

EXHIBIT 1

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

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

Plaintiffs,)

v.)

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

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

Defendants.)

**FEDERAL DEFENDANTS' MEMORANDUM IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

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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. However, the Health Resources and Services Administration, 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 religious employers remained subject to the contraceptive mandate and were left either to violate their sincerely held religious beliefs or to be liable for significant fines.

Years of litigation in dozens of cases followed. In *Burwell v. Hobby Lobby Stores, Inc.*, the Supreme Court held that the “contraceptive mandate imposes a substantial burden on the exercise of religion” in violation of the Religious Freedom Restoration Act (RFRA). 134 S. Ct. 2751, 2779 (2014). Instead of extending the exemption, however, the government tried “accommodating” religious objectors who did not qualify for that exemption. That decision triggered a new round of litigation challenging the accommodation that generated decisions in nine federal courts of appeals. Ultimately, the Supreme Court vacated those decisions and instructed the courts of appeals to give the parties time to try to resolve their differences. *See Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016) (per curiam).

On October 6, 2017, in an attempt to address serious religious and moral objections and finally bring the litigation to a close, the Departments of HHS, Labor, and the Treasury (collectively, the Agencies) issued interim final rules with requests for public comments (IFRs) that kept the mandate in place, but exempted religious and moral objectors. *See* 82 Fed. Reg. 47,792 (Oct. 13, 2017); 82 Fed. Reg. 47,838 (Oct. 13, 2017). After reviewing all the comments received on the IFRs, and making some changes in response, the Agencies promulgated Final Rules superseding the IFRs. *See* 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).

Pennsylvania and New Jersey (Plaintiffs or the States) seek to reverse this considered decision, demanding that religious and secular groups facilitate services to which they deeply object on religious or moral grounds. They contend that the new rules violate the Administrative Procedure Act (APA) and the ACA. Their positions, if adopted, would equally sweep away the longstanding exemption for churches and their integrated auxiliaries, exposing churches to the contraceptive-coverage mandate for the first time. Plaintiffs also dismiss the benefit of the Rules to employers whose religious obligations or duties of conscience would preclude them from offering coverage to which they object.

Plaintiffs' arguments are unfounded because the Agencies acted lawfully—in accordance with both the ACA and RFRA—to protect a narrow class of sincere religious and moral objectors from being forced to facilitate practices that conflict with their beliefs. In any event, Plaintiffs lack standing and are in the wrong court: venue is not proper here. Finally, the States fail to satisfy the remaining requirements for preliminary injunctive relief. Defendants thus respectfully request that the Court deny the motion for a preliminary injunction.

BACKGROUND

A. 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 issued 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 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 to its health insurer or its third-party administrator (in the case of self-insured plans). 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. (The Agencies later amended the accommodation to permit an objecting employer to instead provide notice directly to HHS. *See* 80 Fed. Reg. 41,318, 41,322-23 (July 14, 2015).)

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

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).

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

B. Challenges to the Contraceptive-Coverage Mandate and Accommodation

Many employers objected to the contraceptive-coverage mandate. In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Supreme Court held that RFRA prohibited applying the mandate to closely held for-profit companies with religious objections to providing contraceptive coverage because the mandate “impose[d] a substantial burden on [such employers’] exercise of religion,” *id.* at 2779, and 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 2780. The Court observed that the Agencies had already established an accommodation for not-for-profit employers and that this less-restrictive alternative could be extended to closely held for-profit companies with religious objections. *Id.* at 2782. The Court

did not decide, however, “whether an approach of this type complies with RFRA for purposes of all religious claims.” *Id.*

In response to *Hobby Lobby*, the Agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. *See* 80 Fed. Reg. at 41,323-28. But numerous entities continued to challenge the mandate. They argued that the accommodation burdened their exercise of religion because they sincerely believed that the required notice and the provision of contraceptive coverage in connection with their health plans made them complicit in providing such coverage, in contravention of their faith.

A split developed in the circuits,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*, 136 S. Ct. at 1557 (2016). 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 parties should “be *afforded an opportunity* to arrive at an approach going forward that accommodates [the plaintiffs’] religious exercise while at the same time ensuring that women covered by [the plaintiffs’] health plans receive full and equal health coverage, including contraceptive coverage.” *Id.* (quotation marks omitted) (emphasis added). 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. Similar orders were entered in other pending cases.

In response to the Supreme Court’s order in *Zubik*, the Agencies issued a request for information seeking public comment to determine whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while

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 by *Zubik*, 136 S. Ct. at 1557, 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).

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 could not find a way to amend the accommodation to both account for employers' religious obligations and provide coverage to their employees. *See* FAQs About Affordable Care Act Implementation Part 36 (also FAQs), at 4 (Jan. 9, 2017).³ The pending litigation—more than three dozen cases brought by more than 100 separate plaintiffs—thus remained unresolved. In addition, some nonreligious organizations with moral objections to providing contraceptive coverage had filed suits challenging 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).

C. 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. at 47,799. The Agencies subsequently issued two 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.” *Id.* 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

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

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 the States, *id.* at 47,847. The rule 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 to notice-and-comment requirements, 5 U.S.C. § 553(b), the Agencies issued the rules without prior notice and comment. The Agencies also solicited comments for 60 days post-promulgation in anticipation of final rulemaking. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838.

D. Pennsylvania’s Challenge to the IFRs and the District Court’s Preliminary Injunction

Pennsylvania sued in this Court, challenging the IFRs and seeking a preliminary injunction. Compl., ECF No. 1, Prayer for Relief, at 33; Mtn. for Prelim. Inj., ECF No. 9. Pennsylvania claimed that the IFRs violated (1) the equal protection component of the Due Process Clause; (2) Title VII of the Civil Rights Act and the Pregnancy Discrimination Act; (3) the Establishment Clause; (4) the notice and comment provisions of the APA, and (5) the APA’s prohibition on

agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). Compl., ECF No. 1, ¶¶ 141-176.

