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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STATE OF CALIFORNIA, *et al.*

Plaintiffs,

STATE OF OREGON

Plaintiff-Intervenor,

v.

ALEX M. AZAR, II, Secretary of Health and Human Services, *et al.*,

Defendants,

and

THE LITTLE SISTERS OF THE POOR, JEANNE JUGAN RESIDENCE, *et al.*

Defendant-Intervenors.

Case No. 4:17-cv-5783-HSG

DEFENDANTS' MOTION TO DISMISS, OR IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT, AND DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Hearing Date: September 5, 2019
Time: 2:00 p.m.
Courtroom: Two, Fourth Floor
Judge: Hon. Haywood S. Gilliam, Jr.

PLEASE TAKE NOTICE that on September 5, 2019, at 2:00 p.m., in Courtroom 2 of the above-entitled court, at 1301 Clay Street, Oakland, California, pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(6) and 56, Federal Defendants Alex M. Azar, Secretary of Health and Human Services, in his official capacity; United States Department of Health and Human Services; R. Alexander Acosta, Secretary of Labor, in his official capacity; United States Department of Labor; Steven Mnuchin, Secretary of the Treasury, in his official capacity; and the United States Department of the Treasury ("Defendants" or "Federal Defendants") will and hereby do respectfully move this Court to dismiss Plaintiffs' Second Amended Complaint, or to enter summary judgment for Defendants. In accordance with the Local Rules of this Court, this motion is accompanied by a memorandum of points and authorities in support of the motion, and a proposed order.

Dated: May 31, 2019

Respectfully submitted,

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DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS, OR IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT, AND DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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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. But 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 insurance coverage for some or all forms of contraception, but decided to exempt only a fraction of those employers—churches and their integrated auxiliaries—from the requirement. Other entities were not required to provide contraceptive coverage because they were grandfathered by the ACA. 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." But the accommodation still substantially burdened the religious exercise of some objecting entities, and years of litigation ensued.

To address these serious religious objections and to resolve the litigation, the Agencies promulgated final rules that expand the prior religious exemption and also provide for a moral exemption to the contraceptive-coverage mandate. 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). The same provision of the ACA that authorized the Agencies to issue the prior exemption for churches and their integrated auxiliaries equally authorizes the expanded exemptions. Moreover, the Religious Freedom Restoration Act (RFRA) independently

authorizes, and indeed requires, the religious exemption as a means of eliminating the substantial burden on religious exercise that *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), held was imposed by the contraceptive-coverage mandate.

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.

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 to dismiss or, in the alternative, 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* 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* 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* 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* 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.[1] 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 participating in those plans—to provide or arrange for such coverage or impose fines or penalties for failing to provide such coverage. *See* 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

Even apart from the exemption for churches and their integrated auxiliaries, the contraceptive-coverage 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),

[1] A church plan can include a plan maintained by a "principal purpose" organization 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).

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 *Hobby Lobby*, the Supreme Court held that RFRA prohibited the government from 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. at 726, 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 728. 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 like Hobby Lobby with religious objections to the mandate but not the accommodation. *Id*. at 731-32. 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 (July 14, 2015). But numerous entities continued to challenge the mandate and the accommodation. 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,[2] 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 v. Burwell*, 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* 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 objections and provide seamless coverage to their employees. *See* FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).[3] The pending litigation—more than three dozen cases brought by more than 100 separate plaintiffs—thus remained unresolved.

[2] *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*, 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).

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

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).

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. 82 Fed. Reg. 47,792, 47,799 (Oct. 13. 2017). Following that reexamination, 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 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. *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* 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 resolve legal challenges by moral objectors that had given rise to conflicting court decisions. *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 service 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 also 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, the District Court's Opinion, and the Ninth Circuit's Ruling

California and four other states sued, challenging the IFRs. They claimed that the IFRs (1) failed to comply with the APA's notice-and-comment requirements; (2) were arbitrary and capricious, an abuse of discretion, or otherwise contrary to law; (3) violated the Establishment

Clause; and (4) violated the Equal Protection Clause. Am. Compl., Nov. 1, 2017, ECF No. 24, ¶¶ 116-137.

The Court granted Plaintiffs' motion for preliminary injunctive relief on the first claim, issuing a "nationwide" preliminary injunction against the IFRs. Order Granting Pls.' Mot. for a Prelim. Inj., Dec. 21, 2017, ECF No. 105, at 28-29. On December 13, 2018, the Ninth Circuit affirmed the Court's decision in part and vacated it in part. *California v. Azar*, 911 F.3d 558 (9th Cir. 2018). That court concluded that venue was proper in this district. *Id*. at 569. It also held that Plaintiffs had standing to challenge the IFRs because the "states show[ed], with reasonable probability, that the IFRs will first lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states." *Id*. at 571. Next, the Court of Appeals decided that the Agencies "did not have statutory authority for bypassing notice and comment" with respect to the IFRs, and that doing so was not harmless. *Id*. at 580-81. The Ninth Circuit also held that the injunction "must be narrowed to redress only the injury shown as to the plaintiff states." *Id*. at 584.

V. The Final Rules

After considering, for over 11 months, the more than 110,000 comments 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 IFR expanding the religious exemption, 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 do is "finalize 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 also 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. But the Department made changes to the rule 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." *Id*.

VI. Plaintiffs' Second Amended Complaint and the Second Preliminary Injunction

Plaintiffs (joined by nine other states) filed a second amended complaint raising claims under the APA, the Establishment Clause, and the Equal Protection Clause. Second Am. Compl., Dec. 18, 2018, ECF No. 170, ¶¶ 235-260. Plaintiffs also moved to preliminarily enjoin the Final Rules, but only with respect to their APA claims, not their constitutional claims.

The Court granted Plaintiffs' motion for a preliminary injunction with respect to their APA claims. *California v. HHS*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019). As an initial matter, the Court rejected arguments that Plaintiffs had not demonstrated standing and that venue was not proper in the Northern District of California. *Id*. at 1280-84. The Court concluded that Plaintiffs were likely to succeed on their APA claims. *Id*. at 1284-97. However, the Court enjoined "the implementation

of the Final Rules in the Plaintiff States only." *Id*. at 1301. Defendants have appealed that decision;[4] the appeal is fully briefed, and the Ninth Circuit will hear argument on June 6, 2019.

LEGAL STANDARDS

A suit brought by a plaintiff without standing, as is the case here, should be dismissed for lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1). *Cetacean Cmty. v. Bush*, 386 F.3d 1169, 1174 (9th Cir. 2004). If the Court determines that jurisdiction exists, then the Court should dismiss Plaintiffs' claims under the Women's Health Amendment, the Constitution, and the notice-and-comment requirement of the APA, for failure to state a claim upon which relief can be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6). The Court should enter summary judgment in favor of Defendants on the remainder of Plaintiffs' claims under Federal Rule of Civil Procedure 56.[5] "[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). In other words, summary judgement is an "appropriate mechanism" in an APA case for "determin[ing] whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 769 (9th Cir. 1985).

[4] An appeal of this second preliminary injunction has been docketed in the Ninth Circuit. See *California v. Little Sisters of the Poor*, No. 19-15072, *California v. HHS*, No.19-15118, and *California v. March for Life*, No. 1915150 (9th Cir. 2019).

[5] The Court could, of course, also enter summary judgment in favor of Federal Defendants on the claims under the Women's Health Amendment and the Constitution.

ARGUMENT[6]

I. The Rules Are Consistent with the ACA[7]

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 the Plaintiffs had shown a substantial likelihood of success on the merits with respect to this argument in resolving the Plaintiffs' preliminary injunction motion, the Agencies respectfully urge this Court to consider this issue anew now that it is presented for decision on the merits at summary judgment. .

