the agencies published a third IFR, again without preceding notice or comment. J.A. 228.

Response: Undisputed.

41. The agencies issued the IFR despite the fact that the Supreme Court in *Wheaton* stated that its order "'should not be construed as an expression of the Court's views on the merits' of

Wheaton College’s challenge to the accommodations.” J.A. 221.

Response: Undisputed that the Supreme Court’s *Wheaton* decision contains the quoted language.

42. The Third IFR amended the Mandate to allow a religious objector to “notify HHS in writing of its religious objection” rather than notifying its insurer or third-party administrator. J.A. 230.

Response: Disputed to the extent Paragraph 42 suggests this regulation was the “Third IFR.” Paragraph 42 otherwise states a legal conclusion to which no response is required. The regulation speaks for itself.

43. The Third IFR was ultimately finalized on July 14, 2015. J.A. 188-89.

Response: Undisputed.

44. The final rule implementing the Third IFR stated: “the third party administrators and health insurance issuers already paying for other medical and pharmacy services on behalf of the women seeking the contraceptive services are better placed to provide seamless coverage of the contraceptive services, than are other providers that may not be in the insurance coverage network, and that lack the coverage administration infrastructure to verify the identity of women in accommodated health plans and provide formatted claims data for government reimbursement.” J.A. 198-99.

Response: Paragraph 44 states a legal conclusion to which no response is required. The regulation speaks for itself.

45. The Third IFR did not accommodate the religious beliefs of the Little Sisters and other religious objectors, leading to more litigation. J.A. 1951.

Response: Paragraph 45 contains a legal conclusion to which no response is required.

To the extent a response is required, the States dispute that the accommodation, as amended on July 14, 2015, did not accommodate the religious beliefs of the Little Sisters and other religious objectors for the purposes of the Religious Freedom Restoration Act.

II. The Challenges to the Mandate and the Resulting Injunctions

Response Paragraphs 46–49, 51–54, 56, 58–60: The States are without information to confirm or deny the specific factual allegations related to Little Sisters of the Poor. The States further object to the use of the words “abortion,” “abortion-inducing,” and “abortifacient” when referring to methods of contraception covered by the HRSA Guidelines.

46. The Little Sisters of the Poor is an international Roman Catholic organization of nuns that has provided care to the elderly poor—of any race, sex, or religion—for over 175 years. J.A. 2285.

47. The Saints Peter and Paul Home of the Little Sisters of the Poor in Pittsburgh is a Pennsylvania non-profit corporation that qualifies as a tax-exempt organization under section 501(c)(3) of the Internal Revenue Code of 1986. The Pittsburgh home is under the direct authority of Mother Superior Marie Vincente. J.A. 2286.

48. The Little Sisters home in Pittsburgh employs around 67 full-time employees. J.A. 2286.

49. The Little Sisters Pittsburgh have adopted the Christian Brothers Employee Benefit Trust to provide medical benefits coverage for their employees. Christian Brothers Trust is a Catholic entity designed to serve the Catholic Church and related faith-based entities. The Little Sisters chose to use the Christian Brothers Trust for their health benefits because it shares and is administered in accordance with the Little Sisters' religious beliefs and provides benefits accordingly. J.A. 2286-87.

50. As an employer participating in the Christian Brothers Employee Benefit Trust Plan, the Little Sisters Pittsburgh Home is currently protected by an injunction from enforcement of the Mandate. Order, *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611 (D. Colo. May 29, 2018), Dkt. 82.

Response: Undisputed.

51. The Little Sisters homes are not under the civil legal ownership and control of the dioceses in which they are located. Instead, the Little Sisters of the Poor own and control the homes themselves, through local corporations. J.A. 2286.

52. The Little Sisters' homes are not directly funded by the dioceses in which they are located. They take responsibility for funding their own operations. J.A. 2286.

53. The Little Sisters follow all the teachings of the Catholic Church, including its teachings that abortion, contraception, sterilization, and cooperation with such acts are intrinsically immoral. J.A. 2288-89.