The Court granted Pennsylvania’s motion for preliminary injunctive relief. As an initial matter, the Court rejected the Agencies’ argument that Pennsylvania had not demonstrated standing, concluding that the special solicitude owed to states and the impact on Pennsylvania’s coffers supported finding standing.⁴ PI Opinion, ECF No. 59, at 8-17. Next, the Court held that Pennsylvania was likely to succeed on the merits. To that end, the Court concluded that the Agencies lacked the authority to issue interim final rules and were instead required to engage in notice and comment rulemaking. *Id.* at 19-29. The Court also held that the IFRs violated the text of the ACA, deciding that the statute does not allow the Agencies to create exemptions to the requirement to cover contraceptives at no-cost. *Id.* at 29-37. Next, the Court decided that, absent an injunction, Pennsylvania would suffer irreparable financial harm and irreparable harm to the health of its citizens. *Id.* at 37-42. The Court also held that the balance of equities and public interest weighed in favor of issuing a preliminary injunction. *Id.* at 42-43. Accordingly, the Court enjoined the Agencies from enforcing the IFRs. *Id.* at 44.

E. The Final Rules

After considering, for over 11 months, the more than 110,000 comments received on the IFRs, the Agencies issued final versions of the religious exemption and the moral exemption rules. Throughout the preamble, the Final Rules address the significant comments received by the Agencies. Changes were made in response to the comments, but the changes do not alter the fundamental substance of the exemptions set forth in the IFRs.

The religious exemption, in its final form, as in its interim final form, “[is] necessary to expand the protections for the sincerely held religious objections of certain entities and individuals.” 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

⁴ The Court did not address the Agencies’ argument that the Eastern District of Pennsylvania is not a proper venue for this suit.

contraceptive services with no cost-sharing.” *Id.* The final religious exemption “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 Rule] 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 a number of clarifying or technical changes in the final rule. The Agencies made clarifying changes regarding the scope of the exemption. For example, “the prefatory language to the exemptions is clarified 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). Also, the Agencies “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 Agencies also made “technical changes to the accommodation regulations maintained in parallel” by the Agencies. 83 Fed. Reg. at 57,537- 57,538.

The final moral exemption rule also continues to fulfill the same purpose that it did in interim form, namely, 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 “does not remove the contraceptive coverage requirement generally from HRSA’s guidelines.” *Id.* at 57,593. And “[t]he changes to the rule[] being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA’s decision to otherwise require contraceptive coverage.” *Id.*

F. Plaintiffs’ Amended Complaint and Second Motion for a Preliminary Injunction

Following the issuance of the Final Rules, New Jersey joined Pennsylvania’s suit and the two States filed an amended complaint challenging the Final Rules. Am. Compl. ¶ 33, ECF No. 89. The five counts track the five counts in the original complaint. *Id.* ¶¶ 156-194. Plaintiffs also filed a motion for a preliminary injunction on the basis of their procedural and substantive APA claims. Mem. of Law in Support of Plaintiffs’ Mtn. for a Prelim. Inj. (PI Mem.), ECF No. 91-2. On the procedural front, Plaintiffs contend primarily that, although the Agencies received and considered thousands of comments before issuing the Final Rules, the Rules are irredeemably tainted by the fact that the Agencies did not consider comments before issuing the IFRs. *Id.* at 11-15. With respect to their substantive APA claim, Plaintiffs contend that the Final Rules violate the ACA, that the Agencies’ reliance on RFRA is improper, and that the Agencies provided arbitrary and capricious rationales for the Final Rules. *Id.* at 19-38. They also argue that they will be irreparably harmed because of the Rules’ alleged direct fiscal impact and effect on the health of Plaintiffs’ citizens. *Id.* at 38-44.

ARGUMENT

I. PLAINTIFFS’ ATTEMPTS TO INCORPORATE ARGUMENTS BY REFERENCE ARE IMPROPER.

Plaintiffs purport to “incorporate by reference the discussion and arguments made in” Pennsylvania’s first preliminary injunction motion. PI Mem. at 3, *see also* PI Mem. at 11 n.15. The Court should ignore any such discussion and arguments. The Court granted Plaintiffs an extension of the page limit for their brief, affording them up to 45 pages. Their brief runs right up

to the limit. Allowing the States to incorporate their previous brief by reference would “effectively nullify the page . . . limits imposed by . . . local rules,” or, in this case, the Court. *Papp v. Fore-Kast Sales Co.*, 842 F.3d 805, 816 (3d Cir. 2016) (rejecting effort by appellee to incorporate by reference arguments made in district court). Plaintiffs’ request is also confusing. All of Pennsylvania’s arguments in the first preliminary injunction motion were aimed at the IFRs, which are not the subject of the amended complaint. How do those arguments apply? Plaintiffs do not say. Blunderbuss incorporation, of the kind attempted by Plaintiffs, generates unnecessary confusion about a party’s position. For this reason too, any incorporated arguments should be ignored. If the Court nonetheless allows these arguments to be incorporated by reference, it should deem Defendants’ response to Pennsylvania’s first motion for a preliminary injunction incorporated by reference as well.

II. PLAINTIFFS LACK STANDING.

To establish standing, Plaintiffs must show they have “suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and . . . (b) actual or imminent, not conjectural or hypothetical.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (citations omitted). Allegations of possible future injury do not suffice; “[a] threatened injury must be certainly impending to constitute injury in fact.” *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990). Likewise, a party that “alleges only an injury at some indefinite future time” has not shown injury in fact; “the injury [must] proceed with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all.” *Lujan*, 504 U.S. at 564 n.2.

Previously, this Court held (1) that the States are entitled to “special solicitude” in the standing analysis under *Massachusetts v. EPA*, 549 U.S. 497, 521 (2007), and *Texas v. United States*, 809 F.3d 134 (5th Cir. 2015), *aff’d by an equally divided Court*, 136 S. Ct. 2271 (2016)⁵;

⁵ “[I]t’s true the Supreme Court granted certiorari in *Texas v. United States*, but then deadlocked 4–4, and as a result the Fifth Circuit’s decision stands, though its soundness has been questioned.” *Robledo-Soto v. Lynch*, 845 F.3d 834, 836 (7th Cir. 2017) (internal citation omitted). Because the Fifth Circuit’s decision was affirmed by an equally divided Supreme

and (2) that Pennsylvania has standing because the IFRs would impose a financial burden on the State's coffers. P.I. Opinion, ECF No. 59, at 8-17. Defendants respectfully request that the Court reconsider these determinations in the context of the Final Rules and deny Plaintiffs' motion for preliminary injunction for lack of Article III standing.

