

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

COMMONWEALTH OF)
PENNSYLVANIA and)
STATE OF NEW JERSEY,)

Plaintiffs,)

v.)

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

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

Defendants.)

FEDERAL DEFENDANTS’ MOTION FOR SUMMARY JUDGMENT

Federal Defendants hereby move for summary judgement, under Federal Rule of Civil Procedure 56, with respect to the claims in Plaintiffs’ Amended Complaint for Declaratory and Injunctive Relief [ECF No. 89]. The accompanying memorandum provides the bases for this motion.

DATED: June 14, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on June 14, 2019, a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

DATED this 14th day of June, 2019.

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG

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**FEDERAL DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION FOR
SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR
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INTRODUCTION

As part of the Patient Protection and Affordable Care Act (ACA), Congress required employers to cover some recommended preventive services without cost sharing. That law does not mention contraceptive coverage. The Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services (HHS), issued guidelines mandating coverage of all FDA-approved contraceptives. At the same time, the government recognized that some employers hold sincere religious objections to providing coverage for some forms of contraception, but decided to exempt only a fraction of those employers—churches and their integrated auxiliaries—from the requirement. The Departments of HHS, Labor, and the Treasury (the Agencies) ultimately recognized that the contraceptive-coverage mandate imposed a substantial burden on the exercise of religion of certain entities, and attempted to alleviate that burden through an “accommodation.” Yet the accommodation still substantially burdened the religious exercise of some entities, and led to years of litigation. To address these serious religious objections and parallel moral objection, and to conclude the litigation, the Agencies enacted final rules that expand the prior exemption.¹

Both RFRA and the ACA authorize the government to satisfy its obligations under RFRA by using the straightforward exemption provided by the Rules rather than attempting to rely only on the novel accommodation previously created by the government. That is especially true because the accommodation itself violates RFRA as to certain entities or is, at a minimum, subject to significant legal doubt. As the Agencies concluded and some courts have held, the accommodation imposes a substantial burden on some employers by using the plans they sponsor to provide contraceptive coverage that they object to on religious grounds, which some employers sincerely believe makes them complicit in the provision of such coverage.

¹ Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,536 (Nov. 15, 2018) (the Religious Exemption Rule); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (the Moral Exemption Rule) (collectively, the Rules).

Furthermore, the Rules are not arbitrary and capricious under the Administrative Procedure Act (APA): The Rules are a reasonable response to years of litigation over the scope of the contraceptive-coverage mandate, well-founded in the evidence before the Agency, and responsive to the significant comments that were presented. The Rules also comply with the procedural requirements of the APA, as they were promulgated after notice and an opportunity for comment. Finally, the Rules comport with both the Establishment and Equal Protection Clauses, as they neither establish religion nor discriminate against women. The Court, therefore, should deny Plaintiffs' motion for summary judgment and grant Federal Defendants' motion for summary judgment.

BACKGROUND

I. The Affordable Care Act and the Contraceptive-Coverage Mandate.

The ACA requires most group health plans and health-insurance issuers that offer group or individual health coverage to provide coverage for certain preventive services without "any cost sharing requirements." 42 U.S.C. § 300gg-13(a). The Act does not specify the types of women's preventive care that must be covered. Instead, as relevant here, the Act requires coverage, "with respect to women," of such "additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration ["HRSA"]." *Id.* § 300gg-13(a)(4).

In August 2011, HRSA adopted the recommendation of the Institute of Medicine, a part of the National Academy of Sciences, to issue guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods, including oral contraceptives, diaphragms, injections and implants, emergency contraceptive drugs, and intrauterine devices. *See Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventing Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). As a result, coverage for such contraceptive methods was required for plan years beginning on or after August 1, 2012. *See Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventing*

Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011).

At the same time, the Agencies, invoking their statutory authority under 42 U.S.C. § 300gg-13(a)(4), promulgated interim-final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623; 77 Fed. Reg. at 8,725. Various religious groups urged the Agencies to expand the exemption to all religious not-for-profit organizations and other organizations with religious or moral objections to providing contraceptive coverage. *See* Coverage of Certain Preventative Services Under the Affordable Care Act, 78 Fed. Reg. 8,456, 8,459 (Feb. 6, 2013). Instead, in a subsequent rulemaking, the Agencies offered only what they termed an “accommodation” for religious not-for-profit organizations with religious objections to providing contraceptive coverage. *See* Coverage of Certain Preventative Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,874-82 (July 2, 2013). The accommodation allowed a group health plan established or maintained by an eligible objecting employer to opt out of any requirement to directly “contract, arrange, pay, or refer for contraceptive coverage,” *id.* at 39,874, by providing notice of its objection. The regulations then generally required the employer’s health insurer or third-party administrator to provide or arrange contraceptive coverage for plan participants. *See id.* at 39,875-80.

In the case of self-insured church plans, however, coverage by the plan’s third-party administrator under the accommodation was voluntary.² Church plans are exempt from the Employee Retirement Income Security Act of 1974 (ERISA) under section 4(b)(2) of that Act, and the authority to enforce a third-party administrator’s obligation to provide separate contraceptive coverage derives solely from ERISA. The Agencies thus could not require the third-party administrators of church plans—and, by extension, many nonprofit religious organizations

² A church plan can include a plan maintained by a “principal purpose” organization (typically, a religious nonprofit) regardless of who established it. *See Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1655-63 (2017); *see also* 29 U.S.C. § 1002(33).

participating in those plans—to provide or arrange for such coverage or to impose fines or penalties for failing to provide such coverage. *See* Coverage of Certain Preventative Services Under the Affordable Care Act, 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

Even apart from the exemption for churches and their integrated auxiliaries, the mandate did not apply to many employers. The ACA itself exempts from the preventive-services requirement, and therefore from any contraceptive-coverage mandate imposed as part of that requirement, “grandfathered” health plans (generally, those plans that have not made specified changes since the Act’s enactment), *see* 42 U.S.C. § 18011, which cover tens of millions of people, *see* 83 Fed. Reg. 57,541 (Nov. 15, 2018) (estimating over 25 million individuals enrolled in such plans). And employers with fewer than fifty employees are not subject to the tax imposed on employers that fail to offer health coverage, *see* 26 U.S.C. § 4980H(c)(2), although such small employers that provide non-grandfathered coverage must comply with the preventive-services requirement.

II. Challenges to the Contraceptive-Coverage Mandate and Accommodation

Many employers objected to the contraceptive-coverage mandate. In *Burwell v. Hobby Lobby Stores, Inc.*, the Supreme Court held that RFRA prohibited applying the mandate to closely held for-profit companies with religious objections to providing contraceptive coverage. The Court held that the mandate “impose[d] a substantial burden on the exercise of religion” for employers with religious objections, 573 U.S. 682, 726 (2014), and that even assuming a compelling governmental interest, application of the mandate to such employers was not the least restrictive means of furthering that interest, *id.* at 727. The Court observed that, at a minimum, the less-restrictive accommodation made available to not-for-profit employers by the Agencies could be extended to closely held for-profit companies with religious objections to the mandate but not the accommodation. *Id.* at 730. The Court did not decide, however, “whether an approach of this type complies with RFRA for purposes of all religious claims.” *Id.* at 731.

In response to *Hobby Lobby*, the Agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing

contraceptive coverage. *See* 80 Fed. Reg. at 41,323-28. But numerous entities continued to challenge the mandate. They argued that the accommodation burdened their exercise of religion because they sincerely believed that the required notice and the provision of contraceptive coverage in connection with their health plans made them complicit in providing such coverage, in contravention of their faith.

A circuit split developed,³ and the Supreme Court granted certiorari in several of the cases. The Court vacated the judgments and remanded the cases to the respective courts of appeals. *See Zubik*, 136 S. Ct. 1557 (2016) (per curiam). The Court “d[id] not decide whether [the plaintiffs’] religious exercise ha[d] been substantially burdened, whether the Government ha[d] a compelling interest, or whether the current regulations [we]re the least restrictive means of serving that interest.” *Id.* at 1560. Instead, the Court held that, on remand, the Courts of Appeals should afford the parties an opportunity to resolve the dispute. In the meantime, the Court precluded the government from “impos[ing] taxes or penalties on [the plaintiffs] for failure to provide the [notice required under the accommodation].” *Id.* at 1561.

In response to the Supreme Court’s *Zubik* order, the Agencies requested public comment to determine whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while providing a mechanism for coverage for their employees. *See* Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies received over 54,000 comments, but they could not find a way to amend the accommodation to both account for employers’ religious obligations and provide coverage to their employees. *See* FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).⁴

³ Compare, e.g., *Priests for Life v. HHS*, 772 F.3d 229 (D.C. Cir. 2014) (accommodation does not substantially burden religious exercise), *vacated and remanded*, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), with *Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927 (8th Cir. 2015) (accommodation violates RFRA), *vacated by HHS v. CNS Int’l Ministries*, 136 S. Ct. 2006 (2016).

⁴ Available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf>.

The pending litigation—more than three dozen cases brought by more than 100 separate plaintiffs—thus remained unresolved.

In addition, some nonreligious organizations with moral objections to providing contraceptive coverage challenged the mandate. That litigation also led to conflicting decisions by the courts. *Compare Real Alternatives, Inc. v. Secretary, HHS*, 867 F.3d 338 (3d Cir. 2017) (rejecting challenge), with *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015) (issuing permanent injunction against the government), *dismissing appeal*, 2018 WL 4871092 (D.C. Cir. Sept. 17, 2018).

III. The Interim Final Rules

In an effort “to resolve the pending litigation and prevent future litigation from similar plaintiffs,” the Agencies concluded that it was “appropriate to reexamine” the mandate’s exemption and accommodation. Religious Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,799 (Oct. 13, 2017). In October 2017, the Agencies issued two interim final rules, or IFRs, that requested public comments and that expanded the exemption while continuing to offer the existing accommodation as an optional alternative.

The first rule expanded the religious exemption to all nongovernmental plan sponsors, as well as similar institutions of higher education in their arrangement of student health plans, and to individuals able to obtain religiously compliant plans from willing employers and issuers. *See id.* at 47,806. The Agencies relied in part on their consistent interpretation of the preventive-services provision to convey “broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women’s preventive care and screenings in the Guidelines.” *Id.* at 47,794.

The Agencies acknowledged that contraceptive coverage is “an important and highly sensitive issue, implicating many different views.” 82 Fed. Reg. at 47,799. But “[a]fter reconsidering the interests served by the [m]andate,” the “objections raised,” and “the applicable Federal law,” the Agencies “determined that an expanded exemption, rather than the existing

accommodation, [wa]s the most appropriate administrative response to the religious objections raised by certain entities and organizations.” *Id.* The Agencies also explained that the new approach was necessary because “[d]espite multiple rounds of rulemaking,” and even more litigation, they “ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations” or resolved the pending legal challenges that had divided the courts. *Id.*

The second rule created a similar exemption for entities with sincerely held moral objections to providing contraceptive coverage; unlike the religious exemption, though, this rule did not apply to publicly traded companies. *See* Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017). This rule was issued “in part to bring the [m]andate into conformity with Congress’s long history of providing or supporting conscience protections in the regulation of sensitive health-care issues,” *id.* at 47,844, as well as similar efforts by states, including Plaintiffs, *id.* at 47,847. The IFR further reflected the Agencies’ attempts to address conflicting court decisions in legal challenges from moral objectors. *Id.* at 47,843.

Invoking agency-specific statutory authority to issue interim final rules, 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92, the Agencies’ use of interim final rules on three prior occasions with respect to the preventive services requirements, and the APA’s general “good cause” exception, 5 U.S.C. § 553(b), the Agencies issued the IFRs without prior notice and comment. The Agencies solicited public comments for 60 days post-promulgation in anticipation of final rulemaking. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838.

IV. Plaintiffs’ Challenge to the IFRs and the Court’s Opinion

Pennsylvania brought suit challenging the IFRs. The Court granted Plaintiffs’ motion for preliminary injunctive relief, concluding that Plaintiffs were likely to succeed on their claims that the Agencies lacked the authority to issue interim final rules and were instead required to engage in notice and comment rulemaking. Opinion, ECF No. 59, at 19-29 (“First PI Opinion”). The Court also held that Plaintiffs were likely to succeed on their claim that the IFRs violated the text of the ACA. *Id.* at 29-37.

V. The Final Rules

After considering, for over 11 months, the more than 110,000 comment submissions on the IFRs, on November 15, 2018, the Agencies issued final versions of the religious exemption and the moral exemption rules. The final rules address the significant comments received by the Agencies. Changes were made in response to questions and concerns raised in various comments, while the fundamental substance of the exemptions was finalized as set forth in the IFRs.