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

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[6] As a threshold matter, the Court should dismiss this case for lack of subject-matter jurisdiction. Defendants have previously explained that Plaintiffs lack standing to bring this suit. Defs.' PI Opp., Nov. 29, 2017, ECF No. 51, at 8-12. The Court of Appeals concluded, at the preliminary injunction stage, that Plaintiffs had established standing. *California v. Azar*, 911 F.3d at 570-74. This case has now moved past the preliminary injunction stage, however, and the elements of standing must be "supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Yet Plaintiffs have provided no additional evidence to demonstrate standing, as they are required to do. As another court in this Circuit wrote: "While the Court previously concluded that both Plaintiffs . . . established standing at the preliminary injunction stage . . . their burden for doing so on summary judgment is more exacting and requires them to set forth 'by affidavit or other evidence 'specific facts' such that a 'fair-minded jury' could find they have standing." *Karnoski v. Trump*, No. C17-1297-MJP, 2018 WL 1784464, at *7 (W.D. Wash. Apr. 13, 2018) (quoting *Lujan*, 504 U.S. at 561). Because Plaintiffs have not provided the evidence of standing needed to satisfy the "more exacting" standard applicable at summary judgment, they have not established standing to bring this suit.

[7] Plaintiffs' motion for summary judgment also addresses the IFRs. But their challenges to the IFRs are moot. Regardless of the outcome of the litigation, the IFRs would not be enforced because they have been superseded by the Final Rules. *See Gulf of Me. Fishermen's All. v. Daley*, 292 F.3d 84, 88 (1st Cir. 2002) ("[P]romulgation of new regulations and amendment of old regulations are among such intervening events as can moot a challenge to the regulation in its original form").

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 include 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.[8] *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

[8] Contrary to Plaintiffs' argument, Plaintiffs' Memorandum in Support of Motion for Summary Judgment (SJ Mem.), ECF No. 311, at 9, it is § 300gg-13(a) that authorizes the exemption for churches and their integrated auxiliaries, not the Internal Revenue Code. Indeed, the relevant Internal Revenue Code provisions, 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i) & (iii), are wholly unrelated to the provision of contraceptive coverage. Although the Agencies borrowed the definition of a "religious employer" from § 6033 when exercising their authority under 42 U.S.C. § 300gg-13(a) to provide the exemption for churches and their integrated auxiliaries, nothing in § 6033 serves as an independent source of authority for the government to create exemptions.

of contraceptive coverage by exempting churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623.

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 jurisdiction. *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.

Plaintiffs' arguments to the contrary are unavailing. 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. With respect to grandfathered plans, they are significant but not for the reasons Plaintiffs assert. The grandfathering exemption demonstrates that Congress did not intend fully 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 exempted 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*, 572 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 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.").

Plaintiffs further argue, without explanation, that the statute should be read to preclude the moral and religious exemptions because the ACA elsewhere prohibits "unreasonable barriers" to medical care and requires "timely access" to medical care. *See* SJ Mem. at 18 (citing 42 U.S.C. § 18114(1), (2)). But, as described *infra*, (Argument § 1.B), those provisions have not been violated. The Rules merely narrow the scope of employers subject to the contraceptive-coverage mandate rather than impose any affirmative barriers on access to contraception. *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].”). In addition, Plaintiffs do not even argue that the purported barrier is unreasonable, nor that the Rules impede the timeliness of care—a difficult showing given the numerous other programs providing contraception, *see* 82 Fed. Reg. at 47,803, and the continued availability of the accommodation. Finally, the fact that the Women’s Health Amendment was added to the ACA after § 18114 demonstrates that § 18114 should not be understood to provide an alternative mandate for preventive or contraceptive coverage. Compare 155 Cong. Rec. S11607, S11646 (daily ed. Nov. 19, 2009) (including the non-discrimination provision at § 1557 and the barriers provision at § 1554) with 155 Cong. Rec. S12265, S12277 (daily ed. Dec. 3, 2009) (adding the Women’s Health Amendment).

Nor have the Agencies ignored the preventive service provision’s purpose. *See* SJ Mem. at 18. Plaintiffs take one broad statutory purpose—to increase access to preventive care—then focus myopically on one preventive service included in HRSA’s guidance and elevate it above all others. “But no legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice . . . .” *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987). Notwithstanding Plaintiffs’ claim to the contrary, the Agencies did, in fact, consider the interests advanced by the Women’s Health Amendment in deciding to issue the Rules. Indeed, HRSA kept the mandate in place for nearly all applicable entities, and HRSA included no exemptions for the other types of preventive services (included in its guidelines) to which conscience exemptions have not been asserted. The Agencies simply did not construe the Women’s Health Amendment to require them to pursue marginal advances to the interests served by that provision at the expense of all other interests. *See, e.g.*, 83 Fed. Reg. 57,556 (“[W]e conclude that the best way to balance the various policy interests at stake . . . is to provide the expanded exemptions set

forth herein . . . ."). Plaintiffs' argument ignores that Congress has long recognized the need for protecting objections of conscience in the area of health care, and also ignores the purposes of RFRA in the Agency's interpretation of the statute. *See infra*, Part II. As demonstrated in the Rules themselves, Congress has protected conscientious objections over many decades, including those based on religious beliefs, in the context of health care and coverage, even as it has sought to promote and expand access to health services. *See* 83 Fed. Reg. at 57,538-39 n.1 (listing conscience protections in federal health care laws). The decision to issue the Final Rules does not contravene the purpose of § 300gg-13(a)(4).

Finally, Plaintiffs argue that the Final Rules are contrary to separation of powers principles, because Plaintiffs contend that the Agency's position would allow HRSA to exempt "any and all" employers from coverage. *See* SJ Mem. at 20. But the Court need not decide what the outer bounds of HRSA's discretion are, as its actions here lie well within its authority under the statute. And in any event, the ACA does not require HRSA to include contraceptives in the Guidelines, so there is, by extension, no general prohibition on HRSA exercising its lesser authority to include contraceptives in the Guidelines in a more limited fashion. The APA's arbitrary and capricious standard requires only that HRSA act rationally – as it has here, for all of the reasons explained in the Final Rules. Ultimately, Plaintiffs' argument regarding separation of powers is based on the contention that the Agencies have misread an unambiguous statute, *see* SJ Mem at 20, but as discussed above, the Agencies' reading of the statute is correct, or at the very least, a reasonable interpretation of statutory ambiguity.

B. The Rules Otherwise Comply with the ACA

The Rules do not violate the ACA's nondiscrimination requirement, 42 U.S.C. § 18116, or its prohibition on unreasonable barriers to healthcare, § 18114. *See* SJ Mem. at 35-37. With respect to section 18116, as explained below, the Rules do not discriminate on the basis of sex,

facially or otherwise. *See infra* Argument § 5 ("The Rules are Consistent with the Equal Protection Clause"). With respect to section 18114, 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. at 316 ("[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]

[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.

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 must be covered in ACA programs. Under Plaintiffs' standardless interpretation of section 18114, it is far from clear that the government could ever impose any limits on the extent to which certain services must be covered or how a court could possibly evaluate such challenges.

C. The Moral Exemption Rule is Not Contrary to Law, and is Grounded in the Agencies' Discretion under the § 300gg-13(a)(4)

Plaintiffs argue that the Agencies "do not point to a specific congressional enactment authorizing [them] to promulgate the Moral Exemption Rule." SJ Mem. at 35. Not so. The Agencies have clearly invoked the discretion provide by § 300gg-13(a)(4) to promulgate the Moral Exemption Rule. *See e.g.*, 83 Fed. Reg. at 57,598; *see* also *supra* Part A. Plaintiffs also argue that the Agencies improperly highlighted the existence of a euthanasia provision elsewhere in the ACA to support the Moral Exemption Rule. *See* SJ Mem. at 35. But this provision simply illustrates that Congress did, in fact, contemplate the existence of exemptions based on moral convictions in the health care context, and supports the Agencies' conclusion that "providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress's intent in the Church Amendments and in later federal statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts." *See* 83 Fed. Reg. 57,601.

II. RFRA Authorizes (and Indeed Compels) the Religious Exemption Rule

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.

RFRA authorizes agencies to proactively create exemptions to avoid substantially burdening religious exercise, just as the Agencies here did with the original exemption and accommodation, which are not challenged by Plaintiffs. The 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 (even assuming such an accommodation could be found). 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.