A. Plaintiffs' Allegations of Economic Injury Are Not Sufficient to Establish Standing.

Plaintiffs speculate that the rules "will result in significant, direct and proprietary harm to Pennsylvania and New Jersey, which will bear increased costs" as women employed by entities claiming the exemption "turn to state-funded programs for their contraceptives." Am. Compl. ¶¶ 138, 146. Plaintiffs' declarants provide, at best, well-reasoned speculation about the likely impact of the exemptions on citizens whose employers avail themselves of the exemption.⁶ But even an "objectively reasonable likelihood" of injury is insufficient under Article III because it is "inconsistent with [the] requirement that 'threatened injury must be *certainly impending* to constitute an injury in fact.'" *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013) (quoting *Whitmore*, 495 U.S. at 158) (emphasis added). And there are too many contingencies in Plaintiffs' theory to meet that threshold.⁷

Court, the Supreme Court's decision is not binding outside of that case. *See Durant v. Essex Co.*, 74 U.S. (7 Wall.) 107, 113 (1868); *cf. Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 420 (2011).

⁶ Allen Decl., Ex. Q, at ¶ 23 ("not unreasonable to expect" women will turn to state services if employers drop coverage); Steinberg Decl., Ex. R at ¶ 29 ("we expect that the new exemptions . . . will lead to an increase in the number of women" who rely upon Medicaid and Family Planning Services); Adelman Decl., Ex. S, ¶ 19 ("DMAHS anticipates that some women . . . who lose contraceptive coverage" will seek coverage from NJ FamilyCare, Plan First, and Title X); Gennace Decl., Ex. T, ¶ 17 ("Many New Jersey women are likely to lose the medical coverage for contraceptive care" under the exemptions, and "DOBI anticipates that some women" will seek coverage from state-funded programs); Coulter Decl., Ex. U, ¶ 25 ("[W]e expect that many women . . . will seek care from one of the 47 New Jersey Family Planning Clinics"); *see also* Kost Declaration, Ex. K, at ¶ 54 ("Many women who lose or lack contraceptive coverage because their employer or university objects, however, would not meet the strict income and eligibility requirements of public programs").

⁷ Even if these purported harms were deemed to satisfy the requirement of "certainly impending" injury, Plaintiffs should not be able to establish standing by virtue of spending more money on social services when they remain free to decide whether or not to do so. *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (per curiam). *See California v. Azar*, ___ F.3d ___ No.

Plaintiffs allege that some entities operating within Pennsylvania and New Jersey are likely to take advantage of the relevant exemptions, based on their decisions to pursue litigation or prior outreach to the Agencies. Am. Compl. ¶ 136. But this allegation does not take into consideration whether entities are likely to use the exemption or whether they will rely on the preexisting accommodation, under which employees receive contraceptive coverage. In *Hobby Lobby*, the Supreme Court acknowledged that the accommodation would have satisfied the religious objections of the plaintiffs in that case (Conestoga and Hobby Lobby), *see* 134 S. Ct. at 2780-83; *id.* at 2782 (the accommodation “does not impinge on the plaintiffs’ religious belief”), and the accommodation was made available to Hobby Lobby, Conestoga, and other for-profit companies as a result of the plaintiffs’ victory in that case. Moreover, with the exception of Hobby Lobby, Inc., all of the entities listed in the amended complaint provided notice to HHS of their objection to providing contraceptive coverage for purposes of using the accommodation. Employers that want to shift to the exemption must provide sixty days’ notice pursuant to the Public Health Service Act, 83 Fed. Reg. at 57,538, and Plaintiffs do not allege that any employer within their states has taken this step.

There are other shortcomings as well. Many of the named employers, including Hobby Lobby, Conestoga, Cummins Allison, Geneva College, and Bingaman & Son Lumber, only object to a subset of FDA-approved contraceptives. *See* Ex. W at 2 (Cummins Allison and Bingaman & Son object to four specific contraceptive methods); *id.* at 12 (Geneva College objects to “abortion inducing drugs”). Plaintiffs have no data to support their assumptions that any individuals will be denied coverage for their preferred contraceptive method and will meet “the strict income and eligibility requirements of public programs.” Kost Decl. ¶ 54. Nor do they account for employers that decline to provide contraceptive coverage on separate legal grounds, like Geneva College, which obtained an injunction against the Agencies preventing enforcement of the contraceptive

18-15144, 2018 WL 6566752, at *17 (9th Cir. Dec. 13, 2018) (Kleinfeld, J., dissenting) (concluding states lacked standing to challenge IFRs under the “self-inflicted harm” doctrine of *Pennsylvania*).

mandate against it. *Geneva College, et al. v. Azar*, No. 2:12-cv-00207, Order Granting Permanent Injunction & Declaratory Relief, ECF No. 153 (W.D. Pa. July 5, 2018). In short, Plaintiffs' predictions do not constitute allegations of "certainly impending" harm. *Clapper*, 568 U.S. at 410.

Moreover, Plaintiffs' lack of evidence of injury is particularly telling given the mandate's history. Churches and their integrated auxiliaries, nonprofit organizations in self-insured church plans using the accommodation, grandfathered plans, and the litigating entities about which Plaintiffs complain have all been left out of the contraceptive mandate for all or significant portions of the mandate's duration, because of various exemptions, loopholes, and court injunctions. Yet Plaintiffs present no data showing how many women in those plans, if any, actually used resources from the States' fisc during that time. Plaintiffs' mere speculation about the purported impact of the Final Rules is not reliable when they cannot point to any costs of state subsidized coverage due to women participating in plans not subject to the mandate since 2012.

Other entities challenging the rules have managed to identify individuals actually affected by the Agencies' policy changes. *See, e.g., Irish 4 Reproductive Health v. U.S. Dep't of Health & Human Servs.*, No. 3:18-cv-00491, Compl., ECF No. 1, at ¶¶ 12-16 (N.D. Ind. June 28, 2018) (providing background on named and unnamed individual plaintiffs who assert they "will be personally harmed" by the IFRs). No less should be expected of Plaintiffs here. Accordingly, the Court should deny Plaintiffs' motion for a preliminary injunction for lack of standing.