As was true of the religious exemption IFRs, the final religious exemption rule is “necessary to expand the protections for the sincerely held religious objections of certain entities.” 83 Fed. Reg. at 57,537. It “minimize[s] the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing.” *Id.* The rule “do[es] not remove the contraceptive coverage requirement generally from HRSA’s Guidelines.” *Id.* What it does is this:

[F]inalize exemptions [for] the same types of organizations and individuals for which exemptions were provided in the Religious [IFR]: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals.

Id. “In addition, the [religious exemption] maintain[s] a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators.” *Id.*

In response to comments on the religious IFR, the Agencies made numerous clarifying or technical changes in the final religious exemption rule. For example, the final rule clarified the prefatory language to the exemptions “to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections.” *Id.*; *see also id.* (listing modifications). The Agencies also “revise[d] the exemption applicable to health insurance issuers

to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement.” *Id.*

The final moral exemption rule continues to fulfill the purpose that it did in interim form: to “protect sincerely held moral objections of certain entities and individuals.” 83 Fed. Reg. at 57,592. The Agencies considered public comments asking for the moral exemption to be expanded to publicly traded or government entities, but declined to do so. *Id.* at 57,616-19. Importantly, like the religious exemption rule, the moral exemption rule “do[es] not remove the contraceptive coverage requirement generally from HRSA’s guidelines.” *Id.* at 57,593. And “[t]he changes to the rule[] being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA’s decision to otherwise require contraceptive coverage.” *Id.* The Agencies observed that they knew of only two entities claiming non-religious moral objections, and both hired only employees who shared their views. *Id.* at 57,617. The Agencies thus concluded that “subjecting this subset of organizations to the Mandate does not advance any governmental interest.” *Id.* at 57,602.

VI. Plaintiffs’ Amended Complaint and the Second Preliminary Injunction

Following the issuance of the Final Rules, New Jersey joined Pennsylvania’s suit and the two States filed an amended complaint challenging the Final Rules. Am. Compl. ¶ 33, ECF No. 89. The five counts tracked the five counts in the original complaint. *Id.* ¶¶ 156-194. The Court granted Plaintiffs’ second motion for a preliminary injunction. Opinion, ECF No. 136 (“Second PI Opinion”). As an initial matter, the Court rejected arguments that Plaintiffs had not demonstrated standing and that venue was improper in this District. *Id.* at 13-23. The Court also rejected Plaintiffs’ argument that in promulgating the Final Rules, the Agencies’ actions failed to adequately address comments. *Id.* at 25-27. Next, the Court found that Plaintiffs were likely to succeed on their claim that issuance of the Final Rules violated the APA’s notice-and-comment

requirements. *Id.* at 27-33. The Court further determined that Plaintiffs were likely to succeed on their claim that the Final Rules were contrary to law because neither the ACA nor RFRA justified the expanded exemptions from the mandate. *Id.* at 34-52. The Court issued a nationwide injunction barring enforcement of the Final Rules. *Id.* at 65.

LEGAL STANDARD

The Court should enter summary judgment in favor of Defendants on Plaintiffs' claims under Federal Rule of Civil Procedure 56. "[D]istrict courts reviewing agency action under the . . . [APA] do not resolve factual issues, but operate instead as appellate courts resolving legal questions." *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). And "because the district judge sits as an appellate tribunal in such cases" "summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency's action is supported by the administrative record and consistent with the APA standard of review." *Dorley v. Cardinale*, 119 F. Supp. 3d 345, 351 (E.D. Pa. 2015).⁵

ARGUMENT

I. The Rules Are Authorized by the ACA and RFRA, and Are Otherwise Consistent with the Law.

A. The Rules Comport with the Women's Health Amendment

Plaintiffs' argument that the Rules violate the Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4), fails because the ACA grants HRSA, and in turn the Agencies, significant discretion to shape the content and scope of any preventive-services guidelines adopted pursuant to § 300gg-13(a)(4). Although this Court concluded that Plaintiffs had shown a likelihood of success on the merits with respect to this argument in resolving Plaintiffs' preliminary injunction motion, the Agencies respectfully urge this Court to consider this issue anew at the summary judgment stage.

⁵ Plaintiffs have not established that they have standing, thus, the Court should dismiss this suit for lack of subject-matter jurisdiction. *See* Federal Defs.' Mot. to Dismiss, March 28, 2019, ECF No. 157.

The ACA does not specify the types of preventive services that must be included in such guidelines. Instead, as relevant here, it provides only that, “with respect to women,” coverage must include “such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a)(4). Several textual features of § 300gg-13(a) demonstrate that this provision grants HRSA broad discretionary authority, authority that the Agencies have recognized since HRSA first announced the contraceptive mandate and its accompanying church exemption.

First, unlike the other paragraphs of the statute, which require preventive-services coverage based on, *inter alia*, “current recommendations of the United States Preventive Services Task Force,” recommendations “in effect . . . from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention,” or “the comprehensive guidelines” that HRSA had already issued with respect to preventive care for children, the paragraph concerning preventive care for women refers to “comprehensive guidelines” that did not exist at the time of the ACA’s enactment. *Compare id.* § 300gg-13(a)(1), (2), (3), *with id.* § 300gg-13(a)(4). That paragraph thus necessarily delegated the content of the guidelines to HRSA.

Second, nothing in the statute mandates that the guidelines include contraception at all, let alone all types of contraception for all types of employers with covered plans. On the contrary, the statute provides only for coverage of preventive services “as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph.” *Id.* § 300gg-13(a)(4). The use of the phrase “for purposes of this paragraph” makes clear that HRSA should consider the particular context of the employer mandate in creating the guidelines, and the use of the phrase “as provided for” indicates that HRSA has discretion to define not only the services to be covered, but also the manner or reach of that coverage. *See also* 83 Fed. Reg. at 57,540 n.10; 57,541 (discussing the Agencies’ interpretation of the word “as” to confer discretion on the Agencies). The broad discretion granted to HRSA is further reinforced by the absence of the words “evidence-based” or “evidence-informed” in this subsection, as compared with § 300gg-13(a)(1), (3), which confirms

that Congress authorized HRSA to consider factors beyond the scientific evidence in deciding whether to support a coverage mandate for particular preventive services.

Accordingly, § 300gg-13(a)(4) must be understood as a positive grant of authority for HRSA to develop the women's preventive-services guidelines and for the Agencies, as the administering Agencies of the applicable statutes, to shape that development. *See* 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. That is especially true for HHS, as HRSA is a component of HHS that HHS created and that is subject to the HHS Secretary's general supervision. *See* HRSA; Statement of Organization, Functions, and Delegations of Authority, 47 Fed. Reg. 38,409 (Aug. 31, 1982). The text of § 300gg-13(a)(4) thus authorized HRSA to adopt guidelines for coverage that include an exemption for certain employers, and nothing in the ACA prevents HHS from supervising HRSA in the development of those guidelines. Indeed, since their first rulemaking on this subject in 2011, the Agencies have consistently interpreted the broad delegation to HRSA in § 300gg-13(a)(4) to include the authority to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage by exempting churches and their integrated auxiliaries from the contraceptive-coverage mandate.⁶ *See* 76 Fed. Reg. at 46,623. Plaintiffs do not challenge that

⁶ Plaintiffs argue that Congress's exemption of certain employers with grandfathered plans, and its rejection of a conscience amendment, mean that the statute should be read to preclude the creation of religious or moral exemptions. *See* Pls.' Mot. for Summ. J., May 15, 2019, ECF No. 170 ("SJ Mem."), at 13 n.5. With respect to grandfathered plans, they are significant but not for the reasons Plaintiffs assert. The grandfathering exemption demonstrates that Congress did not intend uniform coverage of preventive services across all employers, which is consistent with the Agencies' interpretation of the statute: although grandfathered plans are required to comply with numerous provisions of the ACA, they are exempt from the law's requirement to provide coverage for preventive services. *See* 83 Fed. Reg. 57,541. And no federal law requires phasing out of the exemption for grandfathered plans. *See Hobby Lobby*, 573 U.S. at 700 n.10. In light of Congress' decision to provide exemptions from all preventive services coverage for grandfathered plans, it is not unreasonable to interpret the statute to also provide the Agencies with discretion to create exemptions for certain preventive services for religious and moral objectors. Nor should the rejection of a conscience amendment bear on this Court's assessment of the meaning of § 300gg-13(a)(4). "Failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute." *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994) (citation

exemption, and because it was not limited in any way to those with sincerely held religious beliefs in opposition to contraception, it could be authorized only under § 300gg-13(a)(4).

In light of this statutory and regulatory backdrop, the Agencies' exercise of authority to expand the exemption is, at the very least, a reasonable construction of the statute entitled to deference. *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). Under Step Two of the *Chevron* doctrine, a court must defer to an agency's reasonable interpretation of an ambiguous statute. *Id.* at 843 (“ . . . if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute”). An agency is entitled to *Chevron* deference not only with regard to interpretations of substantive law, but also with regard to the scope of that agency's authority. *City of Arlington v. FCC*, 569 U.S. 290 (2013). Hence, if this Court concludes that the statute is ambiguous as to whether it provides the Agencies with discretion to create or modify contraceptive coverage exemptions, the Agencies' construction must prevail because it is a reasonable one.

B. RFRA Authorizes and Compels the Religious Exemption

RFRA independently authorizes the religious exemption. RFRA prohibits the government from “substantially burden[ing] a person's exercise of religion” unless the application of the burden to that person is “the least restrictive means” of furthering a “compelling governmental interest.” 42 U.S.C. § 2000bb-1(b). RFRA thus requires the government to eliminate any substantial burden imposed by the contraceptive-coverage mandate, including the substantial burden recognized by the Supreme Court in *Hobby Lobby*. The expanded religious exemption is a permissible—and in the case of some objecting employers, required—means of doing so. The

omitted). Congress may decline to adopt a proposal for any number of reasons, including “that the existing legislation already incorporated the offered change.” *Id.* See also 158 Cong. Rec. S485 (Feb. 9, 2012) (statement of Sen. Reid) (“They are talking about first amendment rights, the Constitution. I appreciate that. But that is so senseless. This debate that is going on dealing with this issue, dealing with contraception, is a rule that has not been made final yet. There is no final rule. Let's wait until there is at least a rule we can talk about.”).

Agencies were not required to repeatedly amend the accommodation in response to litigation in an attempt to find the singular accommodation that would be *least* protective of objectors' religious exercise while still prevailing in a RFRA lawsuit brought by objectors. Put another way, RFRA authorizes the Agencies to provide an exemption to eliminate the substantial burden imposed by the mandate rather than continue the protracted litigation that has thus far been the hallmark of the contraceptive-coverage mandate.

1. RFRA Permits Agencies to Create Exemptions to Alleviate Substantial Burdens on Religious Exercise

Plaintiffs argue that RFRA permits only individual, judicially-created exemptions, SJ Mem. at 15-16, and that the Agencies must therefore await a lawsuit before they bring their actions into compliance with the law. Yet, by its own text, RFRA applies to “the implementation of” “all Federal law,” 42 U.S.C. § 2000bb-3(a), which necessarily includes agency regulations and guidance. In addition, RFRA provides that the “Government shall not substantially burden a person’s exercise of religion” unless strict scrutiny is satisfied. *Id.* § 2000bb-1(a)-(b). The plain text of the statute itself thus prohibits a federal agency from promulgating a regulation that it knows would impose such an unjustified burden and authorizes agencies to take affirmative steps to eliminate substantial burdens on religious exercise. Furthermore, an interpretation that required agencies to await inevitable litigation would perpetuate burdens on religious exercise—after the Supreme Court’s decision in *Hobby Lobby*, should every closely held for-profit corporation with a religious objection to providing contraceptive coverage still have been put to the expense and burden of filing their own lawsuit? Such an interpretation would also lead to perverse results: here, for example, the Agencies would not have been able to create the accommodation for employers that do not object to it, and instead would have been forced to provide even those employers an exemption when they invoked RFRA as “a claim or defense” against enforcement of the contraceptive coverage mandate. *See* 42 U.S.C. § 2000bb-1(c).

The fact that RFRA *also* provides for judicial review of private claims is not inconsistent with the Agencies' own burden to comply with RFRA. *Cf.* SJ Mem. at 16. As this Court recognized, the Final Rules are in keeping with the Agencies' prior practice of responding to the Supreme Court's decisions concerning religious objections by "expand[ing] or modif[y]ing] the exemption and accommodation framework in an attempt to bring the Agencies' actions in line with what the Supreme Court said RFRA commands." Second PI Opinion, at 51 n.23.