A. Religious Objectors are Substantially Burdened in the Absence of the Religious Exemption Rule

The Religious Exemption Rule is necessary to alleviate the substantial burden that some employers would otherwise face under the accommodation. These employers have "a sincere religious belief that their participation in the accommodation process makes them morally and spiritually complicit" in providing contraceptive coverage, because their "self-certification" triggers "the provision of objectionable coverage through their group health plans." *See Sharpe Holdings, Inc. v. HHS,* 801 F.3d 927, 942 (8th Cir. 2015), *vacated and remanded sub nom. HHS v. CNS Int'l Ministries*, 136 S. Ct. 2006 (2016) (mem.); *see also* 82 Fed. Reg. at 47,798, 47,800.

In light of that sincere religious belief, forcing objecting employers to violate that belief by using the accommodation or incur substantial financial penalties constitutes a substantial burden under *Hobby Lobby*. *Sharpe,* 801 F.3d at 939-43; *Priests for Life v. HHS*, 808 F.3d 1, 16-21 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from denial of rehearing en banc). Faced with this substantial burden, the Agencies previously determined that they could not find a way to amend the accommodation to both satisfy objecting organizations and provide seamless coverage to their employees. See FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).[10] And on further examination the Agencies determined that "that the application of the Mandate to certain objecting employers was [not] necessary to serve a compelling governmental interest." 83 Fed. Reg. 57,546. In such circumstances, RFRA requires the burden to be lifted.

Plaintiffs' argument that the accommodation does not substantially burden religious practice, SJ Mem. at 22-26, 29, invites precisely what RFRA does not allow and what the Supreme Court has prohibited: "it is not for [a court] to say that [an objector's] religious beliefs are mistaken." *Hobby Lobby*, 573 U.S. at 725. As this Court acknowledged, "[u]nder RFRA, a substantial burden is imposed only when individuals are forced to choose between following the tenets of their religion and receiving a governmental benefit . . . or coerced to act contrary to their religious beliefs by the threat of civil or criminal sanctions . . . ." Order Granting Pls.' Mot. PI, ECF No. 234, at 25 (quoting *Navajo Nation v. United States Forest Serv.*, 535 F.3d 1058, 1070 (9th Cir. 2008) (internal quotation marks omitted)). Here, entities with sincere religious objections to the accommodation face just such coercion when they are forced to choose between using that accommodation or facing severe financial penalties for failing to provide contraceptive coverage.

[10] Available at https://www.dol.gov/sites/default/files/ebsa/aboutebsa/our-activities/resource-center/faqs/aca-part-36.pdf

Employers with religious objections to the accommodation sincerely believe that the "accommodation process itself triggers the provision of objectionable coverage . . . making them complicit in conduct that violates their religious beliefs." *Sharpe Holdings*, 801 F.3d at 939. And *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, 725 (cleaned up).[11]

Plaintiffs also incorrectly assert that the Agencies ignored the requirement that a burden be substantial under RFRA. SJ Mem. at 22-23. Not so. As *Hobby Lobby* illustrates, where a court has held that the plaintiff has identified a sincerely held religious belief that a law requires it to violate, the court then determines whether the claimed burden is substantial—an independent inquiry that turns on the severity of the pressure the government's action imposes on the objector's religious exercise. *See* 573 U.S. at 719-20; *see also Sharpe*, 801 F.3d at 938. Here, the 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. That is the same penalty the plaintiffs faced in *Hobby Lobby*, where the Court had "little trouble" concluding that the mandate imposed a substantial burden. 573 U.S. 719; *see also Priests for Life*, 808 F.3d at 16 (Kavanaugh, J., dissenting from denial of rehearing en banc).

Plaintiffs argue that a parade of horribles would result if the Court—as it must—gave credence to the objecting entities' view that their religious beliefs are violated. SJ Mem. at 24.

[11] Plaintiffs assert that the Court in *Hobby Lobby* suggested that the accommodation did not impose a substantial burden on religious exercise. SJ Mem. at 26. But *Hobby Lobby* noted only that the accommodation satisfied the religious objections of the plaintiffs in that case, *see* 134 S. Ct. at 2782, not that the accommodation would satisfy the religious objections of other employers. Indeed, the Court made clear that it did not "decide today whether an approach of this type [i.e., the accomodation] complies with RFRA for purposes of all religious claims." *Id.*

Yet Plaintiffs' concerns are illogical. For example, the States raise the hypothetical of "a religious conscientious objector to the military draft" objecting to "notifying the government of his religious opposition," SJ Mem. at 24, but that hypothetical is doubly inapposite: the military's drafting of a replacement would not violate the objector's religious exercise, because it would neither depend on the form of the objector's notification nor involve the objector's own contracts, and the government's need to conscript citizens to fight a war, unlike its purported need to conscript employers to subsidize their employees' contraception, would undoubtedly serve a compelling governmental interest, *see, e.g.*, *Eternal Word Television Network, Inc. v. Secretary of HHS*, 818 F.3d 1122, 1188 n.32 (11th Cir. 2016) (Tjoflat, J., dissenting) (rejecting the draft hypothetical), *vacated*, No. 14-12696, 2016 WL 11503064 (11th Cir. May 31, 2016).

B. There Is No Compelling Government Interest in Forcing Employers With Religious Objections to Provide Contraceptive Coverage

Contrary to Plaintiffs' position, SJ Mem. 26-29, the Agencies reasonably concluded that there is no compelling interest that justifies the imposition of this substantial burden on the exercise of religion. The existence of a compelling interest is measured not by the governmental interests served by the mandate in general, but only the governmental interests served by applying the mandate to the small percentage of employers with sincere religious objections to it. *Hobby Lobby*, 573 U.S. at 725-26. In the Rules, the Agencies provided multiple reasons for their conclusion that application of the mandate to objecting entities neither serves a compelling governmental interest nor is narrowly tailored to any such interest:

1. Congress did not mandate coverage of contraceptives. 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. In the Agencies' expert view, 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. Some objecting entities are willing to cover some (even if not all) contraceptives, and contraceptives are available from alternative sources, including from government programs for low-income women. *Id.* at 57,548. This is particularly relevant given research analyzing the effect of ACA implementation on contraceptive use, which 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. AR at 00804231 (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), AR 00804227).

In addition, although the Agencies had previously sought to provide contraceptive coverage to women "seamlessly," the Agencies determined that the government did not have a compelling interest in such seamlessness because of the disunity caused by the exemptions for grandfathered plans and for churches and their integrated auxiliaries, as well as the application of the accommodation to self-insured church plans. 83 Fed. Reg. 57,548.

These considerations are more than sufficient to support the Agencies' conclusion that the mandate does not further a compelling government interest as applied to employers with religious objections. Although the existence of exceptions is by no means dispositive, "a law cannot be

regarded as protecting an interest of the highest order . . . when it leaves appreciable damage to that supposedly vital interest unprohibited." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 547 (1993) (cleaned up).

Plaintiffs' attempts to dispute the Agencies' reasoning fall flat. SJ. Mem. 26-29. Plaintiffs try to distinguish the Religious Exemption Rule from the exemption for churches and their integrated auxiliaries (which Plaintiffs apparently tolerate) by pointing to "our nation's longstanding history of deferring to a house of worship's decisions about its internal affairs." SJ Mem. at 28 (citation omitted). But HRSA did not afford churches and their integrated auxiliaries an exemption from any of the other preventive services included in its guidelines. And of course, our nation also has a longstanding history of recognizing protections for religious objectors other than houses of worship, as seen in the passage of RFRA, which compels the Religious Exemption Rule at issue here. Plaintiffs also seek to discount the availability of contraception from other sources based on the fact that these programs may not be available to all women. SJ Mem. at 29. But empirical evidence in the record concluded that the implementation of the mandate was not accompanied by an uptick in contraceptive use in general or forms of contraception other than implants. Such empirical analysis would, of course, have reflected the actual availability of contraceptives from alternative sources.

In sum, Plaintiffs cite no case law supporting the proposition that they, and not the Agencies, are the arbiters of the *Government's* interest, and, in any event, the Government is unaware 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. Alleged Third Party Harm Is Not a Reason to Neglect RFRA's Requirements

Plaintiffs argue erroneously in several places that the Rule will cause harm to third parties.