B. Plaintiffs' Status as Sovereign States Does Not Affect the Standing Analysis.

The Supreme Court has long held that "[a] State does not have standing as *parens patriae* to bring an action against the Federal Government." *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982). And in *Pennsylvania v. Porter*, which this Court did not consider in its opinion granting Pennsylvania's previous request for a preliminary injunction, the Third Circuit concluded that Pennsylvania lacked standing on this basis because "[i]t has been settled since *Massachusetts v. Mellon*, [262 U.S. 447, 486 (1923)], that a state may not attempt as *parens patriae* to enforce rights of its citizens in respect of their relations with the Federal Government." 659 F.2d 306, 317 (3d Cir. 1981) (en banc) (citation omitted). *Porter* did not limit

this conclusion to challenges by states to federal statutes. See *Pennsylvania v. Nat'l Ass'n of Flood Insurers*, 520 F.2d 11, 15 (3d Cir. 1975); see also *Maiden Creek Assocs. v. U.S. Dep't of Transp.*, 823 F.3d 184, 193 (3d Cir. 2016). *Massachusetts v. EPA*, 549 U.S. 497 (2007), is not to the contrary. There, the Supreme Court concluded that Massachusetts had standing to challenge the EPA's decision not to regulate greenhouse-gas emissions. But in finding standing, the Court did not invoke Massachusetts's *parens patriae* interests—i.e., its interests in protecting its citizens' well-being. Rather, the Court relied on Massachusetts's own interests in protecting its sovereign territory. *Id.* at 522; see also *Center for Biological Diversity v. U.S. Dep't of the Interior*, 563 F.3d 466, 476 (D.C. Cir. 2009) (observing that Massachusetts was suing in its individual interest).

This Court previously held that Plaintiffs were entitled to “special solicitude” in assessing standing because “contraceptives offer significant health benefits” to women and the rules will force more women to “seek state-funded sources of contraceptive care,” which “will likely cause the [States] to expend more funds to protect [their] quasi-sovereign interest.” P.I. Opinion, ECF No. 59, at 13. To begin, “special solicitude” would be of no help to Plaintiffs, as it does not alter the requirement to demonstrate a concrete injury. Indeed, in *Massachusetts*, there was no dispute that the State was already being injured—“rising seas ha[d] already begun to swallow Massachusetts' coastal land.” *Massachusetts*, 549 U.S. at 522; see also *Delaware Dep't of Nat. Res. & Envtl. Control v. FERC*, 558 F.3d 575, 579 n.6 (D.C. Cir. 2009) (“This special solicitude does not eliminate the state petitioner's obligation to establish a concrete injury, as Justice Stevens' opinion amply indicates.”). As discussed, Plaintiffs have not demonstrated injury to their fisc or to the well-being of their residents, as they have not even identified a single woman who is likely to lose contraceptive coverage she wants.

In any event, Plaintiffs have not asserted the sort of sovereign interest that warrants special solicitude. In *Massachusetts*, the State asserted an injury akin to the harm that would occur if a contiguous State redrew its boundaries to assert dominion over part of Massachusetts's territory: Massachusetts alleged that rising seas would “lead to the loss of [its] sovereign territory.” 549 U.S. at 523 n.21. Such a loss of territory would mean the loss of Massachusetts's ability to regulate

conduct—either because Massachusetts has no jurisdiction over adjacent water or because that loss of territory would move inland the outer boundaries of Massachusetts’s jurisdiction over adjacent water (e.g., if Massachusetts’s jurisdiction extends a certain distance from the coastline). The special solicitude afforded Massachusetts should not be extended to the type of injury that is asserted here—whether the alleged economic injury asserted directly by Plaintiffs or the alleged injury to the well-being of residents asserted by Plaintiffs in their *parens patriae* capacity. The standing doctrine is built on separation-of-powers principles and “concern about the proper—and properly limited—role of the courts in a democratic society.” *Allen v. Wright*, 468 U.S. 737, 750, 752 (1984). These concerns apply with special force where, as here, the actions of one of the branches of the government are being challenged, *see Raines v. Byrd*, 521 U.S. 811, 819-20 (1997), and thus, in the absence of an overriding sovereign interest—such as the interest a State has in its own territorial boundaries—the Supreme Court’s “standing inquiry has been especially rigorous,” *id.* at 819.

III. VENUE IS NOT PROPER IN THIS DISTRICT.

Plaintiffs asserts that venue is proper in this district because Pennsylvania “resides in this district and because a substantial part of the events giving rise to this action occurred in this district.” Am. Compl. ¶ 31; 28 U.S.C. § 1391(e)(1). Plaintiffs are wrong on both counts.

The Commonwealth resides in the Middle District of Pennsylvania, not here. A non-natural plaintiff (such as a State) is “deemed to reside . . . only in *the* judicial district in which it maintains its principal place of business.” *Id.* § 1391(c)(2) (emphasis added). “[R]eference to ‘the’ and the singular ‘its principal place of business’ compels the conclusion that an entity plaintiff (unlike an entity defendant) can reside in only one district at a time.” Wright & Miller, 14D Federal Practice and Procedure § 3805 (4th ed.). The Commonwealth resides in the Middle District of Pennsylvania because that is “the judicial district” in which its “principal place of business,” Harrisburg—the state capital—is located. Harrisburg is the “permanent seat of government.” *Harrisburg Sch. Dist. v. Hickok*, 762 A.2d 398, 409 (Pa. Commw. Ct. 2000), *as amended* (Nov. 15, 2000) (citing the Act of February 21, 1810, PL 30, § 1). Harrisburg is where the Pennsylvania

legislature sits and where the Governor's primary office and official residence are located. It is also the home to numerous government offices. *Cf. Hertz Corp. v. Friend*, 559 U.S. 77, 92-93 (2010) (defining "principal place of business" for diversity-jurisdiction purposes as the place where "officers direct, control, and coordinate the corporation's activities"). Because Harrisburg must be the State's "principal place of business," the Middle District is "the" judicial district in which the State "resides" for venue purposes.⁸

It is no answer to cite *Alabama v. U.S. Army Corps of Engineers*, 382 F. Supp. 2d 1301 (N.D. Ala. 2005), as Pennsylvania did earlier in the litigation, as that case involved an earlier version of the venue statute that, unlike the current version, provided that a defendant corporation resided "in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced," 28 U.S.C. § 1391(c) (2002). Nor is it persuasive to assert that the venue statute, in the provision entitled "Residency-For all venue purposes," 28 U.S.C. § 1391(c), does not address the residency of states, as the Ninth Circuit recently did. *California v. Azar*, ___ F.3d ___ No. 18-15144, 2018 WL 6566752, at *4 (9th Cir. Dec. 13, 2018). The residency provision divides parties into three categories: (1) natural persons; (2) entities with the capacity to sue and be sued; and (3) foreign defendants. *See* 28 U.S.C. § 1391(c). Pennsylvania plainly is "an entity with the capacity to sue and be sued," *id.* § 1391(c)(2).