Nor do the Agencies maintain that RFRA authorizes them to create any exemptions they want. The Agencies' actions are subject to "arbitrary and capricious" review under the APA, and the Religious Exemption Rule at issue here *is* tailored because it applies only to employers with a sincere religious objection to the mandate. Plaintiffs contend that the Agencies should be required to "find an alternative means of achieving the goals of that statute," SJ Mem. at 17, but this suggestion finds no support in RFRA, and here, as the Rule thoroughly explains, the Agencies have already spent nearly a decade unsuccessfully attempting to satisfy all parties.⁷

Plaintiffs also point to the alleged burdens imposed on third parties in their discussion of RFRA. SJ Mem. at 17. For the reasons discussed below, the Religious Exemption Rule complies with all requirements of the Establishment Clause and does not unduly burden third parties, because no "burden" exists when the government chooses to narrow the scope of a subsidy it had previously required employers to provide. See Argument § I.F.. In any event, RFRA contains no separate restriction on exemptions that may affect third parties, likely because nearly all exemptions—even the individual, judicially-imposed RFRA exemptions that Plaintiffs favor—

⁷ Plaintiffs would also argue that objectors are not required to "provide notice" of their religious objection. SJ Mem. at 17. But, under ERISA, objecting entities must provide notice of a change in coverage to their employees. *See* 83 Fed. Reg. at 57,558.

will have some effect on third parties, just as the prior exemption for churches and their integrated auxiliaries did.

2. Religious Objectors Are Substantially Burdened in the Absence of the Religious Exemption Rule.

Contrary to Plaintiffs' assertions, SJ Mem. at 17-19, the Religious Exemption Rule is necessary to alleviate the substantial burden that some employers would otherwise face under the accommodation. The Final Rules are a permissible response by the Agencies to precisely the substantial burden identified by the Court in *Hobby Lobby* (on objecting for-profit corporations)—although the Agencies had previously attempted to address that burden through the accommodation, RFRA does not specify the method that the Agencies must use to address the substantial burden. RFRA does not require the government to inch forward one quantum of accommodation at a time—all the while defending against RFRA lawsuits by religious objectors—until it stumbles upon the precise accommodation that a court will uphold as to all religious objectors. Indeed, if the Agencies had simply adopted an exemption similar to the Religious Exemption Rule from the outset, no one could reasonably have argued that doing so was improper because the Agencies should have invented the accommodation instead, and the outcome should not be different simply because the Agencies attempted the accommodation first. A contrary rule would trap the Agencies in endless litigation every time they attempt to accommodate religion, as has occurred here regarding religious exemptions to the contraceptive-coverage mandate. 82 Fed. Reg. at 47,798; *see also Ricci v. DeStefano*, 557 U.S. 557, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate-impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban); *cf. Walz v. Tax Comm'n of the City of N.Y.*, 397 U.S. 664, 669 (1970) (recognizing “room for play in the joints” when accommodating exercise of religion).

In addition, the logic of *Hobby Lobby* compels the conclusion that an *additional* substantial burden exists on entities that sincerely believe complying with the accommodation process violates their religious exercise, and the Religious Exemption Rule is an acceptable response by the

Agencies to alleviate that burden. *Hobby Lobby* establishes that a court’s “narrow function in this context is to determine whether the line drawn [by a religious objector] reflects an honest conviction,” as opposed to “in effect tell[ing] the plaintiffs that their beliefs are flawed.” 573 U.S. at 724-25 (cleaned up); *see also id.* at 725 (“[I]t is not for [a court] to say that [an objector’s] religious beliefs are mistaken.”). It is thus 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. The substantiality analysis is straightforward because the substantial burden resulting from the accommodation is the significant financial penalty imposed for failure to comply with the mandate or accommodation—the same penalty the plaintiffs faced in *Hobby Lobby*, where the Court had “little trouble” concluding that the mandate imposed a substantial burden.⁸ 573 U.S. at 719.

Plaintiffs also argue that *Real Alternatives, Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338 (3d Cir. 2017), compels a different outcome, SJ Mem. at 18, but the language Plaintiffs reference from *Real Alternatives* is dicta because *Real Alternatives* required the court to decide only whether the accommodation substantially burdened *employees*—not objecting employers or schools, *see id.* at 355 & n.17 (noting that the relevant question “is distinct from an employer’s RFRA claim objecting to the mandated provision of contraceptive services that was found to be meritorious in [*Hobby Lobby*]”). To the extent Plaintiffs suggest that the Agencies are required to point to judicial opinions identifying a substantial burden before the Agencies

⁸ To the extent that the Court is concerned that *Hobby Lobby* held that RFRA cannot support broader exemptions, Second PI Opinion at 48 (citing *Hobby Lobby*, 573 U.S. at 719 n.30), it need not be. The Supreme Court merely noted that little significance should be given to Congress’s rejection of a conscience amendment because Congress was well aware that RFRA was a background norm governing all federal law when the ACA was enacted. *Hobby Lobby*, 573 U.S. at 719 n.30. The Court also noted that the failed amendment extended beyond religious objections, and would not subject objections to “the judicial scrutiny called for by RFRA” which includes “the government’s interest and how narrowly tailored the requirement is.” *Id.* The Court in no way suggested that a broader exemption could never be required under RFRA, let alone where, as here, the Court has already determined that the contraceptive-coverage mandate imposes a substantial burden and the Agencies have concluded that application of the mandate to religious objectors does not serve a compelling governmental interest

recognize such a burden themselves, SJ Mem. at 18-19, that is incorrect—as stated above, RFRA requires agencies to assess the potential impact of their rules on religious exercise independent of a specific court case, and here the Agencies reevaluated their conclusions, applied *Hobby Lobby*'s logic, and concluded that entities that objected to complying with the accommodation were substantially burdened. 83 Fed. Reg. 57,546.

3. There Is No Compelling Interest in Requiring Objectors to Provide Contraceptive Coverage

Plaintiffs' brief does not engage at all with the multiple reasons on which the Agencies relied to conclude that applying the contraceptive mandate to objecting employers is not the least restrictive means of furthering a compelling governmental interest as applied to those objectors. SJ Mem. at 19-20. These reasons include:

1. Congress has a history of providing flexibility in what contraceptives must be covered. 83 Fed. Reg. at 57,546-47.

2. Many other health plans are not required to provide contraceptive coverage apart from the Rule, including grandfathered plans, exempt churches and their integrated auxiliaries, and self-insured church plans that availed themselves of the accommodation. *Id.* at 57,547; *cf. Advocate Health Care Network*, 137 S. Ct. at 1658-59.

3. The Agencies reached the expert determination that the administrative record does not contain adequate evidence to meet the high standard of demonstrating a compelling interest. 83 Fed. Reg. at 57,547.

4. Contraceptives are available from alternative sources, including from government programs for low-income women and from objecting entities that are willing to cover some but not all contraceptives. *Id.* at 57,548. In noting this point, the Agencies considered research analyzing the effect of ACA implementation on contraceptive use. *Id.* (citing M.L. Kavanaugh et al., *Contraceptive Method Use in the United States: Trends and Characteristics Between 2008, 2012 and 2014*, 97 *Contraception* 14, 14–21 (2018), Joint Appendix (“JA”) at 2650-57). That

research concluded that: “The role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012-2014) excepting small increases in implant use,” perhaps because “many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid” prior to implementation of the ACA. JA 2654-55.

In any event, the Government is not aware of any case in which a court has held that the Government has a compelling interest when the Government itself has not asserted such an interest.

C. The Rules Do Not Create an Unreasonable Barrier to Healthcare

The Rules do not “(1) create[] any unreasonable barriers to the ability of individuals to obtain appropriate medical care; [or] (2) impede[] timely access to health care services.” 42 U.S.C. § 18114(1), (2).

As an initial matter, the sub-sections of section 18114 are quite open-ended. Nothing in section 18114 specifies, for example, what constitutes an “unreasonable barrier[],” “appropriate medical care[,]” or “timely access.” As far as Defendants are aware, this provision was not the subject of any meaningful legislative history before the ACA’s enactment, and Plaintiffs provide none. Under these circumstances, section 18114 claims are not reviewable under the APA at all. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (APA bars judicial review of agency decision where, among other circumstances, “statutes are drawn in such broad terms that in a given case there is no law to apply” (citation omitted)).

In any event, the Rules do not implicate section 18114 because “the decision not to impose a governmental mandate is not the ‘creation’ of a ‘barrier.’” 83 Fed. Reg. at 57,552. The Rules do not prevent women from obtaining medical care, including contraceptive care. They merely provide that certain employers need not furnish cost-free *coverage* for such services to their employees when doing so violates the employers’ religious or moral convictions. *Cf. Harris v.*

McRae, 448 U.S. 297, 316 (1980) (“[A]lthough government may not place obstacles in the path of a woman’s exercise of her freedom of choice, it need not remove those not of its own creation[, such as indigency].”).⁹

Furthermore, under Plaintiffs’ interpretation, section 18114 would mandate the provision of all “appropriate medical care,” rendering the ACA’s extensive discussion of Essential Health Benefits surplusage. *See generally* 42 U.S.C. §§ 18021, 18022. Even within the ACA, HHS routinely issues regulations placing criteria and limits on what the government will fund, and on what will be covered in ACA programs. Under Plaintiffs’ standardless interpretation of section 18114, it is far from clear that the government could ever impose any limit on any parameter of a health program and it is unclear how a court could possibly evaluate such challenges.¹⁰

D. The Rules Comply with Title VII and § 18116

Plaintiffs contend that the Rules violate Title VII’s prohibition on sex and pregnancy-related discrimination and, therefore, are “not in accordance with law” under the APA, 5 U.S.C. § 706(2)(A). SJ Mem. at 21-24. More specifically, Plaintiffs argue that the Rules provide “differential treatment of contraceptive benefits” on the basis of sex. *Id.* at 23. The argument is flawed and should be rejected. Similarly, Plaintiffs’ argument that the Rules violate 42 U.S.C. § 18116(a) should be rejected.

Title VII prohibits “employer[s]” from discriminating against an employee or job applicant “because of” or “on the basis of” “sex.” 42 U.S.C. § 2000e-2(a), (b). It extends similar prohibitions to employment agencies and labor organizations. *Id.* § 2000e-2(b), (c). In 1978, Congress enacted the Pregnancy Discrimination Act, Pub. L. No. 95-555, 92 Stat. 2076 (1978), which modified the definition of sex-based discrimination to specify, in relevant part, that “because of sex’ ...

⁹ Free or low-cost contraceptives can be obtained by some women through other means, such as Medicaid or the use of clinics that receive Title X funds.

¹⁰ The out-of-Circuit, preliminary decisions cited by Plaintiffs in support of their section 18114 claim, SJ Mem. at 20-21, are unpersuasive for the reasons explained above. Moreover, these decisions are on appeal in the Ninth Circuit. *See California v. Azar*, No. 19-15974; *Oregon v. Azar*, No. 19-35386; *Washington v. Azar*, No. 19-35394.

include[s] ... because of or on the basis of pregnancy, childbirth, or related medical conditions.” 42 U.S.C. § 2000e(k). Title VII prohibits, absent a showing of good cause, both explicitly sex-based distinctions (disparate treatment) as well as distinctions that have a disproportionate effect on one sex (disparate impact). *Id.*; see *EEOC v. Metal Serv. Co.*, 892 F.2d 341, 346–47 (3d Cir. 1990). To establish a prima facie case of disparate impact in a sex discrimination case, a plaintiff must essentially show “a significant statistical disparity,” *Ricci*, 557 U.S. at 587, in the effect of a regulation on men and women. But the defendant can rebut the suggestion of invidious discrimination by demonstrating that the distinction is required as a matter of “business necessity” or, in the case of the government, the “public interest.” *Id.*; *Tex. Dep’t of Hous. & Cmty. Affairs v. Inclusive Communities Project, Inc.*, 135 S. Ct. 2507, 2518 (2015) (referring to “a business justification— or, in the case of a governmental entity, an analogous public interest”).

First, the Rules do not violate Title VII because they have not been issued as part of an employment relationship. By its text, Title VII prohibits only employment discrimination, i.e., discrimination by employers and entities in the context of employer or employment like-relationships with individuals (e.g., employment agencies and labor organizations). 42 U.S.C. § 2000e-2(a)-(c); see *George v. N.J. Bd. of Veterinary Med. Examiners*, 794 F.2d 113, 114-15 (3d Cir. 1986). Plaintiffs are not in an employment relationship with the Federal Government. Plaintiffs cite two cases in support of the proposition that agency rules that “authorize” employers to violate Title VII can be challenged under the APA. SJ Mem. at 24 (citing *Farrington v. Johnson*, 206 F. Supp. 3d 634, 635, 644 (D.D.C. 2016); *Pima Cty. Cmty. Coll. Dist. v. EEOC*, 1976 WL 548, at *2 (D. Ariz. April 7, 1976)). But neither case actually stands for that proposition. In *Farrington*, the district court rejected the Federal Emergency Management Agency’s motion for summary judgment as to an APA claim regarding the enforcement of an EEOC order; plaintiff’s complaint did not raise and the Court did not adjudicate any Title VII claim. *Farrington*, 206 F. Supp. 3d at 640. And in *Pima*, plaintiff did not allege that the EEOC authorized illegal conduct by other employers, but rather that the EEOC itself violated the provisions of Title VII that dictate how the EEOC is to handle investigations of workplace discrimination. *Pima*, 1976 WL 548, at

1-2. Neither case, then, supports Plaintiffs' position that rules issued by federal agencies in their sovereign capacity can violate Title VII and, by extension, the APA.