SJ Mem. 24-25, 30-32. That argument is erroneous because, as noted elsewhere, contraceptives are available from other sources and evidence indicates that the mandate itself did not cause an increase in the use of contraceptives. In any event, RFRA contains no separate limitation on avoiding exemptions that may affect third-parties. Indeed, nearly all exemptions—even the individual, judicially-imposed RFRA exemptions that Plaintiffs favor—may have some effect on third parties. Here, the agencies reasonably concluded that application of the mandate to employers with religious objections neither serves a compelling interest nor is narrowly tailored to such an interests. That is all RFRA requires. *Cf. Benning v. Georgia*, 391 F.3d 1299, 1312-13 (11th Cir. 2004) (holding that the religious exemption in RLUIPA does not facially burden third party interests unduly, because RLUIPA allows States to satisfy compelling interests). To the extent Plaintiffs seek to reiterate their argument that the Rules violate the Establishment Clause[12]—an argument which would equally apply to the existing exemption for churches and their integrated auxiliaries, as well as to self-insured church plans that avail themselves of the accommodation—those arguments fail for the reasons discussed in Argument § 4; the Rules simply do not "burden" third parties by eliminating a government-imposed requirement that certain employers provide a benefit to those third parties.

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

Plaintiffs argue that RFRA permits only individual, judicially-created exemptions, SJ

[12] Plaintiffs cite to language in *Hobby Lobby* stating that "in applying RFRA 'courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.'" SJ. Mem. at 30 (quoting *Hobby Lobby*, 573 U.S. at 729 n.37). This language quotes *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005), which relies on *Estate of Thornton v. Caldor*, Inc., 472 U.S. 703 (1985), an Establishment Clause case pre-dating RFRA's enactment. This language reiterates the unremarkable proposition that, in alleviating substantial burdens under RFRA, the Government may not violate the Establishment Clause.

Mem. at 32-33, 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.

RFRA's plain text thus authorizes agencies to take affirmative steps to eliminate substantial burdens on religious exercise and does not require that the Agencies await the inevitable lawsuit and judicial order to comply with RFRA. Moreover, if a RFRA violation could be cured only through a judicial proceeding, it would lead to perverse results: here, for example, the Agencies would not have been able to create the accommodation for employers that wish to use 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).

Furthermore, although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive-coverage mandate, per *Hobby Lobby*—RFRA does not prescribe the precise remedy by which the government must eliminate that burden. There may be a range of permissible approaches that the government may take to alleviate the substantial burden, and RFRA does not require the government to inch forward one quantum of exemption at a time—all the while defending against RFRA lawsuits by religious objectors—until it stumbles upon the most restrictive accommodation that withstands the objector's RFRA

objections. This principle is aptly demonstrated by the history of religious exemptions to the contraceptive-coverage mandate.

In *Hobby Lobby*, the Supreme Court held that the contraceptive-coverage mandate, standing alone, "imposes a substantial burden" on objecting employers. 573 U.S. at 726. The Court further held that application of the mandate to objecting employers was not the least restrictive means of furthering any compelling governmental interest, because, at a minimum, the accommodation was a less restrictive alternative that could be extended to the objecting employers in that case. *See id.* at 727-33. Accordingly, the Agencies tried applying the accommodation to all objecting employers. But objections remained. The Supreme Court was expected to decide whether the objections to the accommodation were legally valid in *Zubik*. But the Court instead remanded the matter to allow the parties to try to find another accommodation; they could not. The Agencies could find no way to amend the accommodation to both account for employers' religious objections and provide seamless coverage to their employees. *See* FAQs About Affordable Care Act Implementation Part 36, at 4. After that decision, the Agencies reasonably decided to adopt the Religious Exemption Rule to satisfy their RFRA obligation to eliminate the substantial burden imposed by the mandate, because "many religious entities have objections to complying with the accommodation based on their sincerely held religious beliefs." 82 Fed. Reg. at 47,806, 83 Fed. Reg. at 57,544-48. This was entirely in keeping with the *Hobby Lobby* decision—the Court did not decide whether the accommodation would satisfy RFRA for all religious claimants; nor did it suggest that the accommodation is the only permissible way for the government to comply with RFRA and the ACA, even assuming the existence of a compelling governmental interest.

Nothing in RFRA compelled the Agencies to continue their unsuccessful efforts to find an

accommodation that would satisfy all religious objectors or prohibited them from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. Indeed, if the Agencies had simply adopted an exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because the Agencies should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result here based merely on path dependence.

The Agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the litigation over whether the accommodation violates RFRA. 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);[13] *cf. Walz v. Tax Comm'n of City of N.Y.*, 397 U.S. 664, 669 (1970) (recognizing "room for play in the joints" when accommodating exercise of religion). Here, where the accommodation still imposed a substantial burden on some entities, the Agencies acted reasonably and permissibly in choosing to enact the Religious Exemption Rule rather than attempting to iterate a different version of the accommodation and proceed with decades of litigation over whether that updated accommodation sufficiently removed the substantial burden.

Nor do the Agencies maintain that they are authorized to create any exemptions they want under RFRA. The Agencies' exercise of their authority to shape the content and scope of any preventive-services guidelines is subject to "arbitrary and capricious" review under the APA, and

[13] Defendants seek to clarify that they do not argue that HHS is entitled to deference in interpreting RFRA, *see* Order, ECF No. 234, at 32, but instead argue that there is room for play in the joints such that there are multiple permissible approaches the government may take pursuant to RFRA to alleviate a substantial burden.

the Religious Exemption Rule at issue here is tailored because it applies only to employers with a sincere religious objection to the mandate.[14]

III. The Rules Are Not Arbitrary and Capricious

Plaintiffs argue that the Exemption Rules are arbitrary and capricious for three reasons: (1) Defendants have failed to provide a reasoned explanation for the promulgation of the Religious and Moral Exemption Rules; (2) the Exemptions are not well tailored to the problem they are intended to address; and (3) Defendants failed to meaningfully respond to comments concerning the "Rules' impacts." SJ Mem. 37-51. These arguments fail.

A. Defendants Provided a Reasoned Explanation for the Promulgation of the Rules

1. The Rules Satisfy the *Fox* Standard and Are Consistent with the Evidence Before the Agencies

Plaintiffs claim that the standard for an adequate explanation is particularly high in the circumstances of this case because women have developed "serious reliance interests" related to the availability of cost-free contraceptive coverage. SJ Mem. at 38-39 (quotations omitted). Building from this premise, Plaintiffs contend that "Defendants' Exemption Rules fail to provide the requisite reasoned explanation, particularly given the lack of any material change in the underlying factual and legal circumstances that supported their prior position." *Id.* at 39. Moreover, Plaintiffs contend that the Rules' conclusion that the benefits of contraceptives are "more uncertain" than previously recognized contradicts the fact that the "HRSA guidelines continue to require coverage of the full range of FDA-approved contraceptive methods[,] [a]nd [the fact that] HHS continues to inform women that birth control is generally safe, depending on

[14] Plaintiffs devote significant space to arguing that the accommodation is the "least restrictive means" of furthering a compelling governmental interest. SJ Mem. at 26-34. But, as explained above, the mandate does not further a compelling governmental interest as applied to employers with religious objections, and thus the least-restrictive-means analysis is not relevant.

the type of birth control used and a woman's individual health." *Id.* at 40. They also complain that the Rules' conclusions regarding the benefits of contraceptives and of contraceptive coverage run counter to evidence before the Agencies in the rulemaking. *Id.* at 40-43.

Plaintiffs' scattershot arguments are unpersuasive. "The scope of review under the 'arbitrary and capricious' standard is narrow." *Motor Vehicle Mfrs. Ass'n of 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." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). In situations where the "prior policy has engendered serious reliance interests that must be taken into account," an agency should provide a "reasoned explanation" for treating differently "facts and circumstances that underlay or were engendered by the prior policy." *Id.* at 516; *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

Even assuming that the prior policy could have engendered reliance interests in the face of active litigation and repeated rulemaking efforts in this space, the Agencies did just that: 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 their 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, 83 Fed. Reg. 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). Specifically, with respect to any reliance interests, the Agencies concluded, after reviewing applicable studies and comments, that "it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use," given that "there is conflicting evidence regarding whether the mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing." 83 Fed. Reg. at 57,556.