What is more, it is not true that "a substantial part of the events giving rise to this action occurred in this judicial district." Compl. ¶ 31. Plaintiffs have filed a facial challenge to two Rules issued by federal agencies headquartered in Washington, D.C. and have not alleged that any specific residents of this district would be affected by the Rules. The only "events or omissions" that "giv[e] rise to the claim occurred" when the Agencies promulgated the Rules at their

⁸ Indeed, the Commonwealth itself has previously taken that position. *E.g., Stanton-Negley Drug Co. v. Pa. Dep't of Pub. Welfare*, No. 07-1309, 2008 WL 1881894, at *4 (W.D. Pa. Apr. 24, 2008). The courts agree. *See, e.g., id.; Gaskin v. Pennsylvania*, No. 94-4048, 1995 WL 154801, at *1 (E.D. Pa. Mar. 30, 1995) (accepting Commonwealth's argument). And for good reason: "It is well settled for venue purposes that the residence of a state agency or state official is the state capitol, even when branch offices of the state agency are maintained in other parts of the state." *Bentley v. Ellam*, Civ. A. No. 85-5418, 1990 WL 63734, at *1 (E.D. Pa. May 8, 1990).

headquarters. That cannot support venue here. *See, e.g., Rogers v. Civil Air Patrol*, 129 F. Supp. 2d 1334, 1339 (M.D. Ala. 2001) (noting events giving rise to facial challenge to federal law occurred where law was enacted); *Seariver Maritime Financial Holdings, Inc. v. Pena*, 952 F. Supp. 455, 462 (S.D. Tex. 1996) (same). Section 1391(e) refers in the past tense to events that have already “occurred,” thereby pointedly excluding venue choices based on events that have not yet happened. *See Reuben H. Donnelly Corp. v. FTC*, 580 F.2d 264, 268 (7th Cir. 1978) (“To base a venue determination on the possibility of some future administrative ruling approaches the question backwards.”). Moreover, courts should focus on the actions of the defendant, not of the plaintiff. *Rogers*, 129 F. Supp. 2d at 1338-39. “[T]he purpose of statutorily specified venue is to protect the defendant against the risk that a plaintiff will select an unfair or inconvenient place of trial.” *See Leroy v. Great W. United Corp.*, 443 U.S. 173, 183-86 (1979). The only events giving rise to this suit occurred in Washington, D.C., not here.

IV. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS.

A. Plaintiffs Are Unlikely to Succeed on Their Claim That the Rules Are Procedurally Deficient under the APA.

Plaintiffs claim that the Agencies’ use of a post-promulgation comment period after issuing the IFRs renders the Final Rules invalid under the APA. *See* PI Mem.at 11. The Agencies maintain that they had independent statutory authority to issue the IFRs, and had good cause to do so as well; post-promulgation comments were therefore proper.⁹ *See* ECF No. 51 at 15-18 (arguing in favor of independent statutory authority to issue the IFRs, and in favor of the Agencies’ determination of good cause). But even assuming the IFRs were procedurally improper, the Final Rules now at issue were issued after receiving and carefully considering public comments (and at

⁹ Although this Court did not rule in favor of the Agencies’ position with respect to their independent statutory authority to issue the IFRs and their assertion of good cause in the previous round of litigation over the IFRs, Defendants urge this Court to reconsider its position. *See Fagan v. City of Vineland*, 22 F.3d 1283, 1290 (3d Cir. 1994) (the law of the case doctrine “does not preclude a trial judge from clarifying or correcting an earlier ambiguous ruling,” nor does it strip a “trial judge [of] the discretion to reconsider an issue,” *Swietlowich v. County of Bucks*, 610 F.2d 1157, 1164 (3d Cir. 1979)).

a time after the IFRs were enjoined). Therefore, the APA's notice and comment requirements were satisfied with respect to the Final Rules.

The Agencies provided the notice and comment period required under APA § 553 with respect to the Final Rules. Section 553 requires that an agency provide notice, an opportunity to be heard, and publication of a final rule no less than 30 days before it is to go into effect. *Id.* Plaintiffs have now had that full and timely notice and ample opportunity for comment, and have participated in that process. *See* PI Mem.at 16 n.17. Indeed, the Agencies received and considered more than 110,000 public comment submissions across both Rules, and detailed their consideration of those submissions in the final rulemaking. *See* 83 Fed. Reg. at 57,540; *see also* 83 Fed. Reg. at 57,596 (addressing moral rule). The Agencies also made numerous changes in response to those comments. *See* 83 Fed. Reg. at 57,556-73; 83 Fed. Reg. at 57,613-26 (highlighting comments, responses, and changes). Although Plaintiffs may disagree with those changes, or with the Rules generally, it is not the place of Plaintiffs, or this Court, to substitute their judgment for that of the Agencies. *See Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Instead courts look to whether the Agencies “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action[,] including a ‘rational connection between the facts found and the choice made.’” *Prometheus Radio Project v. F.C.C.*, 652 F.3d 431, 469 (3d Cir. 2011) (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation omitted)).

Plaintiffs rely heavily on *NRDC v. EPA* to argue that the rules should be enjoined on procedural grounds. 683 F.2d 752 (3d Cir. 1982). But that case does not support the broad conclusions Plaintiffs draw from it. The rule at issue in *NRDC* was a decision to indefinitely postpone the effective date of amendments to certain EPA rules under the Clean Water Act. *Id.* at 754-58. This indefinite postponement had been issued without notice and comment. *Id.* After *NRDC* filed suit, however, EPA subsequently proposed to “further suspend” the effective date of these amendments, and took comment on that question. *Id.* at 757.