Moreover, APA relief is unavailable on this claim. A plaintiff may bring an APA claim only if there is no other adequate legal remedy available. 5 U.S.C. § 704. But, if Plaintiffs' Title VII argument had any merit, an adequate remedy would be available: a Title VII suit against allegedly discriminating employers who avail themselves of the exemptions. *See Wash. Legal Found. v. Alexander*, 984 F.2d 483, 486 (D.C. Cir. 1993) (discrimination suits against third parties provide an adequate alternative remedy).

More fundamentally, however, the Rules do not discriminate on the basis of sex or pregnancy. While the Rules allow certain employers to omit contraceptive coverage from their health plans, the Rules do not require employers to do so. And the Rules do not draw sex- or pregnancy-based distinctions. The Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing an exemption for those with religious and conscience objections. The Rules and Guidelines do not require any coverage of male contraceptives. *See* 78 Fed. Reg. at 8458 n.3. Nor could they: The statutory provision requiring coverage for additional preventive services supported by HRSA pertains only to such services for "women." 42 U.S.C. § 300gg-13(a)(4). Thus, the Rules do not treat men more favorably, and any sex-based distinctions flow from the statute requiring preventive services for women only, not from the Agencies improperly "singl[ing] out" women. SJ Mem. at 25; *see In re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 940-42 & n.1 (8th Cir. 2007) (holding that Title VII "does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women"). Moreover, any distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection to facilitating the provision of contraceptives. Thus, the Rules do not violate Title VII's prohibition on sex-based disparate treatment. *Healey v. Southwood Psychiatric Hosp.*, 78 F.3d 128, 131 (3d Cir. 1996) (disparate treatment encompasses facially discriminatory conduct). Nor do they run afoul of Title VII's disparate impact rules. The Rules do not have a disproportionate impact on

women because no males receive coverage of contraceptive services pursuant to 42 U.S.C. § 300gg-13(a)(4), whereas female contraceptive services are covered except where an exemption applies.

Even if the Rules had a statistically disproportionate effect on women, they still would not violate Title VII. First, the Rules are supported by the public interest (the equivalent, in this context, of business necessity), rebutting Plaintiffs' prima facie case. As noted, the Government has a legitimate interest in accommodating sincerely held religious and moral beliefs, and the Rules fulfill this interest by alleviating the burden imposed by the mandate. Second, considerations under RFRA compelled the Agencies to issue the Religious Exemption Rule, *see* Argument, § I.B., and this statute takes precedence over any obligations imposed by Title VII. 42 U.S.C. § 2000bb-3 ("This chapter applies to all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993.").

Plaintiffs also argue that the Rules violate 42 U.S.C. § 18116, which prohibits discrimination on the basis of sex. But as explained above, the Rules do not discriminate against women.

E. The Rules Are Consistent with the Equal Protection Clause

The Rules are consistent with principles of equal protection. When faced with a claim of discrimination on the basis of sex, courts assess (i) whether the classification is facially based upon sex and, if not, (ii) whether there are other factors—such as the purpose of the law or the existence of a disparate impact—that demonstrate an invidious intent to discriminate on the basis of sex. *See Personnel Adm'r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979). With regard to "this second inquiry, impact provides an important starting point, but purposeful discrimination is the condition that offends the Constitution." *Id.* (citations omitted). Sex-based distinctions are subject to intermediate scrutiny, meaning that the distinction must be substantially related to an important governmental interest. *Wengler v. Druggists Mut. Ins. Co.*, 446 U.S. 142, 150 (1980). All other distinctions that do not target a protected class or burden a fundamental right are subject to rational-basis review. *Heller v. Doe*, 509 U.S. 312, 319–20 (1993). Under this standard, "a classification

must be upheld ... if there is any reasonably conceivable state of facts that could provide a rational basis for the classification.” *Id.* at 320 (citation omitted).

Plaintiffs contend that the Rules discriminate against women because they “single out care for women’s reproductive health for different treatment and lesser protection.” SJ Mem. at 25. In fact, the Rules do not discriminate against women on the basis of sex, facially or otherwise, as explained above. Instead, distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection to facilitating the provision of contraceptives.

In addition, Plaintiffs fail to cite any authority suggesting that declining to subsidize contraception constitutes a sex-based equal protection violation. Distilled to its essence, Plaintiffs’ claim is that despite the fact that the Rules do not draw any sex-based distinction, an exemption to subsidizing contraception disparately affects women. But “[t]he equal protection component of the Fifth Amendment prohibits only purposeful discrimination,” not disparate impact. *Harris*, 448 at 323 n.26 (citing *Washington v. Davis*, 446 U.S. 229 (1976)). Accordingly, the claim fails.

Because the Rules do not create sex-based distinctions, they are subject to only rational-basis review. They satisfy this “extremely low” threshold, *United States v. Pollard*, 326 F.3d 397, 408 (3d Cir. 2003), because they are rationally related to legitimate government interests, *Lyng v. Int’l Union United Auto., Aerospace and Agric. Implement Workers of Am., UAW*, 485 U.S. 360, 370 (1988). The Religious Exemption Rule accommodates religion by “expand[ing] exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception.” 83 Fed. Reg. at 57,540. And the accommodation of religious beliefs is an important government interest, as the Supreme Court recognized in *Cutter v. Wilkinson*, 544 U.S. 709, 724-25 (2005). For the same reasons, the Rule would satisfy intermediate scrutiny.

The Moral Exemption Rule also has a rational basis (and satisfies intermediate scrutiny). It is designed to protect “sincerely held moral convictions” by exempting those with such convictions from facilitating the provision of contraceptive services. 83 Fed. Reg. at 57,593. The government may permissibly accommodate deeply held moral, but not religious, convictions and has furthered this important interest in a variety of contexts since the founding. *See Welsh v.*

United States, 398 U.S. 333 (1970); *United States v. Seeger*, 380 U.S. 163 (1965); *Doe v. Bolton*, 410 U.S. 179 (1973); 82 Fed. Reg. at 47,838 n.1. Indeed, Plaintiffs agree that it is legitimate to protect non-religious moral beliefs. See N.J. Stat. Ann. 2A:65A-1 (conscience clause allowing persons to opt out of providing abortions); 18 Pa. Stat. and Cons. Stat. Ann. § 3213 (West) (conscience clause permitting medical professionals and facilities to opt out of providing abortions).

F. The Rules Are Consistent with the Establishment Clause

Federal Defendants have previously explained that the Rules are consistent with the Establishment Clause. See Defs.’ Opp. to Pls. Mot. for Prelim. Inj. (“Defs.’ Opp’n”), ECF No. 15, at 50-54. As the Supreme Court has repeatedly held, “there is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.” *Cutter*, 544 U.S. at 713.

The Third Circuit continues to apply the three-part test articulated in *Lemon v. Kurtzman*, 403 U.S. 602 (1971), to evaluate Establishment Clause challenges to government acts seeking to accommodate the practice of religious beliefs. See *Stratechuk v. Bd. of Educ., S. Orange-Maplewood Sch. Dist.*, 587 F.3d 597, 604 (3th Cir. 2009). The *Lemon* test requires that government actions (1) have “a secular legislative purpose,” (2) have a “principal or primary effect” that “neither advances nor inhibits religion,” and (3) do not “foster an excessive government entanglement with religion.” *Lemon*, 403 U.S. at 612-13 (citations omitted). The Rules easily satisfy that test.

With respect to *Lemon*’s first prong—that the government act serve a secular legislative purpose—the Supreme Court has recognized that it is a permissible legislative purpose to alleviate significant governmental interference with the exercise of religion. *Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 335 (1987); see also *Williams v. Bitner*, 285 F. Supp. 2d 593, 600 (M.D. Pa. 2003) (*Amos* recognized that “ensuring fair treatment for all individuals, regardless of belief, is a valid secular objective”). This was the

precise aim of the Agencies in promulgating the Religious Exemption Rule. *See* 83 Fed. Reg. at 57,540 (purpose of the Rule is to “expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception”). And the aim of the Agencies in promulgating the Moral Exemption Rule was patently secular: the accommodation of moral convictions is *not* based in religion. 83 Fed. Reg. at 57,593.

The first prong of the *Lemon* test “does not mean that the law’s purpose must be unrelated to religion—that would amount to a requirement that the government show a callous indifference to religious groups, and the Establishment Clause has never been so interpreted.” *Amos*, 483 U.S. at 335 (quoting *Zorach v. Clauson*, 343 U.S. 306, 314 (1952)). Rather, this prong “mandates only that [the government’s] main goal not be to support a particular viewpoint.” *Williams*, 285 F. Supp. 2d at 600. “Under *Lemon*, if the [governmental action] has *some* secular purpose, then it survives the first prong.” *Doe v. Indian River Sch. Dist.*, 653 F.3d 256, 283 (3d Cir. 2011) (citation omitted). Courts are “normally deferential” to the government’s articulation of a secular purpose as long as it is “sincere and not a sham.” *Stratechuk*, 587 F.3d at 604 (citation omitted).

Here, nothing in the Rules shows any intent to advance a particular faith or to promote religion in general. Instead, the Rules alleviate substantial hardships faced by entities and individuals in providing health insurance. That the Rules apply to entities and individuals with secular, non-religious moral beliefs regarding the provision of contraception confirms that the Rules possess a secular purpose. *See also Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402, 437-40 (W.D. Pa. 2013) (rejecting Establishment Clause challenge to ACA’s religious-employer exemption).

The second prong of the *Lemon* test requires that a law’s “principal or primary effect ... neither advance[] nor inhibit[] religion.” *Lemon*, 403 U.S. at 612. The Supreme Court has made clear that removing barriers to the exercise of religious freedom does not advance religion; to the contrary, “there is ample room for accommodation of religion under the Establishment Clause.” *Amos*, 483 U.S. at 338. The Rules do not promote or subsidize a religious belief or message; they merely free entities and individuals with objections to contraception based on religious beliefs and

moral convictions to practice those beliefs and convictions as they otherwise would in the absence of certain government-imposed regulations. *See Geneva Coll.*, 929 F. Supp. 2d at 438 (religious-employer exemption to contraceptive-coverage mandate did not “run afoul of the Establishment Clause because it does not make distinctions based upon religious affiliation” and “does not single out one particular religious denomination or religion”).¹¹

Plaintiffs incorrectly contend that the Rules violate the Establishment Clause because they unduly burden Plaintiffs. SJ Mem. at 28-30. Plaintiffs’ characterization of the loss of compelled contraceptive coverage as a governmental burden rests on the “incorrect presumption” that “the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits.” 83 Fed. Reg. at 57,549. “If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce [into providing such coverage], that result exists in the absence of governmental action—it is not a result the government has imposed.” *Id.* Before the mandate, women had no entitlement to contraceptive coverage without cost-sharing. If the same agencies that created and enforce the mandate also create a limited exemption to accommodate sincere religious objections, the women affected are not “burdened” in any meaningful sense, because they are no worse off than before the Agencies chose to act in the first place.

This conclusion is supported by *Amos*, which held that Title VII’s religious exemption to the prohibition against religious discrimination in employment was consistent with the Establishment Clause even though the result was to affirm the employer’s right to terminate the plaintiff’s employment. While the plaintiff was “[u]ndoubtedly” adversely affected, the Court

¹¹ Plaintiffs do not contend that the Rules foster excessive government entanglement with religion under *Lemon*’s third prong. In any event, such a contention would have no merit. *Amos* upheld a statutory provision exempting religious groups from Title VII’s prohibition against religious discrimination, stating that “[i]t cannot be seriously contended that [the statute] impermissibly entangles church and state; the statute effectuates a more complete separation of the two” 483 U.S. at 339. The Rules operate in a similar manner: they reduce state interference with religious exercise by relieving religious institutions from certain government-imposed burdens, and thus achieve a more complete separation of church and state.

noted, “it was the Church[,] . . . not the Government, who put him to the choice of changing his religious practices or losing his job.” 483 U.S. at 337 n.15. Rather than burdening the Church’s employees, the exemption simply left them where they were before Title VII’s general prohibition and exemption were enacted. *See id.* (noting that the plaintiff employee “was not legally obligated” to take the steps necessary to save his job, and that his discharge “was not required by statute”). The same reasoning applies here, and a similar result follows. Any adverse effect results from a decision of private employers, not the government; and the burden—the loss of subsidized contraceptive coverage by an unwilling employer—is less onerous than the loss of a job. As Federal Defendants have explained previously, the contrary reasoning would invalidate the church exemption.