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 contraceptives and the mandate is more mixed—and the religious and conscientious objections to complying with the mandate more substantial—than the Agencies previously acknowledged. To that end, the Ninth Circuit has recognized that—contrary to Plaintiffs' suggestions, SJ Mem. at 39—changed factual circumstances are not a prerequisite to policy change. In *Village of Kake v. U.S. Department of Agriculture*, the Ninth Circuit concluded that an agency was entitled to "give more weight to socioeconomic concerns than it [previously] had [two years earlier], even on precisely the same record." 795 F.3d 956, 968 (9th Cir. 2015) (en banc). Just so here. The record before the Agencies justified a different balancing of "the various policy interests at stake." 83 Fed. Reg. at 57,556. Of course, the uncertainty of the net benefits of contraceptives 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.

What is more, there is nothing inconsistent about the Agencies promulgating the Rules while at the same time recognizing that contraceptives can be beneficial. The Rules do not reach conclusions about whether there are *ever* any benefits to contraceptive use. Rather, they address the proper *balance* between conscience objections and the contraceptive coverage requirement. 83 Fed. Reg. at 57,556. Thus, it is entirely reasonable for the Agencies to recognize that contraceptives—and contraceptive coverage—provide some benefits, while at the same time concluding 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.

Plaintiffs' arguments that the Agencies did not adequately address comments from medical groups regarding the benefits of contraceptives and contraceptive coverage are similarly misplaced. At the outset, it is important to acknowledge the appropriate standard for evaluating such arguments:

> A court generally must be at its most deferential when reviewing scientific judgments and technical analyses within the agency's expertise. We may not impose ourselves as a panel of scientists that instructs the agency, chooses among scientific studies, and orders the agency to explain every possible scientific uncertainty. And when specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive.

Tri-Valley CAREs v. U.S. Dep't of Energy, 671 F.3d 1113, 1124 (9th Cir. 2012) (cleaned up). This deferential standard derails Plaintiffs' efforts to have this Court second-guess the Agencies' handling of comments regarding medical and health policy issues.

Plaintiffs' first science-focused argument is that the medical evidence before the Agencies undercuts the conclusion that the benefits of contraceptives were more uncertain than previously

recognized. SJ Mem. at 39-41. But the efficacy of contraceptives is a medical issue, which lies well within the ambit of HHS's scientific and technical expertise. *See, e.g., Styrene Info. & Research Ctr., Inc. v. Sebelius,* 944 F. Supp. 2d 71, 87 (D.D.C. 2013) (explaining that HHS's scientific judgments are owed deference); *Tozzi v. U.S. Dep't of Health & Human Servs.,* 180 F. Supp. 2d 1, 6 (D.D.C. 2000), *aff'd,* 271 F.3d 301 (D.C. Cir. 2001) (noting, in the context of a challenge to HHS's scientific judgment about the classification of a carcinogen, that "as an agency charged with making scientific judgments, [it] is due great deference"). And the Agencies cite ample medical evidence in the Rules, *see, e.g.*, 83 Fed. Reg. at 57,552-53 nn.28-34, drawn from the Administrative Record,[15] 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). Indeed, in support of the conclusion that the benefits of contraceptives are more uncertain than previously acknowledged, the Rules cite over 20 studies 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. 83 Fed. Reg. at 57,552-53 nn.28-34. Plaintiffs, with their own favored studies in hand, disagree with the Agencies' judgment on this score, but like the Court, they "may not impose [themselves] as a panel of scientists that instructs the agency [and] chooses among scientific studies." *Tri-Valley CAREs*, 671 F.3d at 1124.

[15] *See, e.g.* AR at 00803140-00803154 (Y. Vinogradova et al., "Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases," 350 *Brit. Med. J.* h2135 (2015)); AR at 00803775-00803784)(Ø. Lidegaard *et al*., "Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception, 366 *N. Engl. J. Med.* 2257 (2012)); AR at 00803785-00803791 (M. Vessey *et al*., "Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking," 362 *Lancet* 185 (2003)); and AR at 00803810-00803816 (L.A. Gillum *et al*., "Ischemic stroke risk with oral contraceptives: A meta analysis," 284 *JAMA* 72, 72–78 (2000)).

Plaintiffs also insist that the Agency disregarded evidence regarding the benefits of the contraceptive-coverage mandate. SJ Mem. at 41-43. That is incorrect. Plaintiffs assert that the contraceptive-coverage mandate has increased contraceptive use and reduce unintended pregnancies, and that evidence before the Agencies demonstrated as much. *Id.* But the Agencies reviewed the evidence submitted during the comment period and reached a different conclusion. They determined that "[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." 83 Fed. Reg. at 57,556. In reaching this conclusion, the Agencies relied on evidence submitted during the comment period, including studies by the Guttmacher Institute, to support this conclusion. *Id*. at 57,555 nn.51-53. This issue also falls within the realm of HHS's expertise in health policy, and under the APA, HHS's conclusions are entitled to deference. "[W]hen specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court [or plaintiffs] might find contrary views more persuasive."[16] *Tri-Valley CAREs*, 671 F.3d at 1124.

2. The Agencies Did Not Ignore Plaintiffs' Purported Reasonable Alternative

Plaintiffs contend that the Agencies violated the APA because they did not adequately consider an alternative course to the issuance of the Rules, namely, "why any purported uncertainty regarding health risks [of contraceptives] cannot be adequately addressed through a woman's consultation with her personal physician." SJ Mem. at 41. Under the APA, however, an agency

[16] The Agencies also adequately responded to comments about the efficacy of contraceptives and the contraceptive-coverage mandate, for the reasons described above.

need "consider only significant and viable" alternatives. *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) (quotations omitted). Plaintiffs' physician-consultation suggestion is not a viable alternative because it would not satisfy or mitigate the conscience objections to providing contraceptive coverage.

3. The Agencies Adequately Considered the Costs of the Rules

Plaintiffs initially argue that Defendants' alleged "[f]ailure to account for the actual costs of the Exemption Rules renders them arbitrary and capricious." SJ Mem. at 43. But the Agencies did not ignore the costs of the Rules. Rather, the Religious Exemption Rule notes that it could result in over $67 million in costs being transferred (depending on the number of entities that invoke the exemption), 83 Fed. Reg. at 57,581, while the Moral Exemption Rule notes that it could result in up to $8,760 in transfer costs (with the same caveat). Plaintiffs eventually acknowledge these facts. SJ Mem. at 43. They then, however, move the goal posts and fault the Rules for failing to "explicitly detail who will bear such [future] costs." *Id.* But Plaintiffs cite no cases holding that, to comply with the APA, an agency must "explicitly detail" who will bear various future costs. Nor could they, for the APA demands reasoned decision making, not omniscience. *CHW W. Bay v. Thompson*, 246 F.3d 1218, 1223 (9th Cir. 2001) (explaining that "arbitrary and capricious review under the APA focuses on the reasonableness of an agency's decision-making processes") (quotation marks omitted); *cf. O'Bryant v. Idaho Dep't of Health & Welfare*, 841 F. Supp. 991, 998 (D. Idaho 1993) (concluding that "nothing in the APA 'requires the Secretary to engage in the virtually impossible task of listing every type of benefit which is not excluded from income") (quotation marks omitted). The Agencies could not detail who would bear the costs of employers or schools invoking the exemption, or how much they would bear. The answers to those questions would depend on facts that were not only unknown, but, practically speaking,

unknowable at the time the Rules were promulgated, such as how many entities would invoke the exemptions, whether any affected woman would receive coverage under a spouse's plan or parent's plan, whether a woman would turn to—and qualify for—state programs, whether she would obtain contraceptives through a clinic, and so on.