As Plaintiffs note, PI Mem.at 12, the *NRDC* court found that the provision of post-promulgation notice and comment procedures did not “cure the failure to provide such procedures prior to the promulgation of *the rule at issue*.” 683 F.2d at 768 (emphasis added). This holding itself evinces the flaw in Plaintiffs’ argument. In the *NRDC* case, the “rule at issue” was the pre-comment indefinite postponement action, not the later “further postponement” finalized after the agency took comment. In this case, however, Plaintiffs challenge the Final Rules, not the IFRs that were enjoined in December 2017. The Agencies here provided notice and comment procedures before promulgating the “rule at issue,” i.e., the Final Rules. *NRDC* thus provides no support for Plaintiffs’ procedural challenge.

Plaintiffs attempt to make hay of the fact that the *NRDC* court also struck down the “further suspension” along with the plaintiffs’ successful challenge to the “initial suspension,” arguing that the court found that the two rules were “fatally infected with the same procedural defect.” *See* PI Mem.at 13. But Plaintiffs have the *NRDC* court’s reasoning backwards. The Court found that the further suspension could not cure the infirmity of the initial suspension, *not* that the further suspension was procedurally defective itself. *See* 683 F.2d at 767-68 (discussing proper remedy). This conclusion is unsurprising. Fashioning a proper remedy for the procedural defects in the initial suspension required an examination of “the position [plaintiffs] would have occupied if the Administrator had afforded them their rights prior to notice and opportunity for comment.” *See id.* (citing *Sharon Steel Corp. v. EPA*, 597 F.2d 377 (3rd Cir. 1979)). Without the initial suspension, which was unlawful, the Clean Water Act amendments would have gone into effect on March 30, 1981. Thus, the question on which the agency took comment—whether to “further” suspend the amendments, taking the initial suspension for granted—posed the incorrect NPRM question. The proper question “would have been whether the [Clean Water Act] amendments, which had been in effect for some time, should be suspended, and not whether they should be further postponed.” *Id.* at 768. It therefore makes sense that the *NRDC* court would have consequently enjoined both rules.

The situation here is different. The question posed to the public for comment here, unlike in *NRDC*, was the exact same question that would have been posed had the IFR been an NPRM. Moreover, the IFRs were enjoined shortly after they went into effect, which remedied any procedural defect from the IFRs and negated any reliance interests that would have built up. Thus, even given this Court’s prior conclusion that the IFRs were procedurally defective, the proper remedy, under *Sharon Steel*, is a remedy that Plaintiffs already have—notice of a proposed rule and an opportunity to comment on that *same* rule. *See* 597 F.2d at 381. Plaintiffs admit they took advantage of that opportunity by submitting a comment in response to the IFRs. *See* PI Mem.at 16 n.17. They, thus, have suffered no procedural injury. On the contrary, the Final Rules amply “present 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 v. Block*, 723 F.2d 175, 188 (1st Cir. 1983) (internal quotation marks omitted) (upholding final rule after voiding interim final rule for lack of notice and comment); *see infra* Part IV.B.1.

For these reasons, Plaintiffs are unlikely to succeed on the merits of their claim that the Final Rules are procedurally invalid.

B. Plaintiffs Are Unlikely to Succeed on Their Substantive APA Claims.

1. The Rationale for the Rules Was Not Arbitrary or Capricious.

Plaintiffs contend that the Final Rules are arbitrary and capricious because they lack an adequate explanation for the Agencies’ “reversal on the importance, efficacy, and benefits of contraception.” PI Mem. at 30. More specifically, they contend that the Agencies’ treatment of the “importance, efficacy, and benefits of contraception” is arbitrary and capricious because (i) it is based “on an apparently newly discovered and poorly defined ‘ambiguity’—rather than a careful, rational evaluation of changes in fact or circumstance,” (ii) “basing a major policy reversal on a fabricated debate is likewise the epitome of arbitrary and capricious rulemaking,” and (iii) “Defendants’ fail[ed] to rebut the specious assertions of certain commentators with basic science[.]” PI Mem. at 33-34. Similarly, Plaintiffs contend that the Agencies’ responses to public comments are inadequate. *See* PI Mem.at 15. They assert that the Rules “fail to seriously address”

scientific and other evidence of the harms to the health and economic security of women, and that the Agencies “utterly fail[ed]” to address comments that the religious and moral exemptions will cause women to lose contraceptive coverage. Once again, these contentions attempt to couch Plaintiffs’ disagreement with the substance of the Agencies’ conclusions in the guise of an APA arbitrariness challenge. These objections are even less appropriate than they would be in other contexts given the deference due to HHS in its evaluation of medical and scientific research.

The Agencies’ decision to expand the religious exemption and to provide a moral exemption was not arbitrary or capricious. Plaintiffs’ argument ignores the actual basis of the decision, demands false certainty in the name of science, and substitutes Plaintiffs’ judgment for that of the Agencies. The Agencies recognized that the decision whether to expand the religious exemption (and to create a moral exemption) required them to “balance the various policy interests at stake,” 83 Fed. Reg. at 57,556, *i.e.*, interests in contraceptive coverage on the one hand, and interests in freedom of religion and conscience on the other. They did just that, and they decided as a matter of policy to enact “rules [that] will provide tangible protections for religious liberty” and conscience, and thereby “impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise.” *Id.*; 83 Fed. Reg. at 57,605. In doing so, the Agencies reached a different balance than they had previously. But neither that fact, nor Plaintiffs’ contrary policy preference—nor anything else—renders the decision arbitrary or capricious.

“The scope of review under the ‘arbitrary and capricious’ standard is narrow,” *State Farm*, 463 U.S. at 43, and while its requirements can change depending on the circumstances, the Agencies – contrary to Plaintiffs’ assertions, PI Mem.at 30 – satisfy the standard as articulated *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009). *Fox* is not overly demanding; it simply requires an agency to provide a “reasoned explanation” for treating differently “facts and circumstances that underlay or were engendered by the prior policy.” *Fox Television Stations, Inc., Id.* at 516. The Agencies did just that: The Final Rules contain voluminous explanations of

the Agencies' previous positions, their current positions, recognition that their position changed, discussions of both sides of the issue from public comments, and extensive reasoning why the Agencies support their final conclusion. The Agencies did not ignore their prior findings or 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. After reviewing the litany of competing comments and scientific studies regarding the efficacy and health benefits of contraceptives, the Agencies concluded that an “examination of the record and review of the public comments has reinforced the Departments' conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals.” *Id.* at 57,555. The Agencies' evaluation of the scientific material, which Plaintiffs may not agree with, is accorded deference because it falls within the ambit of HHS's expertise. *N.J. Envtl. Fed'n v. U.S. Nuclear Regulatory Comm'n*, 645 F.3d 220, 228 (3d Cir. 2011) (highest deference is owed to agency conclusions about scientific matters within its area of expertise). Similarly, the Agencies considered potential reliance interests, concluding, 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.” *Id.* at 57,556.