Plaintiffs also incorrectly suggest that the religious exemption constitutes the kind of “absolute and unqualified” exception the Supreme Court held unconstitutional in *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985). SJ Mem. at 29-30. The statute at issue in *Caldor* did not lift any governmental burden on religion, but instead intruded on private relationships by imposing on employers an “absolute duty” to allow employees to be excused from work on “the Sabbath [day] the employee unilaterally designate[d].” 472 U.S. at 709. By contrast, the Rules neither compel nor encourage any action on a private employer’s part. Instead, they *lift* a burden on the free exercise of religion—that employers are required to provide contraceptive coverage to their employees regardless of their contrary religious beliefs or moral convictions—that the government itself imposed, *see Amos*, 483 U.S. at 338. Moreover, the government has done so only after determining that the burden is not narrowly tailored to achieve any compelling interest. The lifting of a *government-imposed* burden on religious exercise is permitted under the accommodation doctrine referenced in *Amos*. *See Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (plurality opinion). In addition, *Caldor* involved government interference with private contracts. By contrast, the Rules involve a benefit that the government need not have required at all.

II. The Rules Are Not Arbitrary and Capricious

A. The Agencies Provided a Reasoned Explanation for the Rules

Plaintiffs, citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009), and *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016), remanded 845 F.3d 925 (9th Cir. 2017), contend that the Agencies needed to provide a “detailed justification” for the Rules because they rest “upon factual findings that contradict those which underlay” their prior policy and unsettle reliance interests. SJ Mem. at 32-33 (internal quotations omitted). This contention is flawed.

The scope of review under the ‘arbitrary and capricious’ standard is narrow.” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency generally need not demonstrate “that the reasons for the new policy are better than the reasons for the old one,” but only that “the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better.” *Fox Television Stations, Inc.*, 556 U.S. at 515. In situations where the “prior policy has engendered serious reliance interests that must be taken into account,” or an agency has reached different factual conclusions, an agency need provide only a “reasoned explanation” for treating differently “facts and circumstances that underlay or were engendered by the prior policy.” *Id.* at 515-16; *see also Encino Motorcars*, 136 S. Ct. at 2127.

Assuming the *Fox/Encino Motorcars* standard applies, the Agencies easily satisfy it. The Final Rules contain voluminous explanations of the Agencies’ previous position, their current position, the Agencies’ recognition that their position had changed, discussions of both sides of the issue from public comments, and extensive reasoning for the Agencies’ conclusions in the Final Rules. *See, e.g.*, 83 Fed. Reg. at 57,546–56. The Agencies did not ignore their prior findings or any reliance interests—over the course of four pages of the Federal Register, *Id.* at 57,552-56, the Agencies discuss the efficacy and health effects of contraceptive use as well as the effect, if any, the mandate had on contraceptive use. *See Fox Television*, 556 U.S. at 516 (rejecting argument that the FCC offered an inadequate explanation in an order by noting, in part, that “[t]he

Remand Order does, however, devote four full pages of small-type, single-spaced text . . . to explaining” the relevant conclusion).¹²

Through this discussion in the Rules, the Agencies demonstrated why, in their judgment, the policy interests in favor of expanding the exemptions outweigh the interests in leaving the contraceptive-coverage mandate unchanged: the evidence on the benefits of the contraceptive-coverage mandate is more mixed—and the religious and conscientious objections to complying with the mandate more substantial—than the Agencies previously acknowledged. For example, commenters submitted a study from 2017 that concluded there was no evidence showing the contraceptive-coverage mandate led either to an increased use in contraceptives generally, or to an increased use of more effective methods from less effective methods. 83 Fed. Reg. at 57,548. By extension, the Agencies concluded exempting a very small percentage of entities subject to the mandate, by providing expanded religious and moral exemptions, would not be inconsistent with the government’s interests. Of course, the uncertainty of the net benefits of the contraceptive-coverage mandate is just one reason for the Agencies’ conclusion that there is no compelling interest in requiring those with conscience objections to provide contraceptive coverage; the Rules provide other independent and sufficient reasons for reaching that conclusion. *Id.* at 57,546-48.

The moral exemption is also supported by adequate reasons. There are two entities known to have non-religious moral objections to the mandate, and both hire only employees who share the entities’ views on contraception. 83 Fed. Reg. at 57,617. Plaintiffs have not identified any other entity that claims the moral exemption. The Agencies concluded that because women

¹² Plaintiffs contend that the Agencies had “rejected expanding the exemption to other employers [than houses of worship and their integrated auxiliaries] precisely because female employees of non-religious employers are less likely than individuals in plans of religious employers to share their employer’s (or institution of higher education’s) faith and objection to contraceptive coverage on religious grounds,” and that the Agencies have not “reverse[d] this conclusion.” SJ Mem. at 32 n. 12. This assertion is incorrect. In the Final Rules, the Agencies explain that they “no longer adhere” to their previous position that women who work at religious non-profits are less likely to share the faith of their employer than women who work at houses of worship or their integrated auxiliaries. 83 Fed. Reg. at 57,561.

employees of such entities would, by definition, not want contraceptive coverage, “subjecting this subset of organizations to the Mandate does not advance any governmental interest.” *Id.* at 57,602. Individual policy holders, too, who have non-religious moral objections to contraceptive coverage, would be positively, not negatively, impacted by the moral exemption applied to their own plans. Following Congress’s longstanding practice of providing parallel moral exemptions with religious exemptions, *id.* at 57,618, and in light of the fact that the ACA does not itself impose a contraceptive mandate in the first place, the Agencies reasonably concluded that it is consistent with the government’s interests under the ACA to provide exemptions for non-publicly traded entities, and certain individuals, with non-religious moral objections to the mandate.

Plaintiffs’ more specific arguments fare no better. Plaintiffs maintain that the “Agencies arbitrarily treat all 18 forms of contraception categorically,” SJ Mem. at 33, when concluding that there is “significantly more uncertainty and ambiguity” about the health effects of contraception than previously acknowledged, 83 Fed. Reg. at 57,552-53, 57,555. They add: “The Agencies point to no new evidence suggesting that all 18 forms of contraception are all categorically unsafe for women, nor any evidence countermanding their prior conclusion that unintended pregnancy is a health risk for women.” SJ Mem. at 33.

Plaintiffs’ argument misses the point. Some entities with conscience objections to contraceptives object to *all* FDA-approved contraceptives. *See* 83 Fed. Reg. at 57,575. Thus, it makes sense for the Agencies to assess the overall effects of Rules that permit—but do not require—those entities to decline to provide coverage for all FDA-approved contraceptives. The effects of the Rules, even if indirect, include not only any costs associated with an entity declining to provide contraceptive coverage of any of the drugs, but also the benefits—such as possible side effects avoided for each drug. In this context, it was entirely reasonable for the Agency to assess the health effects of contraceptives categorically when assessing the effects of the Rules. And there was no need for the Agencies to “point to . . . new evidence suggesting that all” FDA-approved contraceptives are unsafe or that there are no health risks for unintended pregnancies, SJ Mem. at 33, because the Rules do not reach those conclusions. The Rules instead reach the much

more modest conclusion that the net benefits of employer-provided contraceptive coverage are less certain than previously acknowledged and do not justify demanding that those with sincere conscience objections be required to provide such coverage. 83 Fed. Reg. at 57,556.

Next, Plaintiffs contend that “[t]he Agencies also use the assertion by some commenters that certain forms of contraception are abortifacients to justify their conclusions on the health effects of contraception and pregnancy,” and that “such personal religious beliefs . . . do not provide a basis for the Agencies to make new factual findings about the health effects of contraception.” SJ Mem. at 34-35 (citation omitted). This argument fails because Plaintiffs again misinterpret the Rules. The Agencies did not rely on the fact that some comments view certain contraceptives as abortifacients to assess the health effects of contraception, but instead as further evidence that some entities have conscience objections to the provision of contraceptive coverage: “The Departments . . .recogniz[e] that some people have sincere religious objections to providing contraception coverage on this basis.” 83 Fed. Reg. at 57,554. Indeed, contrary to Plaintiffs’ argument, the Agencies explicitly “declined to take a position on the scientific . . . debate[] on th[e] issue” of whether some contraceptives are abortifacients. *Id.*

Plaintiffs argue that the Rules “ignore” prior conclusions that HHS has reached about the efficacy of contraceptives in reducing teen pregnancy. *See* Ex. 152 to SJ Mem. But that is not the case. In the exhibit Plaintiffs reference, HHS does not reach a definitive conclusion about the efficacy on contraceptives in reducing teen pregnancy. First, HHS simply states that contraceptives play a role in reducing teen pregnancy “according to recent research,” *id.*, without clearly adopting the conclusion as its own. Second, the exhibit also notes that “according to recent research” another factor was at play, namely, teenagers delaying sexual intercourse. *Id.* And HHS does not reach a conclusion about the extent to which contraceptives, as opposed to this other factor, contribute to any reduction in teen pregnancy rates. This is entirely consistent with the Rules, which state, “it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general.” 83 Fed. Reg. at 57,554.

Plaintiffs also incorrectly insist that the Agencies have not explained their conclusion that the Rules “are not likely to have negative effects on the health or equality of women nationwide.” SJ Mem. at 35-36 (citing 83 Fed Reg. at 57,556). “Under the arbitrary and capricious standard set forth in the APA, a court's deference to the agency is greatest when reviewing technical matters within [the agency's] expertise.” *Nat'l Ass'n of Metal Finishers v. EPA*, 719 F.2d 624, 657 (3d Cir.1983), *rev'd on other grounds sub nom. Chem. Mfrs. Ass'n v. NRDC*, 470 U.S. 116, (1985); *see also Kleissler v. U.S. Forest Serv.*, 183 F.3d 196, 198 (3d Cir. 1999) (“When reviewing scientific and technical data we defer to the findings and expertise of the [agency].”). Under this deferential standard, the Agencies furnished ample support for their conclusion that the benefits of contraceptives and the mandate are more mixed than previously recognized. 83 Fed. Reg. 57,552-56. For example, the Agencies cited numerous articles, including several from well-established peer-reviewed medical journals such as the New England Journal of Medicine, The Lancet, and the Journal of the American Medical Association, *Id.* at 57,552-53 nn.28-34, to support their conclusion that the benefits of contraceptives are more uncertain than previously recognized, *see, e.g.*, 78 Fed. Reg. at 39,872 (discussing the benefits of contraceptives). The Rules similarly support the conclusion regarding the benefits of the mandate. 83 Fed. Reg. at 57,555-556. Crucially, the Agencies did not conclude that contraceptives and the contraceptive-coverage mandate have no benefits. Rather, they determined that the net benefits are less certain than previously acknowledged and do not justify demanding that those with sincere conscience objections be required to provide contraceptive coverage.¹³

¹³ It is also worth noting that the statement on which Plaintiffs focus about “negative effects . . . [on] women nationwide,” 83 Fed Reg. at 57,556, SJ Mem. at 35-36, is primarily a statement about the number of women affected. The entire quotation, from which Plaintiffs have drawn their excerpt, demonstrates as much:

Without taking a definitive position on those evidentiary issues, however, we conclude that the Religious IFC and these final rules—which merely withdraw the Mandate’s requirement from what appears to be a small group of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide.

Plaintiffs finally contend that the Agencies ignored “comments proving that Colorado’s contraceptive mandate reduced the unintended pregnancy and abortion rate” and comments showing that the contraceptive-coverage mandate has allowed women to choose more effective methods of contraception. SJ Mem. at 36. These contentions do not hold water.

First things first: The Court has already rejected arguments like this. In its decision on Plaintiffs’ second motion for a preliminary injunction, the Court explained that “a review of the Final Rules demonstrates that the Agencies acknowledged the comments and provided an explanation as to why the Agencies did (or did not) amend the Final Rules based on the comment.” Second PI Opinion at 26. In any case, the Agencies explicitly considered comments that the mandate has “led women . . . to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods,” 83 Fed. Reg. at 57,556. And as for the Colorado-related comments, the Agency did not ignore them, but also relied on other evidence submitted by commenters, such as the study showing this specific mandate did not have an appreciable effect on contraceptive use in general or use of more effective contraceptive methods. *Id.* at 57,555. Based on the conflicting evidence, and the fact that the rules did not repeal the mandate entirely but only expanded the exemption to a small subset of covered entities, the Agencies reasonably concluded that some evidence of effects from local contraceptive coverage mandates did not override the reasons the Agencies had to issue the final rules.