4. The Rules Accord with Congressional Intent

Next, Plaintiffs contend that the Agencies violated the APA "by independently . . . concluding that some uncertainties with respect to the efficacy and safety of contraceptives exist" because Congress identified "HRSA as the arbiter of safe and efficacious women's preventive care" and charged HRSA with "promulgating guidelines that define preventive services." SJ Mem. at 44.

This argument is flawed. The ACA states, in relevant part, that "[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall" cover "such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4). HRSA is a component of HHS. *See* 47 Fed. Reg. at 38,409 ("Part H of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services is amended to . . . establish a new Chapter HB (Health Resources and Services Administration) which replaces Chapters HR [Health Resources Administration] and HS [Health Services Administration] in their entirety."); HHS Statement of Organization, Functions, and Delegations of Authority, Part H, § HB-00, 47 Fed. Reg. at 38,409-02 ("HRSA is directed by an Administrator who is responsible to the Assistant Secretary for Health"). HHS, and the other Defendant agencies, engaged in notice and comment rulemaking to best determine how to address conscience objections, and, by extension, to what

extent contraceptive coverage should be "provided for" in HRSA's guidelines. *See* 83 Fed Reg. at 57,540; 83 Fed. Reg. at 57,592-57,593. Indeed, HRSA modified the "comprehensive guidelines" to reflect the content of the Rules. *See* HRSA, Women's Preventive Service Guidelines, at https://www.hrsa.gov/womens-guidelines/index.html.

Thus, to the extent Plaintiffs are raising a technical objection that the Guidelines—and not the Rules—control the scope of the required coverage, that objection fails because, among other reasons, the Guidelines have been amended to incorporate the exemptions recognized by the Rules. *Id.* And to the extent Plaintiffs are raising a more fundamental objection that HRSA could not be guided by the Secretary of HHS in issuing the guidelines, that argument fails because HRSA is a component of HHS under the Secretary's control. The ACA did not change that fundamental fact of agency structure *sub silentio* by tasking HRSA with certain duties in the implementation of the APA.[17] *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

B. The Exemptions Are Tailored to the Problem They Are Intended to Address

According to Plaintiffs, "[t]he serious lack of alignment between the purported problems Defendants cited as a basis for the Exemption Rules and the scope of the new policy they seek to implement demonstrates that the Rules are arbitrary and capricious." SJ Mem. at 45 (quotation marks omitted). Plaintiffs are wrong again, because they misidentify the "problems" that the Rules were designed to address. They maintain that the Rules are not adequately tailored to address concerns about the safety of contraceptives, contraceptive access and teen pregnancy, or the

[17] To the extent Plaintiffs' argument here is a recycled version of their argument that the ACA does not afford the Agencies the discretion to create or expand the exemptions, Defendants address it in Argument § 1.A above.

tailoring of the contraceptive-coverage mandate. *Id.* at 44-45. But these are not the problems that the Rules were intended to address. The Rules were intended to address religious and moral objections to the provision of contraceptive coverage. *See* 83 Fed. Reg. at 57,540; 83 Fed. Reg. at 57,592-93. The matters that Plaintiffs identify as the "purported problems" to be solved by the Rules are, in fact, policy issues that the Agencies considered in determining how best to address the conscience objections to the provision of contraceptive coverage. *Id.* at 57,547-57,548, 57,552-57,556. An example illustrates the difference. If a state were considering what the maximum speed limit should be on its highways, then it might consider what percentage of the cars that use the road have certain advanced safety features, as a higher percentage would auger in favor of a higher speed limit. Consideration of that fact does not transform the problem – about what the speed limit should be – into a different one – how can the number of cars with advanced safety features be increased. The same reasoning applies here.

Plaintiffs embellish their argument by announcing that "the Rules are a solution in search of a problem." SJ Mem. at 45. Dozens of cases and years of litigation, including several stops in the Supreme Court, say otherwise: Determining how best to balance conscience objections with the provision of contraceptive coverage is a real "problem," not a figment of the Agencies' collective imaginations. And Plaintiffs' supporting arguments do not fare any better. They assail the Agencies for extending the Religious Exemption Rule to publicly traded companies, even though the Agencies have stated they are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage based on a religious belief (83 Fed. Reg. at 57,626). SJ Mem. at 46. But there is nothing "arbitrary or capricious" about including publicly traded entities within the scope of the Religious Exemption Rule. For one thing, RFRA applies to publicly traded entities, 83 Fed. Reg. at 57,626, *see Hobby Lobby*, 573 U.S. at 707–08 (discussing

the definition of "person" in RFRA), and for another, the invocation of the Religious Exemption by a publicly traded entity is not a logical or legal impossibility. In any case, if there is no publicly traded entity that has invoked the religious exemption, then the extension of the exemption to publicly traded companies has not caused any harm to Plaintiffs. (And if a publicly traded entity does properly invoke the exemption, then the Exemption could not be said to be unnecessarily broad.) Plaintiffs lodge a similarly meritless objection to the Moral Exemption Rule, arguing that the Moral Exemption Rule "cite[s] only three employers" to justify its existence. SJ Mem. at 46. But Plaintiffs (of course) identify no case holding that the APA requires that a rule be expected to affect a minimum number of entities before it can be issued—and, in any case, more entities may invoke the Rule in the future.

Finally, Plaintiffs argue that the Final Rules are unnecessary because "Defendants have stipulated to injunctions barring them from enforcing [the] contraceptive-coverage requirement against several employers, including 'open-ended' injunctions that allow additional employers to join." SJ Mem. at 46. But if Plaintiffs think that Rules will not have a real-world effect, then the real problem is with Plaintiffs' standing, not the reasonableness of the Rules. In any case, the Agencies do not believe that the injunctions protect—or will protect—all those with conscience objections, and Plaintiffs presumably agree, given that they have brought this suit and insist that they have standing to do so.

C. Defendants Appropriately Responded to Comments About the Effects of Unintended Pregnancy and the Impact of the Rules on Victims of Domestic Violence

Plaintiffs argue that the Rules are arbitrary and capricious because the Agencies did not "meaningfully acknowledge, engage, and [ ] respond to," SJ Mem. at 50, comments regarding the "significant burdens associated with unintended pregnancies," *id.* at 48. They also insist that the

Rules do not address the effect of the Rules on women who are victims of domestic violence. *Id.* at 50-51. These arguments are incorrect: The Agencies acknowledged and fulsomely responded to the comments regarding the burdens of unintended pregnancies and any connection to "societal inequality." 83 Fed. Reg. at 57,548, 57,549-50. The Agencies explained that the Rules would not be imposing the burdens of any unintended pregnancies or creating societal inequality: "These rules simply relieve part of that governmental burden [of providing contraceptive coverage]. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed." *Id.* at 57,549. They also noted that there is evidence that the contraceptive-coverage mandate did not affect contraceptive use and that, in any case, the scope of these exemptions is limited to entities with sincere religious and moral objections. *Id.* at 57,550. That Plaintiffs do not agree with these responses does not render them nonexistent.

IV. The Rules Comply with the Establishment Clause

Defendants have previously explained that the Rules are consistent with the Establishment Clause. *See* Defs.' Opp. to Pls.' Mot. for Prelim. Inj., ECF No. 51, at 29-32. 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 (citation and internal punctuation omitted). The Rules serve the legitimate secular purpose of alleviating significant governmental interference with the exercise of religion. Additionally, the Rules neither promote nor subsidize any religious message or belief; rather, they allow 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 state-imposed regulations.

Finally, by reducing government interference with religious exercise, the Rules achieve a more complete separation of church and state, rather than entangling them.

Plaintiffs incorrectly contend that the Rules are inconsistent with the Establishment Clause because they unduly burden third parties. SJ Mem. at 33-55; *see also* Amicus Br. of Church-State Scholars at 2-6, ECF No. 325; Amici Br. of Religious & Civil Rights Organizations at 5-12, ECF No. 337-1. As previously explained, the Agencies expressly determined that application of the mandate to objecting entities neither serves a compelling interest nor is narrowly tailored to any such interest. *See* 83 Fed. Reg. at 57,546-48. This conclusion precludes any finding that the Religious Exemption Rule exceeds the agencies' authority under RFRA by unduly burdening the interests of third parties. *Cf. Benning*, 391 F.3d at 1312-13 (holding that RLUIPA's religious exemption does not facially burden third-party interests unduly, because RLUIPA allows States to satisfy compelling interests). Furthermore, as the Agencies reasonably concluded, the burden the mandate imposes on the small number of objecting employers is greater than previously thought, and outweighs the burden on women who might lose contraceptive coverage. *See* 83 Fed. Reg. at 57,545-48.