In short, the Agencies did not ignore or provide arbitrary explanations for their conclusions; they rationally explained their policy decisions based on the available facts related to the efficacy and health effects of contraceptives and any reliance interests engendered by the mandate. In doing so, they 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 – and the religious

and conscientious objections to complying with the mandate more substantial – than the Agencies previously acknowledged. Accordingly, the record before the Agencies justified a different balancing of “the various policy interests at stake,” 83 Fed. Reg. at 57,556.

Plaintiffs’ more specific objections fare no better.

First, Plaintiffs contend that the Agencies based their decision to protect more entities with religious and moral objections “on an apparently newly discovered and poorly defined ‘ambiguity’—rather than a careful, rational evaluation of changes in fact or circumstance.” PI Mem. at 33. But there is nothing poorly defined about the ambiguity that the Agencies identified: they found that the evidence on both the benefits of contraceptives and the mandate is more ambiguous than they had previously thought. *See, e.g.*, 83 Fed. Reg. at 57,555, 57,556. And the notion that “careful, rational evaluation” of evidence cannot lead to the recognition of ambiguity is, of course, false: certainty and correctness are not the same thing.

Second, the Agencies did not base their decision on a “fabricated debate” about the efficacy or benefits of contraception. PI Mem. at 33. Plaintiffs’ (over)confident assertion to the contrary is based on their own view of the health benefits of contraception, which apparently stems from evidence outside the administrative record, *see id.* (citing Kost, Chuang, and Weisman declarations). But under the arbitrary and capricious standard, Plaintiffs do not get to “substitute [their] judgment for that of the agency[.]” *State Farm*, 463 U.S. at 43. And the Agencies’ decision should be evaluated to determine whether the Agencies’ “explanation for [the] decision [] runs counter to the evidence before the agency.” *Id.* The Agencies’ decision is consistent with the record evidence, including the studies cited by the Agencies. 83 Fed. Reg. at 57,552-55 nn.28-50. Indeed, Plaintiffs’ argument seems to be that the decision runs counter to the conclusions of their own declarants, rather than that it runs counter to the evidence in the record. This is improper. As Defendants have previously argued, Mtn. in Limine, ECF No. 48, under the APA, the Agencies’ decision should be reviewed on the basis of the administrative record. While the Court concluded that Pennsylvania could introduce extra-record evidence, ““for background information . . . or for the limited purposes of ascertaining whether the agency considered all the relevant factors or fully

explicated its course of conduct or grounds of decision,” Order, Dec. 13, 2017, ECF No. 56, at 1 n.1 (quoting *Asarco, Inc. v. U.S. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980)), Plaintiffs’ use of the declarations goes beyond that. Plaintiffs rely on the declarations to attempt to demonstrate that the Agencies erred in the exercise of their judgment about the efficacy and health benefits of contraceptives. This is improper, and it fails to state a claim under the APA. As the *Asarco* court explained, “[c]onsideration of the [extra-record] evidence to determine the correctness or wisdom of the agency’s decision is not permitted[.]” 616 F.2d at 1160.

Finally, Plaintiffs’ argument that the Rules are arbitrary and capricious because the Agencies allegedly “fail[ed] to seriously address” harms to health and economic security of women, and allegedly failed to “rebut the specious assertions of certain commentators with basic science,” falls flat. PI Mem. at 15-16; 34. Here again, Plaintiffs seek to substitute their judgment for that of the Agencies, and improperly use extra-record material to challenge the correctness of the Agencies’ decision.

They first contend that the Agencies “thr[e]w up their hands in the face of [] conflicting comments” and arbitrarily decided on their course of action without taking a position on the evidence of the efficacy of the mandate. *See* PI Mem. at 15; *see* 83 Fed. Reg. at 56,555-56. But Plaintiffs conveniently ignore that the Agencies gave a rational reason for declining to take a stand on these general empirical questions: the Agencies concluded, among other reasons, that because the Rules merely withdraw the mandate’s requirement from a small group of newly exempt entities and plans, and because at least one recent study showed that the contraceptive mandate did not change women’s use of certain contraceptives or contraceptives in general, the exemptions are unlikely to have negative effects on the health or equality of women nationwide. *See* 83 Fed. Reg. at 57,555-56. Second, Plaintiffs allege that the Agencies arbitrarily asserted that the Rules relieve, rather than create, a governmental burden, describing the choice as “blithe[.]”. *See* PI Mem. at 16. But again, Plaintiffs overlook the Agencies’ reasoned explanation: the Agencies point out that HHS exercised the discretion granted to HRSA in the statute to include contraceptive coverage in the Guidelines, and the exemptions relieve part of that burden. *See* 83 Fed. Reg. at 57,549. This

explanation is perfectly logical, not arbitrary.

Plaintiffs take the Agencies to task for differentiating, in a discussion of unintended pregnancies, between studies that demonstrate an associative relationship and those that demonstrate a causal relationship. PI Mem. at 34. But there is nothing irrational about that. *See, e.g., Brown v. Entertainment Merchants' Association*, 564 U.S. 786, 800 (2011) (noting the difference between studies that demonstrate causation and those that show correlation). A study that establishes a causal relationship provides stronger evidence for its hypothesis than one that demonstrates only an associative relationship, and this is no less true if the circumstances make conducting a study that would demonstrate a causal relationship infeasible. Next, Plaintiffs assail the Agencies for not rejecting out of hand a study about whether contraceptives may increase the risk of venous thromboembolic disease. PI Mem. at 34. But Plaintiffs are not allowed to substitute their judgment for the Agencies, and they do not suggest that any evidence in the record required the Agencies to ignore this study. Plaintiffs rely on the *Chuang* declaration to support their assertion, but, as noted above, Plaintiffs cannot use extra-record evidence to “determine the correctness or wisdom of the agency’s decision.” *Asarco*, 616 F.2d at 1160. Lastly, Plaintiffs criticize the Agencies for not concluding that contraceptives are a net benefit when it comes to considering the risks of cancer. PI Mem. at 34. Yet again, Plaintiffs substitute their judgment for the Agencies, fail to demonstrate that the Agencies reached an incorrect conclusion on the record before them, and improperly rely on extra-record evidence.