54. Catholic teachings also instruct the Little Sisters to provide their employees and their employees' families with adequate healthcare benefits. J.A. 2290-91.

55. The agencies' contraceptive mandate, as it existed before the Final Rules, requires the Little

Sisters to participate in the provision of contraception, abortion, and sterilization to their employees via the use of their health plans, health plan information, and health plan infrastructure. J.A. 2291.

Response: Disputed. Prior to the Final Rules, the Little Sisters were free to take advantage of the accommodation. *E.g.*, Ex. 10. The States dispute Paragraph 55 as mischaracterizing how the accommodation functions. *E.g.*, J.A. 245. The States further dispute Paragraph 55 to the extent it implies that the accommodation substantially burdens the Little Sisters' religious beliefs in violation of the Religious Freedom Restoration Act.

56. Because of their religious beliefs, the Little Sisters sincerely believe that they cannot:
- a. participate in the Mandate's program to promote and facilitate access to the use of sterilization, contraceptives, and abortion-inducing drugs and devices. J.A. 2291.
 - b. provide health benefits to their employees and plan beneficiaries that will include or facilitate access to sterilization, contraceptives, and abortion-inducing drugs and devices. J.A. 2292.
 - c. designate, authorize, or incentivize any third party to provide their employees or plan beneficiaries with access to sterilization, contraception, and abortion-inducing drugs and devices. J.A. 2292.
 - d. sign, execute, deliver, or otherwise file documents with a third party or the government which could then be used to require, authorize, or incentivize a third party to provide their employees with access to sterilization, contraception, or abortion-inducing drugs. J.A. 2292.

- e. agree to refrain from speaking with a third party to ask or instruct it not to deliver contraceptives, sterilization, and abortifacients to their employees and plan beneficiaries in connection with the Little Sisters' health plan. J.A. 2292.
- f. create or facilitate a provider-insured relationship, the sole purpose of which would be to provide contraceptives, sterilization, and abortifacients in connection with the Little Sisters' health plans. J.A. 2292.
- g. create, maintain, support, or facilitate health insurance plans, information, and infrastructure that would be used to provide contraceptives, sterilization, and abortifacients to their employees and plan beneficiaries. J.A. 2292-93.
- h. take any action that would require, authorize, or incentivize Christian Brothers Trust or Christian Brothers Services to violate their own Catholic religious beliefs. J.A. 2293.
- i. Provide employee health benefits that include access to contraception. J.A. 2292.
- j. Execute Form 700 to use the "accommodation." J.A. 2292.
- k. Provide the notice to HHS to use the "accommodation." J.A. 2291.

57. The "accommodation" cannot result in the Little Sisters' employees receiving contraceptive coverage "seamlessly" with the Little Sisters' plan unless the Little Sisters take actions that violate their sincerely held religious beliefs. J.A. 2295, 2297.

Response: Disputed. Paragraph 57 mischaracterizes how the accommodation functions. *E.g.*, J.A. 245. The States further dispute Paragraph 57 as implying that the accommodation substantially burdens the Little Sisters' religious beliefs in violation of the Religious Freedom Restoration Act.

58. Even the so-called accommodation would require the Little Sisters to act as a necessary link in the government's plan to provide contraceptive measures to their employees, in violation of their beliefs. J.A. 2295.

Response: Disputed. Paragraph 58 mischaracterizes how the accommodation functions. *E.g.*, J.A. 245. The States further dispute Paragraph 58 as implying that the accommodation substantially burdens the Little Sisters' religious beliefs in violation of the Religious Freedom Restoration Act.

59. Without an exemption, the Mandate would require the Little Sisters Pittsburgh home to pay millions of dollars in fines each year for not providing contraceptive coverage. J.A. 2294.

60. The Little Sisters cannot in good conscience avoid the fines by choosing not to provide health benefits at all, but even if they did, they would face annual fines of approximately \$134,000 for dropping benefits altogether. J.A. 2294-95.