B. The Agencies Addressed Other Significant Comments

Plaintiffs attack the Rules because the majority of the comments opposed extension of the religious exemption and creation of the moral exemption. Plaintiffs cite no precedent supporting this novel head-counting approach to rulemaking, and the D.C. Circuit rejected an analogous argument decades ago: “The substantial-evidence standard has never been taken to mean that an agency rulemaking is a democratic process by which the majority of commenters prevail by sheer weight of numbers. Regardless of majority sentiment within the community of commenters, the

83 Fed. Reg. at 57,556 (emphasis added). Plaintiffs do not dispute this point. Nor could they, as they have yet to identify even a single entity in their states that intends to invoke the exemptions.

issue is whether the rules are supported by substantial evidence in the record. The number and length of comments, without more, is not germane to a court's substantial-evidence inquiry.” *Nat. Res. Def. Council, Inc. v. EPA.*, 822 F.2d 104, 122 n.17 (D.C. Cir. 1987). Plaintiffs’ argument deserves a similar fate.

Next, Plaintiffs argue that “[t]he American medical community,” as defined by Plaintiffs, “unequivocally opposed the Rules.” SJ Mem. at 37. But Plaintiffs cite no precedent for their assertion that agencies must deem comments from certain groups of “elevated importance.” *Id.* And the APA contains no such requirement. *See* 5 U.S.C. §§ 702-706. The APA requires that the Agencies consider significant comments—a designation that is made based on the content of the comment, not the identity of the commenter, *see City of Portland v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007)—and the Agencies have done that in seeking to balance objections of conscience with the interests of women in receiving contraceptive coverage.

Plaintiffs’ other arguments fare no better. Plaintiffs assert that the Agencies ignored comments regarding the capacity of Title X fund recipients to assist women whose employer or school might invoke an exemption. SJ Mem. at 37. The Court already rejected this kind of argument in its preliminary injunction opinion. Second PI Opinion at 26-27. In any case, the Agencies never stated that Title X recipients would be able to help all such women. To the contrary, they simply stated that “contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X . . .),” and they explicitly recognized that these programs have limits, such as income restrictions. 83 Fed. Reg. at 57,551. Moreover, given the recognition of these limits, the Rules give no indication that they are premised on Title X recipients being able to assist all women who might be affected by the Rules. *Id.* (“The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules.”).

C. The Agencies’ Regulatory Impact Analysis is Reasonable

The Agencies estimated the financial impact of the Rules. 83 Fed. Reg. 57,575-580. Plaintiffs flyspeck these estimates, but their arguments fail. Again, it is blackletter law that

“[r]eviewing courts must be extremely deferential when the agency is making predictions within the agency's area of special expertise.” *Cloud Found., Inc. v. Salazar*, 999 F. Supp. 2d 117, 123 (D.D.C. 2013), dismissing appeal 2015 WL 1606931 (D.C. Cir. March 16, 2013). Estimating the likely healthcare costs of regulations falls well within the ambit of HHS’s expertise. *See Nat’l Tel. Co-op. Ass’n v. FCC*, 563 F.3d 536, 541 (D.C. Cir. 2009). (noting that APA review is deferential and that this is “particularly true with regard to an agency's predictive judgments about the likely economic effects of a rule”). Thus, the Agencies’ estimates easily pass muster under the applicable deferential standard—and, in any case, they would pass muster under a less deferential standard as well.

To start, the Agencies specified that the economic impact estimates were undertaken for a purely administrative purpose of determining whether the rules would have an annual impact of \$100 million under Executive Order 12,866, which specifies that it provides no rights of relief. 58 Fed. Reg. 51,735 (Oct. 4, 1993). The Agencies further emphasized that they had inadequate data to make reliable estimates of the number of women impacted by the rules, and that their assumptions were set forth on highly speculative grounds they were obliged to propose under EO 12,866. *See, e.g.*, 83 Fed. Reg. at 57,574.

Plaintiffs object that the Agencies did not estimate the effect of the exemption for individuals. Plaintiffs, however, did not challenge the individual exemption in their Amended Complaint, *see* Am. Compl. ¶¶ 133-155, so they have no standing to complain about whether the Agencies appropriately estimated its effects. In any case, the Agencies determined that any economic impact from the individual exemption would be minimal because spouses and dependents would likely share the faith of the policy holder. *See* 83 Fed. Reg. at 57,568-69.

Plaintiffs also complain that “the Agencies continue to assume that only 209 employers are using the accommodation—despite admitting that the number of persons covered by accommodated plans more than doubled from 2015 to 2017.” SJ Mem. at 38. This argument too fails. The Agencies explained in the Final Rules what their new assumptions for their economic impact estimates were, and the differences between the estimates in the IFRs and in the final rules

is attributable to those differences in assumptions. *See* 83 Fed. Reg. at 57,577-79. Furthermore, the Agencies' assumption regarding the number of employers using the accommodation did not play a determinative role in the Rule's assessment of the number of women affected by the Rules. Any alleged error is, therefore, harmless. *See* 5 U.S.C. § 706 (stating that "due account shall be taken of the rule of prejudicial error" when assessing whether agency action is arbitrary and capricious). In the relevant section of the Rules, the Agencies estimate "the number of women affected among entities using the expanded exemptions," 83 Fed. Reg. at 57,575, based on data regarding the number of women covered by plans of litigating entities and the number of women covered by plans making use of user fee adjustments, not on the assumption that 209 employers are using the accommodation. *Id.* at 57,575-76. In other words, the estimate of the number of women affected would not have changed if the Agencies had assumed that 209, 309, or 409 employers were using the accommodation; the estimate of the number of employers using the accommodation simply provides added color or context to the estimate of the number of women affected. Plaintiffs' argument is meritless.

Next, Plaintiffs challenge the Agency's prediction that "the majority of persons currently working for an accommodated employer will not lose contraceptive coverage." SJ Mem. at 39. But this prediction was reasonable given the information available to the agency. As the Rules explain, "religious nonprofit hospitals or health systems" sponsor plans covering "more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments [which are paid when the accommodation is invoked]." 83 Fed. Reg. at 57,576. And "[a] broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation." *Id.* Thus, the Agencies reasonably conclude that "accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans." *Id.* 57,577.

Finally, Plaintiffs maintain that "the Agencies arbitrarily cut the purported upper bound of women [a]ffected by the Religious Rule by two thirds." SJ Mem. at 39. Not so. The Agencies estimated that "private, non-publicly traded employers that did not cover contraception pre-

Affordable Care Act, and that were not exempt by the previous regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 [i.e., of childbearing age] that use contraceptives covered by the Guidelines.” 83 Fed. Reg. at 57,580. But the Agencies sensibly reasoned that not all such employers would have a religious objection. *Id.* Based on this sensible conclusion, which Plaintiffs do not challenge, the Agencies estimated that about one-third of the 379,000 women “would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules.” *Id.* This estimate is reasonable. The Agencies were “not aware of information, or of data from public comments, that would lead [them] to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or, specifically, religious beliefs, as opposed to having done so for other reasons.” *Id.* The Agencies explained that “only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective)” and that “various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage,” such as “the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts.” *Id.* at 57,580-81. The Agencies provided other reasons for this conclusion as well. *Id.* at 57,581. Plaintiff may not agree with the Agencies’ well-reasoned conclusion, but that does not make it irrational.

III. The Rules Were Properly Promulgated After a Period of Notice and Comment

Plaintiffs claim that the Agencies’ use of a post-promulgation comment period after issuing the IFRs renders the Rules invalid under the APA. *See* SJ Mem. at 40-45. The Agencies maintain that they had independent statutory authority to issue the IFRs, and had good cause to do so as well.¹⁴ *See* Defs.’ Opp’n, ECF No. 15, at 22-28 (arguing in favor of independent statutory

¹⁴ Plaintiffs also argue that the IFRs were not validly promulgated. SJ Mem. at 41-42. Plaintiffs’ claims as to the IFRs are moot. *See, e.g., California v. Azar*, 911 F.3d 558, 569 (9th

authority to issue the IFRs, and in favor of the Agencies' determination of good cause). Accordingly, taking post-promulgation comments on the IFRs was proper. But even if, as this Court previously concluded, the IFRs violated the APA's procedural requirements, the Final Rules now at issue fully comply with the APA. What were post-promulgation comments with respect to the enjoined IFRs are now pre-promulgation comments with respect to the Rules. As such, the Agencies have now provided the notice-and-comment period required under APA § 553 with respect to the Rules, which this Court found to be previously lacking.

Section 553(b) requires that an agency provide notice, an opportunity to be heard, and publication of a final rule no less than 30 days before it is to go into effect. *Id.* Plaintiffs have now had that full and timely notice and ample opportunity for comment, and have participated in that process. Indeed, the Agencies received and considered around 110,000 public comment submissions, and detailed their consideration of those submissions in their final rulemaking. *See* 83 Fed. Reg. 57,540 (religious rules); 83 Fed. Reg. at 57,596 (moral rules). The Agencies also made changes in response to those comments, *see* 83 Fed. Reg. at 57,556-73; 83 Fed. Reg. at 57,613-26 (highlighting comments, responses, and changes). Although Plaintiffs may disagree with those changes, or with the proposal generally, it is not the place of Plaintiffs, or this Court, to substitute their judgment for that of the Agencies. *See Citizens to Preserve Overton Park, Inc.*, 401 U.S. at 416. Instead, the Court should consider whether the Agencies examined the relevant data and articulated a satisfactory explanation for their actions, including a "rational connection between the facts found and the choice made," which they plainly did. *Motor Vehicle Mfrs. Ass'n.*, 463 U.S. at 43 (citation omitted).

Plaintiffs rely heavily on *NRDC v. EPA*, 683 F.2d 752 (3d Cir. 1982), where the Third Circuit upheld a challenge to an interim rule that indefinitely suspended the implementation of certain Clean Water Act Amendments. *Id.* at 768. This Court also relied on this ruling in concluding that Plaintiffs were likely to succeed on this claim in the context of Plaintiffs' second

Cir. 2018) ("If the final rules become effective as planned on January 14, there will be no justiciable controversy regarding the procedural defects of IFRs that no longer exist.").

preliminary injunction motion. Second PI Opinion at 28-32. Defendants respectfully request that this Court reconsider its conclusion. Although the Third Circuit’s remedy in *NRDC* included enjoining a later rule to “further suspend” the amendments, which *had* been promulgated with notice and comment, this aspect of the court’s ruling was *not* based on the procedural inadequacy of the “further suspen[sion]” rules. *See* 683 F.2d at 757. Instead, the court enjoined both rules because the question on which the public commented, *i.e.*, whether to “further suspend” the amendments, was not the question that would have been asked had the APA been followed. The question “would have been whether the amendments, which had been in effect for some time, should be suspended, and not whether they should be further postponed.” *Id.* at 768.

Unlike in *NRDC*, the question posed to the public for comment here was the same question that would have been posed had the IFR been an NPRM. Moreover, the IFRs were enjoined shortly after they went into effect, mitigating any concerns that the Agencies had a thumb on the scale to avoid “upsetting the status quo by amending a rule only recently implemented.” *Levesque v. Block*, 723 F.2d 175, 187–88 (1st Cir. 1983). Thus, even given this Court’s prior conclusion that the IFRs were procedurally defective, the proper remedy is one the Plaintiffs have already received—notice of the proposed rule and an opportunity for comment. *See Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979); *see also U.S. Steel Corp. v. US EPA*, 595 F.2d 207, 215 (5th Cir. 1979) (ordering EPA to “give notice of the proposed designation[s]” that were set aside on appeal “and allow comment in accordance with § 553” after remand to the agency). Plaintiffs took advantage of that opportunity by submitting comments before issuance of the Final Rules, and the Agencies considered those comments in issuing the Final Rules. *See* Second PI Mot. at 16 n.17, ECF No. 91. Plaintiffs thus have suffered no remediable procedural injury. On the contrary, the Rules amply reveal that the Agencies “present[ed] 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.” *Levesque*, 723 F.2d at 188.

For these reasons, the Final Rules comply with the APA’s procedural requirements, and this Court should revisit its previous ruling on the question.