Moreover, 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." *Id*. 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 contraceptive 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 *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327 (1987), 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 noted, "it was the Church[,] . . . not the Government, who put him to the choice of changing his religious practices or losing his job." *Id*. 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 effects result from a decision by private employers, not the government; and the burden is much less than the loss of a job, as it is merely the loss of subsidized contraceptive coverage by an employer with sincerely-held religious or moral objections to providing such coverage. As Defendants have explained previously, contrary reasoning would invalidate the church exemption.[18]

[18] The attempt by Amici Religious and Civil Rights Organizations to distinguish *Amos*—and the Supreme Court's later decision in *Hosanna-Tabor Evangelical Lutheran Church & School v. EEOC*, 565 U.S. 171 (2012)— is not persuasive. ECF 337-1 at 6. Contrary to Amici's assertion, *Amos* is not inapposite because it concerned the institutional autonomy of religious congregations and religious not-for-profits to control their own leadership and membership. That cramped view of the permissibility of accommodating religious beliefs finds no support in *Amos*, which spoke broadly of the government's authority to alleviate governmental interference with the ability of religious organizations to "define and carry out their religious missions." 483 U.S. at 335. That is precisely what the religious exemption here seeks to accomplish. *See also*

Plaintiffs and Amici 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 52, 54; *see also* Amicus Br. of Church-State Scholars at 13-17; Amici Br. of Religious & Civil Rights Organizations at 5-7. 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]." *Caldor,* 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 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 substantial burden on religious exercise 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 Tex. 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.[19]

Cutter, 544 U.S. at 720 (finding RLUIPA's institutionalized-persons provision "compatible with the Establishment Clause because it alleviates exceptional government-created burdens on private religious exercise" and citing *Amos*, 483 U.S. at 349, for the proposition that "removal of government-imposed burdens on religious exercise is more likely to be perceived as an accommodation of the exercise of religion rather than as a Government endorsement of religion") (internal punctuation omitted)).

[19] Amici Religious and Civil Rights Organizations misplace their reliance on Free Exercise jurisprudence. Amici Br. of Religious & Civil Rights Organizations, ECF No. 337-1, at 5-6. Contrary to Amici's characterization, the reason that the Supreme Court in *United States v. Lee*, 455 U.S. 252 (1982), rejected an Amish employer's request for an exemption from paying social security taxes was because "the 'tax system could not function if denominations were allowed to

Additionally, Amici is simply incorrect that the Rules contain no oversight mechanisms aimed at preventing insincere assertions of religious belief. As the Agencies explained, "the mandate is enforceable through various [statutory] mechanisms" and "[e]ntities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement and accountability under such mechanisms." 83 Fed. Reg. at 57,615.

The Rules also "do[] not single out a particular class of [religious observers] for favorable treatment and thereby have the effect of implicitly endorsing a particular religious belief." *Hobbie v. Unemployment Appeals Comm'n of Fla.*, 480 U.S. at 136, 145 n.11 (1987). Rather, the fact 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. And similar to the religious accommodation the Ninth Circuit upheld in *Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003), which protected all who are religiously motivated to seek health care in 'religious nonmedical health care institutions,' the Religious Exemption Rule provides a sect-neutral exception to the mandate. Moreover, Amici Religious and Civil Rights Organizations cite no authority supporting their assertion that the mere fact that the religious exemption may apply to publicly-traded companies but the moral exemption does not, Amici Br. of Religious & Civil Rights Organizations, ECF No. 337-1, at 19, is tantamount to an Establishment Clause violation. The Agencies explained in the interim moral-exemption rule that "the combined lack of any

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challenge the tax system because tax payments were spent in a manner that violates their religious belief,'" and not because the request allegedly burdened third parties. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 435 (2006) (quoting *Lee*, 455 U.S. at 260). Similarly, the reason that the Sunday closing law in *Braunfeld v. Brown*, 366 U.S. 599 (1961), could be applied constitutionally to Jewish business owners was in large part because of the "strong state interest in providing one uniform day of rest for all workers," which meant that the requested exemption "would have rendered the entire statutory scheme unworkable." *Sherbert v. Verner*, 374 U.S. 398 (1963). No such important state interests in consistency of administration are present here.

lawsuits challenging the mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity" had led them "to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so." 82 Fed. Reg. at 47,851. After considering such comments, the Agencies reasonably decided not to include publicly-traded entities in the moral exemption. Amici are mistaken that any impermissible religious purpose motivated the Agencies in reaching this conclusion.

Finally, Amici's bold argument that the moral exemption itself violates the Establishment Clause, Opp. at 19-20, rests on flawed logic. Accepting Amici's argument would require the Court to agree with the following syllogism: (1) The moral exemption applies to convictions that are deeply and sincerely held. (2) Courts have recognized that such moral beliefs can play a role in a nonreligious person's life that is akin to a religion. (3) Therefore, relieving a government-imposed burden on deeply-held moral beliefs violates the Establishment Clause. But the conclusion does not follow from the stated premises; moreover, Amici cite no case in which a court found an Establishment Clause violation based on an attempt to relieve burdens on non-religious moral beliefs.[20]

V. The Rules Are Consistent with the Equal Protection Clause

The Rules are also 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

[20] *United States v. Ward*, 989 F.2d 1015 (9th Cir. 1992), does not assist Amici because that case does not even mention the Establishment Clause.

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 "explicitly target contraceptive coverage." SJ Mem. at 54. In fact, the Rules do not discriminate against women on the basis of sex, facially or otherwise. 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 8,458 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 54. Moreover, any distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection on the part of an employer to facilitating the provision of contraceptives.

Notably, Plaintiffs fail to cite any authority suggesting that declining to require the subsidization of contraception constitutes a sex-based equal protection violation. *Caban v.*

Mohammed, 441 U.S. 380 (1979), involved a distinction between unwed mothers and unwed fathers in state domestic-relations law, not a subsidization. *Arce v. Douglas*, 793 F.3d 968 (9th Cir. 2015), did not even discuss sex-based discrimination; instead, it concerned claims of racial and ethnic discrimination. Moreover, neither *International Union, United Automobile, Aerospace, and Agricultural Implement Workers of America, UAW v. Johnson Controls, Inc*., 499 U.S. 187 (1991), nor the 2000 EEOC decision cited by Plaintiffs involve alleged constitutional violations; instead, both were exclusively concerned with statutory claims (Title VII) not presented here. That distinction matters because unlike Title VII, "[t]he equal protection component of the Fifth Amendment prohibits only purposeful discrimination" rather than disparate impact. *Harris*, 448 U.S. at 323 n.26 (citing *Washington v. Davis*, 446 U.S. 229 (1976)). 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. That claim is meritless because it does not state a cognizable equal protection claim on the basis of sex.

Because the Rules do not create sex-based distinctions, they are subject to rational basis review. They satisfy this "lowest level of scrutiny," *United States v. Dumas*, 64 F.3d 1427, 1429 (9th Cir. 1995), because they are rationally related to legitimate government interests, *Lyng v. Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW*, 485 U.S. 360, 370 (1988). The Religious Exemption Rule accommodates religion by "provid[ing] conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts." 82 Fed. Reg. at 47,793. The accommodation of religious beliefs is an important

government interest, as the Supreme Court recognized in *Cutter*, 544 U.S. at. 724-25. For the same reasons, the Rule would satisfy intermediate scrutiny.[21]

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. 82 Fed. Reg. at 47,839. The government may permissibly accommodate deeply held moral 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, some of the Plaintiff States protect moral beliefs in healthcare. *See, e.g.*, Cal. Health & Safety Code § 123420; Md. Code Ann., Health – Gen. § 20-214. Plaintiffs cite no authority suggesting that the importance of this or any other long-recognized government interest depends on the number of entities that have expressed interest in an accommodation intended to protect that interest. SJ Mem. at 55-56.