61. The Mandate imposes enormous pressure on the Little Sisters to participate in activities prohibited by their sincerely held religious beliefs. J.A. 2295.

Response: Disputed to the extent that Paragraph 61 suggests the contraceptive mandate, as implemented with the church exemption and accommodation, substantially burdens the Little Sisters' religious beliefs in violation of the Religious Freedom Restoration Act.

62. Lawsuits by the Little Sisters and others have resulted in injunctions from federal courts across the country. J.A. 15, 103-04, 2593.

Response: To the extent Paragraph 62 refers to recently obtained permanent injunctions based on claims that the accommodation violates the Religious Freedom Restoration Act, the States dispute the relevance of these decisions. In every case the Agencies have failed to defend the accommodation and thus each injunction does not constitute a determination about the legality of the accommodation.

63. After the Supreme Court issued an order in *Zubik v. Burwell*, the agencies issued a “Request for Information” in July 2016, to seek input on “whether there are modifications to the accommodation that would be available under current law and that could resolve the RFRA claims raised by organizations that object to the existing accommodation on religious grounds.” J.A. 183.

Response: Disputed to the extent that Paragraph 63 mischaracterizes the full nature of the Agencies’ request, which stressed the importance of “ensuring that women enrolled in the organizations’ health plans have access to seamless coverage of the full range of Food and Drug Administration-approved contraceptives without cost sharing.” J.A. 183.

64. The Request for Information received over 54,000 public comments. J.A. 1806, 1844.

Response: Undisputed.

65. Included in those comments were suggestions for how to provide access to contraceptives for employees of religious and moral objectors that would not require the use of the employers’ plans, including through willing doctors, pharmacies, or contraceptive-only

plan. *See, e.g.*, J.A. 3645-67.

Response: Paragraph 65 is not material or relevant to this litigation.

66. At least one of those comments explained a Missouri law that accomplished such an arrangement in 2001 with an available contraceptive-only plan. J.A. 3650-67.

Response: Paragraph 66 is not material or relevant to this litigation.

67. Another comment suggested ways that pharmacies could be used to seamlessly provide contraceptives to women without the use of an employer's plan. J.A. 3645-49.

Response: Paragraph 67 is not material or relevant to this litigation.

68. The agencies concluded, in a set of FAQs published only on the Department of Labor's website 11 days before inauguration day, that they were unable to modify the accommodation because "no feasible approach has been identified at this time" that would allow them to do so in a way that respected both the agencies' goals and the religious objectors' concerns. J.A. 169, 172.

Response: Disputed. Paragraph 68 mischaracterizes what the Agencies stated in the 2017 FAQs: "[T]he Departments continue to believe that the existing accommodation regulations are consistent with RFRA for two independent reasons. First, as eight of the nine courts of appeals to consider the issue have held, by virtue of objecting employers' ability to avail themselves of the accommodation, the contraceptive-coverage requirement does not substantially burden their exercise of religion. Second, as some of those courts have also held, the accommodation is the least restrictive means of

furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage.” J.A. 172.

69. The agencies never explained why using pharmacies, willing doctors, or contraceptive-only plans would not be feasible solutions. J.A. 172.

Response: Paragraph 69 is not material or relevant to this litigation.

70. On October 13, 2017, the agencies issued the Fourth IFR. J.A. 98.

Response: Undisputed.

71. The Fourth IFR stated the following: “Consistent with . . . the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.” J.A. 105.

Response: It is undisputed that the quoted language appears in the regulation.

72. The Fourth IFR stated that: “we have concluded that requiring such compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many . . . and . . . we conclude requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest. . . .” J.A. 112.

Response: It is undisputed that the quoted language appears in the regulation.

73. The Fourth IFR stated that: “Good cause exists to issue the expanded exemption in these

interim final rules in order to cure such violations [of RFRA] (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters.” J.A. 120.

Response: It is undisputed that the quoted language appears in the regulation.