IV. **If Plaintiffs Prevail, the Court Must Limit any Remedy to the Parties Before the Court**

Should the Court rule in favor of Plaintiffs on the merits, the APA dictates the appropriate remedy: the “set[ting] aside” of the agency action deemed unlawful by the Court. 5 U.S.C. § 706(2)(A) & (D).¹⁵ The matter should then be “remand[ed] to the [A]genc[ies] for additional investigation or explanation.” *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

The scope of this “set aside”—or, indeed, any form of relief the Court may enter—must be limited to the parties before this Court. Under Article III, a plaintiff must “demonstrate standing . . . for each form of relief that is sought.” *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (citation omitted) *remanded* 693 Fed. App’x 69 (2d Cir. 2017); *see also Gill v. Whitford*, 138 S. Ct. 1916, 1930, 1933 (2018) (a “plaintiff’s remedy must be limited to the inadequacy that produced his injury in fact” because “the Court’s constitutionally prescribed role is to vindicate the individual rights of the people appearing before it”). The Third Circuit similarly has recognized that a plaintiff lacks “standing to seek an injunction” beyond what is necessary to “provide [it] full relief.” *Ameron, Inc. v. U.S. Army Corps of Eng’rs*, 787 F.2d 875, 888 (3d Cir. 1986). Equitable principles likewise require that a remedy should be “no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs” before the court. *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979).

Moreover, nationwide injunctions “take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch.” *Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring), *remanded* 893 F.3d 1266 (9th Cir. 2018). Nationwide injunctions also create an inequitable “one-way-ratchet” under which any prevailing party obtains relief on behalf of all others, but a victory by the government would not

¹⁵ The Court should not set aside portions of the Rules that permits issuers and plan sponsors to offer plans to individuals that account for sincerely-held objections the individual may have; Plaintiffs do not demonstrate any harm from that aspect of the Rules. Also, the Rules have severability provisions, to which the Court should conform any ruling. *See, e.g.*, 83 Fed. Reg. 57,589.

preclude other potential plaintiffs from “run[ning] off to the 93 other districts for more bites at the apple.” *City of Chicago v. Sessions*, 888 F.3d 272, 298 (7th Cir. 2018) (Manion, J., concurring in the judgment in part and dissenting in part), *reh’g en banc granted*, 2018 WL 4268817 (7th Cir. June 4, 2018 (vacating panel judgment “insofar as it sustained the district court’s decision to extend preliminary relief nationwide”), *reh’g en banc vacated as moot* 2018 WL 4268814 (7th Cir. Aug. 10, 2018); *cf. United States v. Mendoza*, 464 U.S. 154, 158-62 (1984) (holding that nonparties to an adverse decision against the federal government may not invoke the decision to preclude the government from continuing to defend the issue in subsequent litigation). Indeed, the Third Circuit has repeatedly held that nonparty injunctions should not be used as an end-run around the class-action procedure. *Ameron*, 787 F.2d at 888; *Meyer v. CUNA Mut. Ins. Soc’y*, 648 F.3d 154, 170 (3d Cir. 2011).

For the foregoing reasons, the Rules should not be vacated if the Court rules in favor of Plaintiffs, but rather, the remedy should be tailored only to plaintiffs who have demonstrated standing before the Court. And based on the severability clause in the final rules, *e.g.*, 83 Fed. Reg. at 57,589, no relief should be applied except against specific portions of the rule that injure Plaintiffs (assuming any do). For example, the individual exemption is not challenged by Plaintiffs, and there is no plausible evidence of injury to Plaintiffs by the religious exemption for churches and religious non-profits (due to the existence of the previous exemptions, the self-insured church plan accommodation, and injunctions protecting religious non-profits), nor of injury from the moral exemption (since the only entities known to claim it hire only persons who share their beliefs).

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs’ motion for summary judgment and enter summary judgment in favor of Federal Defendants.

DATED: June 14, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on June 14, 2019, a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

DATED this 14th day of June, 2019.

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG

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

COMMONWEALTH OF)
PENNSYLVANIA and)
STATE OF NEW JERSEY,)

Plaintiffs,)

v.)

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

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

Defendants.)

**FEDERAL DEFENDANTS' STATEMENT OF UNDISPUTED FACTS AND RESPONSE
TO PLAINTIFFS' STATEMENT OF UNDISPUTED FACTS**

**RESPONSE TO PLAINTIFFS' STATEMENT OF
UNDISPUTED MATERIAL FACTS**

The Agencies respond to “Plaintiffs’ Statement of Undisputed Material Facts” (ECF No. 170-3) as follows:

The Agencies object generally to Plaintiffs’ reliance on their own characterization of the Final Rules and the administrative record to the extent those characterizations differ from the text of the documents themselves or omit contextual information that is necessary to understand those characterizations. The Court should refer to the documents cited by the parties for a true and accurate statement of their contents.

The Agencies object generally to reliance on the Plaintiffs’ Statement of Undisputed Material Facts to resolve the legal questions presented in this case. “[D]istrict courts reviewing agency action under the . . . [APA] do not resolve factual issues, but operate instead as appellate courts resolving legal questions.” *James Madison Ltd. By Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). The Court must rely upon “the full administrative record that was before the [agency] at the time’ it took the action under review.” *SIH Partners LLLP v. Commissioner of Internal Revenue*, 923 F.3d 296, 302 (3d Cir. 2019) (quoting *C.K. v. N.J. Dep’t of Health & Human Servs.*, 92 F.3d 171, 182 (3d Cir. 1996)).

The Agencies dispute the following specific assertions made by the Plaintiffs:

Paragraph 32: The Agencies dispute this statement on the grounds that the ACA did not generally impose a “requirement that plans cover preventive services.” For example, “grandfathered plans” have never been required to provide this coverage. J.A. 6.

Paragraph 33: The Agencies state that although “HRSA adopted and released guidelines for women’s preventive services based on recommendations of the independent Institute of

Medicine,” J.A. 270-71, the Agencies dispute the suggestion that HRSA “adopted” the IOM Report in its entirety.

Paragraph 34: The Agencies dispute this statement on the grounds that the HRSA guidelines did not require all “health plans to cover ‘All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.’” J.A. 311. For example, “grandfathered plans” have never been required to provide this coverage. J.A. 6.

Paragraph 35: For the reasons stated above with respect to paragraph 34, the Agencies dispute that all plans were subject to the requirement to cover contraception methods and counseling after HRSA updated the Guidelines in 2016. J.A. 6.

Paragraph 36: For the reasons stated above with respect to paragraph 34, the Agencies dispute that all plans were subject to the requirement to cover contraception methods and counseling after HRSA updated the Guidelines in 2017. J.A. 6.

Paragraph 37: Plaintiffs do not cite to any evidence in support of this statement, and the Agencies dispute it on that basis. The Agencies further dispute the statement to the extent it assumes all entities were subject to the contraceptive mandate, for the reasons stated above with respect to Paragraph 34. J.A. 6. The Agencies further state that the Government’s position in prior litigation was that the contraceptive mandate “furthers a compelling government interest in securing for women the full and equal health coverage the Affordable Care Act provides.” *Zubik v. Burwell*, No. 14-1418, Brief for the Respondents, at 53–54 (U.S. Feb. 10, 2016).

Paragraph 40: Although the February 2012 Final Rules stated that “Congress determined that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women,” J.A. 301, this is a characterization of

congressional intent, and the Agencies dispute that the question of congressional intent is a question of fact appropriate for a statement of material facts.

Paragraph 42: The Agencies dispute that Congress determined “one of the unique health care needs” of women arises from women’s ability to become pregnant,” as the question of what Congress “determined” is one of law, not fact, as explained with respect to Paragraph 40.

Paragraph 43: None of the sources cited by Plaintiffs state that the Agencies “adopted the IOM Report and other studies demonstrating that unintended pregnancy poses health risks for women and fetuses.” J.A. 241, 256, 300. Specifically, although “HRSA adopted and released guidelines for women’s preventive services based on recommendations of the independent Institute of Medicine,” J.A. 270–71, HRSA did not adopt the IOM Report as a whole.

Paragraph 45: The Agencies do not dispute this statement insofar as the February 2012 Final Rules state, “Researchers have shown that access to contraception improves the social and economic status of women.” J.A. 301.

Paragraph 46: Although the July 2013 Final Rules state, “Research also shows that cost sharing can be a significant barrier to access to contraception. . . . Thus, eliminating cost sharing is particularly critical to addressing the gender disparity of concern here,” J.A. 242, the Agencies dispute that Congress’s “motivat[i]ons” are a question of fact appropriate for a statement of material facts.

Paragraph 48: The Agencies state that, as set forth in the Rules, they “received over 56,000 public comment submissions” on the religious rules, J.A. 5, and “received over 54,000 public comment submissions” on the moral rules, J.A. 60.

Paragraph 49: Plaintiffs cite no record evidence to support this statement. Moreover, the religious rule and moral rule specifically state how many public comment submissions were received for each rule. J.A. 5, 60.

Paragraph 50: To the extent Plaintiffs suggest the Agencies did not accurately represent the number of public comment submissions received, the Agencies dispute this paragraph. Both rules accurately represented how many public comment submissions were received. J.A. 5, 60.

Paragraph 52: Disputed as Plaintiffs cite no record evidence for the proposition that only 27 of the 110,000 comments supported the Final Rules.

Paragraph 53: Disputed as Plaintiffs cite no record evidence for the proposition that 13 comments did not clearly take a position for or against the rules.

Paragraph 54: Disputed as Plaintiffs cite no record evidence for the proposition that .025% of commenters supported the Final Rules.

Paragraph 61: The Agencies dispute Plaintiffs' paraphrasing of the Agencies' estimates of how many women would lose contraceptive coverage under the Rules, without explaining the weight, accuracy, or purpose of the Agencies' estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies' estimates. J.A. 40–47 (religious rule); J.A. 89–92 (moral rule).

Paragraph 62: The Agencies dispute Plaintiffs' paraphrasing of the estimate of the number of women affected by the Rules based on the number of employers who have litigated against the contraceptive mandate or taken advantage of the accommodation, without explaining the weight, accuracy, or purpose of the Agencies' estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies' estimates. J.A. 40–47 (religious rule); J.A. 89– 92 (moral rule).

Paragraph 63-69: The Agencies dispute Plaintiffs’ paraphrasing of the estimate of the number of women affected by the religious rule based on litigating entities, without explaining the weight, accuracy, or purpose of the Agencies’ estimates. The Agencies refer the Court to the religious rule for a complete statement of the grounds for the Agencies’ estimates. J.A. 40–47.

Paragraph 64: The Agencies dispute Plaintiffs’ statement that 49,000 persons remained employed by entities “still litigating over the mandate” to the extent that the number actually refers to litigating entities that have not received “permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate.” J.A. 40.

Paragraph 65: The Agencies dispute Plaintiffs’ suggestion that the Agencies miscalculated the number of employees covered by the health benefits of employers who would rely on the expanded exemptions in the religious rule. The religious rule states: “The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent. This amounts to *approximately* 29,000 employees covered under those plans.” J.A. 41 (emphasis added).

Paragraph 66: The Agencies dispute Plaintiffs’ suggestion that the Agencies miscalculated the number of individuals covered by the health benefits of employers who would rely on the expanded exemption in the religious rule, as explained above with respect to Paragraph 65. The religious rule states: “EBSA estimates that for each employee policyholder, there is approximately one dependent. This amounts to approximately 58,000 covered persons.” J.A. 41.

Paragraphs 70-80: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimate of the number of women who will be affected by currently accommodated employers that will choose the expanded exemption in the religious rule, without explaining the weight, accuracy,

or purpose of the Agencies' estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies' estimates. J.A. 40–47.

Paragraph 71: The Agencies dispute Plaintiffs' characterization that they “began by noting” their estimate of 1,823,000 employees and beneficiaries covered by plans offered by self-employed entities who took advantage of the accommodation and sought reimbursement under fee adjustment provisions for doing so. The Agencies refer the Court to the full statement in the religious rule about their estimate of individuals covered by employers who took advantage of the accommodation and whose Third Party Administrators (TPAs) sought reimbursement under the fee adjustment provision of 45 C.F.R. § 156.50(d)(3)(iii), which notes, among other things, that “[s]ome users do not enter all of the requested data,” and that “not all data for the 2017 plan year is complete” before stating the estimate of individuals covered by plans offered by these employers. J.A. 41.

Paragraph 73-74: Plaintiffs' paraphrasing of the religious rule contains an inaccurate figure in Paragraph 73 and does not provide a complete and accurate statement of the basis of the Agencies' estimate of employees and beneficiaries covered by fully-insured plans using the accommodation. The religious rule states: “DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans. Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in plans using the accommodation under the previous regulations.” J.A. 42.

Paragraphs 75-76: Plaintiffs’ paraphrasing of the religious rule does not provide a complete and accurate statement of the basis for the Agencies’ estimate of the number of entities that would continue to use the accommodation. The religious rule states: “Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans.” J.A. 42.