VI. The Rules Were Properly Promulgated After a Period of Notice and Comment Under the APA

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 56–58. The Agencies maintain that they had independent statutory authority to issue the IFRs, and had good cause to do so as

[21] Plaintiffs contend that if (contrary to fact) intermediate scrutiny applied, the means employed by the Rules do not substantially relate to the government's important interests in accommodating sincerely-held religious and moral convictions. SJ Mem. at 56. But the Rules leave the mandate in place for most applicable entities, and the accommodation, by itself, was not satisfactory because it imposed a substantial burden on the exercise of religion of certain entities. *See* 82 Fed. Reg. at 47,800. Thus, Plaintiffs should not be heard to contend that the Rules are "broader than necessary," SJ Mem. at 56, when Plaintiffs themselves fail to present an adequate alternative solution for accommodating religious and moral convictions.

well.[22] *See* ECF No. 51 at 14-18 (arguing in favor of independent statutory 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 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. Plaintiffs have now had that full and timely notice and ample opportunity for comment, and have participated in that process. *See* Second PI Mot. at 15 n.17. 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; *id.* 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. v. Volpe*, 401 U.S. 402, 416 (1971). Instead, the Court should consider whether the Agencies examined the relevant data and articulated a satisfactory explanation for their actions,

[22] Plaintiffs also argue that the IFRs were not validly promulgated. SJ Mem. at 58–59. As noted earlier, Plaintiffs' claims as to the IFRs are moot. *California v. Azar*, 911 F.3d 558, 569 (9th 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.").
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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 (internal quotation omitted).

Plaintiffs continue to claim that the Agencies are using "post-promulgation comments" to "replace pre-promulgation comments." SJ Mem. at 57. But the Agencies are now defending the final version of the Rules, which were promulgated after a period of notice and comment, not the IFRs, which were promulgated contemporaneously with the Agencies' request for comment. The cases Plaintiffs rely upon are solely concerned with agencies' efforts to defend rules intended to take effect prior to the completion of notice and comment rulemaking, like the IFRs.[23] They provide no basis to invalidate the Rules, which were only finalized after the Agencies received and addressed public comments, including from Plaintiffs.

In *Pennsylvania*, the district court reached a contrary conclusion by relying 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 was error. 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 procedural inadequacy of the "further suspen[sion]" rules. *See id.* at 757. Instead, the Court enjoined both rules because the

[23] *Nat. Res. Def. Council v. Nat'l Highway Traffic & Safety Admin.*, 894 F.3d 95, 113–15 (2d Cir. 2018) (holding agency violated the APA by promulgating a rule without notice and comment after rejecting the agency's "good cause" defense); *United States v. Brewer*, 766 F.3d 884, 887–90 (8th Cir. 2014) (rejecting attorney general's assertion of "good cause" to bypass notice and comment and pre-enactment publication of regulation regarding sex offender registration); *United States v. Reynolds*, 710 F.3d 498, 509–23 (3d Cir. 2013) (same); *United States v. Dean*, 604 F.3d 1275, 1278–82 (11th Cir. 2010) (*affirming* attorney general's invocation of good cause in order to bypass the APA's notice and comment requirement); *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 213–16 (5th Cir. 1979) (setting aside designations promulgated without notice and comment and rejecting agency arguments of good cause and harmless error), *reh'g granted*, 598 F.2d 915 (5th Cir. 1979).

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. The *Pennsylvania* court ignored this distinction between *NRDC* and the Agencies' promulgation of the exemptions here, and this Court should not adhere to its reasoning.

Unlike *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*, 595 F.2d at 215 (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 15 n.17. 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.

No Ninth Circuit case cited by Plaintiffs suggests that final rules promulgated after a proper notice-and-comment period are procedurally invalid as a consequence of the issuance of

improperly justified IFRs. To the contrary, the Ninth Circuit has previously suggested that a final rule may be valid notwithstanding the invalidation of a prior interim rule for failure to provide notice and comment. *See Paulsen v. Daniels*, 413 F.3d 999 (9th Cir. 2005) (invalidating an interim rule for failure to comply with notice-and comment procedures and holding that the rule in effect was the final rule, where the rule previously in force erroneously interpreted a statutory provision); *Buschmann v. Schweiker,* 676 F.2d 352 (9th Cir. 1982) (invalidating interim rule and accepting parties' agreement, without discussion, that the final rule was valid). And the Ninth Circuit has also recognized that even where an agency has been found to have improperly dispensed with notice and comment procedures, the proper remedy is to offer the lost opportunity to comment rather than enjoining the rules. *See Western Oil & Gas Ass'n v. EPA*, 633 F.2d 803, 812-13 (9th Cir. 1980) (in a case in which petitioners had not been afforded the opportunity to comment on an EPA rule, "[t]he proper remedy . . . is a reenactment of the deliberative process with correct provision for the petitioners' participation"). That participation has already been afforded to Plaintiffs, who have thus suffered no remediable procedural injury.

VII. Even if Plaintiffs Prevail, A Set-Aside Is the Only Appropriate Remedy

Should the Court rule in favor of the 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).[24] 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). Plaintiffs suggest that the Court should enter further relief in the form of a declaratory

[24] The Court should not set aside portions of the Rules that permit 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. at 57,589.

judgment or permanent injunction against the Agencies. SJ Mem. at 60. But their motion does not articulate why the Court needs to go beyond the relief afforded under § 706. If the Rules are set aside as to the Plaintiffs, the responsibility falls to the Agencies, not Plaintiffs or this Court, to reconsider how best to address the tension between contraceptive coverage and religious freedom interests that the Supreme Court asked the Agencies to navigate in *Zubik*.

The scope of this "set aside"—or, indeed, any form of relief the Court may enter—also 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) (quotation omitted); *see also Gill v. Whitford*, 138 S. Ct. 1916, 1930 (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."). Although the Ninth Circuit's decision in *Earth Island Inst. v. Ruthenbeck*, 490 F.3d 687, 699 (9th Cir. 2007), *rev'd in part on other grounds sub nom. Summers v. Earth Island Inst.*, 555 U.S. 488 (2009), asserted that a "nationwide injunction . . . is compelled by [§ 706] of the Administrative Procedure Act," this Court has acknowledged that "*Earth Island Inst.* recognized that a nationwide injunction is discretionary relief" that must be analyzed in light of recent "Ninth Circuit guidance" about the permissible scope of relief in an APA action, even when considering final relief under section 706. *City & Cty. of S.F. v. Sessions*, 349 F. Supp. 3d 924, 971 n.7 (N.D. Cal. 2018), *appeal filed*, No. 18-17308 (9th Cir. 2018); *see also California*, 911 F.3d at 582–84. As this Court previously explained, Plaintiffs have failed to meet "the high threshold set by the Ninth Circuit for a nationwide injunction," particularly in light of concerns that "parallel litigation" ongoing in courts in the First and Third Circuits may lead to "direct legal

conflicts" between this Court and others.[25] Order Granting Pls.' PI Mot. at 44. "[A]n injunction that applies only to the plaintiff states would provide complete relief" to them, *California*, 911 F.3d at 584, and Plaintiffs adduce no further evidence in their summary judgment motion to support a contrary conclusion. As such, the Rules should be "set aside" with respect to the named Plaintiffs only.

CONCLUSION

For the reasons stated above, the Court should dismiss this suit or, in the alternative, enter judgment in favor of Federal Defendants.

Dated: May 31, 2019

Respectfully submitted,

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[25] It is of no moment that the First Circuit recently reversed the holding of a district court in Massachusetts that the state plaintiff in that case lacked standing to bring similar claims. *Massachusetts v. U.S. Dep't of Health & Human Servs.*, 923 F.3d 209 (1st Cir. 2019). It remains the case that interlocutory, merits, and appellate proceedings in other courts may be disrupted by the entry of nationwide relief here.