74. The Fourth IFR provided that the Mandate would not be enforced against “employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs.” J.A. 114.

Response: It is undisputed that the quoted language appears in the regulation.

75. The IFRs left the Mandate and the accommodation in place as they applied to other employers who do not have religious or moral objections. J.A. 98.

Response: Paragraph 75 states a legal conclusion to which no response is required. The regulation speaks for itself.

76. There was a 60-day comment period for the IFRs. J.A. 98.

Response: Undisputed.

77. Pennsylvania did not provide comments to the federal government during any of the comment periods related to the contraceptive mandate from 2010-2016.

Response: Paragraph 77 is not material or relevant to this litigation.

78. New Jersey did not provide comments to the federal government during any of the comment periods related to the contraceptive mandate from 2010-2016.

Response: Paragraph 78 is not material or relevant to this litigation.

79. Pennsylvania, for the first time in six notice and comment periods, filed comments on the Fourth IFR on December 5, 2017. J.A. 1384-1392.

Response: Undisputed that Pennsylvania filed comments on December 5, 2017, opposing the Religious and Moral Exemption IFRs. Disputed that whether Pennsylvania filed comments previously is relevant or material to this litigation.

80. New Jersey did not join that comment. J.A. 1384-1392.

Response: Disputed that whether New Jersey filed comments previously is material or relevant to this litigation.

81. After receiving comments and reviewing them over a period of several months, the agencies finalized the IFRs in final rules that took effect on January 14, 2019, 60 days after they were published in the Federal Register. J.A. 1, 5.

Response: Disputed. The final rules did not take effect on January 14, 2019, because they were enjoined by this Court. The States also dispute Paragraph 81 to the extent it implies that the Agencies complied with the notice and comment requirements of the APA.

82. The Commonwealth of Pennsylvania does not have a contraceptive mandate of its own. J.A. 3565.

Response: Paragraph 82 states a legal conclusion to which no response is required. Pennsylvania has taken several steps to provide its citizens with access to healthcare, including contraceptive care. J.A. 3563-66; 3703-08.

83. New Jersey's state contraceptive mandate has a religious exemption that is broader than the agencies' initial religious exemption. J.A. 3569.

Response: Paragraph 83 states a legal conclusion to which no response is required. The States dispute that New Jersey's state contraceptive mandate has a broader religious exemption. J.A. 3568-69.

84. Between 1995 and 2010, 28 states instituted mandates similar to the HHS Mandate, requiring private health insurance plans to cover various forms of contraception. J.A. 2261.

Response: Disputed. Paragraph 84 cites to a law review article that itself cites an article from 1994 as its sole source of authority for the above claim. J.A. 2261.

85. At least one study has shown that those contraception mandates had little impact on unintended pregnancy rates or abortion rates. J.A. 2282-83.

Response: Disputed. Paragraph 85 cites a law review article, not a research study. The States further dispute that the mandate has not had an impact on unintended pregnancy rates or abortion rates.

86. The States have not provided evidence of a single individual who would lose coverage as a result of the Final Rules. J.A. 1801, 1851.

Response: Disputed. The States have provided evidence that women in Pennsylvania and New Jersey are likely to lose contraceptive coverage as a result of the Final Rules. ECF No. 162.

87. Pennsylvania has never enacted a statute or issued a regulation to ensure that all of its female citizens of reproductive age receive seamless access to cost-free contraceptive coverage.

Response: Disputed. Pennsylvania has taken several steps to provide its citizens with access to healthcare, including contraceptive care. J.A. 3563–66; 3703–08.

88. New Jersey has never enacted a statute or issued a regulation to ensure that all of its female citizens of reproductive age receive seamless access to cost-free contraceptive coverage.

Response: Disputed. Paragraph 88 is misleading. The Gennace Declaration states that “New Jersey law requires employers who offer fully-insured plans to provide coverage for expenses incurred in the purchase of prescription female contraceptives to the same extent as any other outpatient prescription drug under the policy.” J.A. 3568–69.

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