Paragraph 77: Plaintiffs’ paraphrasing of the religious rule does not provide a complete and accurate statement of the basis for the Agencies’ estimate of how many individuals would be covered by plans that continue to use the accommodation. The religious rule states: “The Departments do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.” J.A. 42–43.

Paragraph 78: Plaintiffs’ paraphrasing of the religious rule contains an inaccurate figure and does not provide a complete and accurate statement of the basis for the Agencies’ estimate of employees and beneficiaries covered by fully-insured plans using the accommodation. The

religious rule states: “Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation.” J.A. 43.

Paragraphs 81-87: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimate of the number of women who would lose contraceptive coverage due to the moral rule, without explaining the weight, accuracy, or purpose of the Agencies’ estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies’ estimates. J.A. 89–92.

Paragraph 82: Plaintiffs’ paraphrasing of the moral rule does not provide a complete and accurate statement of the rationale behind the Agencies’ estimate of how many nonprofit entities would claim the exemption. The moral rule states: “With respect to the exemption for nonprofit organizations with objections based on moral convictions, as noted above, the Departments are aware of two small nonprofit organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. . . . Based on comments submitted in response to rulemakings prior to the Moral and Religious IFCs, the Departments believe that at least one other similar entity exists. However, the Departments do not know how many similar entities exist and are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities. The Departments also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with the conclusion in previous regulations that no significant burden or costs would

result from exempting houses of worship and integrated auxiliaries. . . . Therefore, the Departments expect that the moral exemption for nonprofit entities will have a minimal effect of reducing contraceptive coverage with respect to employees who want such coverage.” A.R. 90.

Paragraph 84-86: Plaintiffs’ paraphrasing of the moral rule does not provide a complete and accurate statement of the Agencies’ assumptions with respect to the number of individuals working at for-profit entities that would be affected by the moral exemption. The moral rule states: “It is not known how many employees would be employed by the for-profit employers that might claim this exemption, but as discussed above these final rules do not include publicly traded companies, and both of the two nonprofit entities that challenged the Mandate based on moral objections included fewer than five policyholders in their group plans. Therefore, the Departments assume that the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For 9 entities, the total number of policyholders would be approximately 81. DOL estimates that for each policyholder, there is approximately one dependent. This amounts to approximately 162 covered persons.” A.R. 91.

Paragraphs 88-96: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimate of the number of women who would lose contraceptive coverage based on data regarding employers who did not provide contraceptive coverage prior to the ACA, without explaining the weight, accuracy, or purpose of the Agencies’ estimates. The Agencies refer the Court to the Rules themselves for a complete statement of the grounds for the Agencies’ estimates. J.A. 40-47.

Paragraph 94: The Agencies dispute Plaintiffs’ paraphrasing of the Agencies’ estimates of the number of Catholic churches and integrated auxiliaries in the United States. The religious rule states: “There are 17,651 Catholic parishes in the United States, 197 Catholic dioceses, 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools. Not all Catholic schools are

integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so the Departments use the number of schools as an estimate of the number of integrated auxiliaries.” A.R. 45.

Paragraph 96: Plaintiffs’ paraphrasing of the religious rule does not provide a complete and accurate statement of the Agencies’ assumptions with respect to its estimate of how many private, non-publicly traded employers that did not cover contraception pre-ACA and are not exempt under the Church Exemption would claim the new religious exemption. The religious rule states: “The Departments do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, the Departments believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules.” A.R. 45.

FEDERAL DEFENDANTS' STATEMENT OF UNDISPUTED MATERIAL FACTS

The Agencies object generally to reliance on statements of undisputed material facts to resolve the legal questions presented in this case. “[D]istrict courts reviewing agency action under the . . . [APA] do not resolve factual issues, but operate instead as appellate courts resolving legal questions.” *James Madison Ltd. By Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996). The Court must rely upon “‘the full administrative record that was before the [agency] at the time’ it took the action under review.” *SIH Partners LLLP v. Commissioner of Internal Revenue*, 923 F.3d 296, 302 (3d Cir. 2019) (quoting *C.K. v. N.J. Dep’t of Health & Human Servs.*, 92 F.3d 171, 182 (3d Cir. 1996)).

Subject to this objection, the Agencies provide the following statement of undisputed material facts, in compliance with the Court’s Policies and Procedures:

1. In August 2011, the Health Resources and Services Administration (HRSA) adopted the recommendation of the Institute of Medicine, a part of the National Academy of Sciences, to issue guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods. J.A. 298.
2. Coverage for the FDA-approved contraceptive methods defined by HRSA was required for plan years beginning on or after August 1, 2012. *See* J.A. 306.
3. At the same time HRSA’s guidelines were promulgated, the Agencies, invoking their statutory authority under 42 U.S.C. § 300gg-13(a)(4), promulgated interim final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* J.A. 306, 298.

4. Various religious groups asked the Agencies to expand the exemption to all religious not-for-profit organizations and other organizations with religious or moral objections to providing contraceptive coverage. *See* J.A. 272.
5. In a subsequent rulemaking, the Agencies offered an “accommodation” for religious not-for-profit organizations with religious objections to providing contraceptive coverage. *See* J.A. 243–51.
6. The accommodation allowed a group health plan established or maintained by an eligible objecting employer to opt out of any requirement to directly “contract, arrange, pay, or refer for contraceptive coverage,” by providing notice of its objection. J.A. 243.
7. Once an eligible employer provided notice of an objection, the regulations then generally required the employer’s health insurer or third-party administrator to provide or arrange contraceptive coverage for plan participants. J.A. 244–49.
8. Because church plans are exempt from the Employee Retirement Income Security Act of 1974 under section 4(b)(2) of that Act, the accommodation could not require the third-party administrators of church plans—and, by extension, many nonprofit religious organizations participating in those plans—to provide or arrange for such coverage or to impose fines or penalties for failing to provide such coverage. J.A. 231 (fn. 8).
9. Self-insured church plans that were eligible to use the accommodation and whose third party administrators could not then be required to provide contraceptive coverage or payments to persons covered by those plans included many non-profit religious organizations that were not otherwise exempt under the church and integrated auxiliary exemption to the contraceptive mandate. J.A. 6.

10. Today, the Agencies estimate that over 25 million individuals are enrolled in “grandfathered” health plans (generally, those plans that have not made specified changes since the ACA’s enactment), which are exempt from the ACA’s preventive services requirement, including the contraceptive coverage mandate. J.A. 6.

11. In response to the Supreme Court’s decision in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), the Agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. J.A. 193–98.

12. In response to the Supreme Court’s order in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), the Agencies requested public comment to determine whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while providing a mechanism for coverage for their employees. J.A. 183.

13. The Agencies received over 54,000 comments, but concluded “that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” J.A. 172.

14. The Agencies concluded that it was “appropriate to reexamine” the extant exemption and accommodation to the contraceptive mandate in order “to resolve the pending litigation and prevent future litigation from similar plaintiffs.” J.A. 105.

15. The Agencies determined “that an expanded exemption, rather than the existing accommodation, [was] the most appropriate administrative response to the religious objections raised by certain entities and organizations.” They further explained that, “[d]espite multiple rounds of rulemaking,” the Agencies “ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations.” J.A. 105.

16. In October 2017, the Agencies issued two interim final rules:
 - a. The first rule expanded the religious exemption to all nongovernmental plan sponsors, as well as institutions of higher education in their arrangement of student health plans, to the extent that those entities have sincere religious objections to providing contraceptive coverage, and to individuals able to obtain a religiously compliant plan from willing employers and issuers. J.A. 98–141.
 - b. The second rule created a similar exemption for entities and individuals with sincerely held moral objections to providing contraceptive coverage; unlike the religious exemption, though, this rule did not apply to publicly traded companies. J.A. 142–66.
17. The Agencies “received over 56,000 public comment submissions” on the religious rules, J.A. 5, and “received over 54,000 public comment submissions” on the moral rules, J.A. 60.
18. The Agencies issued final versions of the religious exemption rule and the moral exemption rule on November 15, 2018. J.A. 1–55 (religious rule); J.A. 56–95 (moral rule).
19. The Agencies also made changes to their initial proposed rules in response to the comments received. J.A. 21–38 (religious rule); J.A. 77–90 (moral rule).
20. The Agencies explained that the religious rule “finalize[s] exemptions [for] the same types of organizations and individuals for which exemptions were provided in the Religious [IFR]: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a non-profit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals.” The final religious rule also “maintain[s] a previously

created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators.” J.A. 2.

21. The Agencies explained that the final moral exemption rule “protect[s] sincerely held moral objections of certain entities and individuals” to providing the coverage required by the contraceptive mandate, and that changes to the rule were made to “ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA’s decision to otherwise require contraceptive coverage.” J.A. 45–46.

22. The Agencies reached the determination that the administrative record does not contain adequate evidence to meet the high standard of demonstrating a compelling interest, and provided five independent reasons for their finding. J.A. 11–13.

- a. First, the Agencies observed that “the structure of section 2713(a)(4) and the ACA evince a desire by Congress to grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4).” J.A. 11–12.
- b. Second, the Agencies explained that the contraceptive mandate “has not been applied in many circumstances,” including grandfathered plans and church plans. J.A. 12.
- c. Third, the Agencies explained that they “now believe the administrative record on which the Mandate rested was—and remains—insufficient to meet the high threshold to establish a compelling governmental interest in

ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans.” J.A. 12–13.

- d. Fourth, the Agencies explained that “the availability of contraceptive coverage from other possible sources . . . detracts from the government’s interest to refuse to expand exemptions to the mandate.” J.A. 13. The Agencies noted that, “prior to the implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use.” J.A. 13 (quoting J.A. 2654-55).
- e. Fifth, the Agencies concluded “that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides employers’ religious objections to the contraceptive Mandate.” J.A. 13.

23. The Agencies discussed the efficacy and health effects of contraceptive use in the Final Rules. J.A. 17–21. The discussion included citations to numerous articles, including several from peer-reviewed medical journals such as the New England Journal of Medicine, The Lancet, and the Journal of the American Medical Association. J.A. 17–18 nn.28-34; Exs. 157–76. The Agencies also considered research analyzing the effect of ACA implementation on contraceptive use. J.A. 13 (citing Ex. 156).

24. The Agencies “[did] not take a position on” the empirical questions about the efficacy and health effects of contraceptives, but concluded that “re-examination of the record and review of the public comments has reinforced the [Agencies’] conclusion that significantly more uncertainty

and ambiguity exists on these issues than the [Agencies] previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines.” J.A. 20.

25. The Agencies considered comments that the contraceptive mandate had “led women . . . to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods,” J.A. 21, and comments contending “[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,” J.A. 21 (quoting Ex. 156) and “there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012-2014) excepting small increases in implant use,” J.A. 76, and concluded it was “not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate,” J.A. 21.

26. The Agencies acknowledged “[t]here is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women’s preventive services were covered without cost sharing. Without taking a definitive position those issues, however,” the Agencies “conclude[d] that the Religious IFC and these final rules—which merely withdraw the Mandate’s requirement from what appears to be a small group

of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide.” J.A. 21.

27. In response to comments about “the effects of some FDA-approved contraceptives on embryos,” the Agencies noted that “some people have sincere religious objections to providing contraception coverage” on the basis that certain covered contraceptives purportedly have abortifacient effects, but the Agencies “d[id] not take a position on the scientific, religious, or moral debates on this issue” in the final rules. J.A. 18–19.

28. In response to comments on the “effects of the expanded exemptions on teen sexual activity,” the Agencies “note[d] that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments’ conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general.” J.A. 19.

29. The Agencies determined that the individual exemption “does not undermine the governmental interests furthered by the contraceptive coverage requirement, because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.” J.A. 32–34.

30. The Agencies determined in 2013, in creating exemptions for churches and integrated auxiliaries and the accommodation process (including its inability to impose coverage or payment obligations on third party administrators of self-insured church plans that use the accommodation), that such rulemaking “does not undermine the governmental interests furthered by the contraceptive coverage requirement,” and “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection, and who would therefore be less

likely than other people to use contraceptive services even if such services were covered under their plan.” A.R. 243.

31. To satisfy the directives of Executive Order 12,866, the Agencies provided estimates of the number of women who would be impacted by the Final Rules. J.A. 40–47 (religious rule); 89–92 (moral rule).

DATED: June 14, 2019

Respectfully submitted,

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

COMMONWEALTH OF)
PENNSYLVANIA and)
STATE OF NEW JERSEY,)

Plaintiffs,)

v.)

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

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

Defendants.)

_____)

[PROPOSED] ORDER

Upon consideration of Federal Defendants’ motion for summary judgment and any responses and replies to that motion, it is hereby **ORDERED** that the motion is **GRANTED**.

SO ORDERED.

Date: _____

The Honorable Wendy Beetlestone
United States District Judge