Plaintiffs also assert that estimates of the number of women affected by the Rules are arbitrary and capricious. *See* PI Mem. at 33-37. In making such estimates, agencies can use only the best data sources available, even if inadequate. Here, the Agencies were working with limited information with respect to the estimates, and commenters did not provide any better or more concrete ways to estimate the number of women impacted. *See* 83 Fed. Reg. 57,578. Plaintiffs appear to expect mathematical certainty where the Agencies had to use the limited data available, and expect reliance on their declarations rather than on the administrative record.

Plaintiffs allege that the Agencies have failed to articulate a “rational connection between

the facts found and the choice made,” for two reasons. *See* PI Mem. at 35 (quoting *Prometheus Radio Project*, 652 F.3d at 469). First, they contend that the estimates should have included the impact of the individual exemption on female dependents of plan enrollees, citing their Mendelsohn Declaration. *See id.* at 36. In fact, the Agencies have long made the reasonable assumption that dependents are likely to share the sincere religious or moral beliefs of the policyholder or employer. *See* 78 Fed. Reg. at 39,874 (concluding that exempting churches and integrated auxiliaries without regard to any differing views of dependents, or even of policy holders, “does not undermine the governmental interests furthered by the contraceptive coverage requirement”). Plaintiffs’ disagreement with this assumption does not make it irrational. Second, Plaintiffs contend that the Agencies’ decision to keep the estimate that 209 entities took advantage of the accommodation was irrational in light of the increase in the number of entities with user fee adjustments. *See* PI Mem. at 36. They argue that the estimate is not reasonable because “this means each accommodated entity employs approximately 7,000 employees.” *Id.* To the contrary, what is unreasonable is Plaintiffs’ apparent assumption that there is an even distribution of employees among all accommodated entities. While many entities may be small, the IFRs observe that “[s]ome of those plans [that receive user fee adjustments] cover nearly 100,000 persons each, and several others cover approximately 40,000 persons each,” 82 Fed. Reg. at 47,820, and several of those large plans are likely to remain in the accommodation because they are in a category of religious hospitals that have stated publicly they do not disagree with the accommodation, 83 Fed. Reg. at 57,576-77. A distribution with multiple outliers like this does not render the agency’s estimates unreasonable. Although the estimates are admittedly imperfect, they are the best estimates the Agencies had and no commenters provided better data. And counting all entities that claim user fees adjustments would lead to overinclusion, if you are using that measure to determine how many women would lose coverage because their employers would now opt to be exempt. As noted previously, some entities will likely continue to use the accommodation. *Id.* The APA does not require the exactitude Plaintiffs seek, only the kind of reasonable best estimates described in the Rules.

2. The Rules Are Not Contrary to the Women's Health Amendment.

Plaintiffs' allegations that the Rules violate the Women's Health Amendment, § 300gg-13(a)(4), PI Mem. at 19-22, fail 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). Plaintiffs claim that the Final Rules "suffer from the same defect" as the IFRs with respect to the statute, citing this Court's prior preliminary injunction ruling. But it remains the case that the ACA does not specify the types of preventive services that must be included in such guidelines. Instead, as relevant here, the statute provides only that, "with respect to women," coverage must include "such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA]." 42 U.S.C. § 300gg-13(a)(4). There are numerous reasons that this Court should reject Plaintiffs' argument and reconsider its previous interpretation of the statute, including that, under Plaintiffs' argument, the longstanding exemption from the contraceptive-coverage mandate for churches and their integrated auxiliaries also would be unlawful.

Plaintiffs claim that "[t]here is nothing in the statute" that would allow the Agencies to create exemptions, and that "Defendants cite nothing to the contrary." *See* PI Mem. at 19. This is incorrect: The statute on its face says the women's preventive services mandate will have the scope as provided for and supported by HRSA. *See* 42 U.S.C. § 300gg-13(a)(4). If HRSA provides for and supports a mandate that does not reach the exempted entities (as is the case under the Rules), the statute is satisfied, not infringed. There is more.

First, the Rules make explicit the Agencies' interpretation of the word "as," which this Court's prior ruling misconstrued, Op. at 34, ECF No. 59. *See* 83 Fed. Reg. at 57,540-41; 83 Fed. Reg. at 57,597-98. This Court found that "as" meant "that something happens during the time when something else is taking place." *Id.* (citing *As*, Oxford English Dictionary Online, June 2017). But this is the wrong usage of the word "as" in this context, where the statute uses "as" to mean "in the manner that X happens." *See As* (usage 2), Oxford English Dictionary Online (Feb. 2018) ("[u]sed to indicate by comparison the way something happens or is done"). The "as" in

the statute is not the “as” from the phrase “as the clock struck twelve.” Instead, it is the “as” from “as you like it”—describing an adherence to the manner in which something happens or is done. *See* 83 Fed. Reg. 57,540 n.10. When Congress means to prescribe a temporal requirement, it knows how to do so. *See, e.g.*, 42 U.S.C. § 1395x (“The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment prior to or at the same time as receiving personalized prevention plan services.”). Thus, the inclusion of “as” in Section 300gg-13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has discretion in deciding how the preventive coverage mandate applies.

Moreover, unlike the other paragraphs of the statutory provision, 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. *Compare* 42 U.S.C. § 300gg-13(a)(1), (2), (3), *with id.* § 300gg-13(a)(4). That paragraph thus necessarily delegated the content of the guidelines to HRSA.

Second, nothing in the statute mandates that the guidelines include contraception at all, let alone all types of contraception for all types of employers with covered plans. On the contrary, the statute provides only for coverage of preventive services “as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph.” 42 U.S.C. § 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 mandate in shaping the guidelines. That suggestion is further reinforced by the absence of the words “evidence based” or “evidence-informed” in this subsection, as compared with § 300gg-13(a)(1), (3), which confirms that Congress authorized HRSA to consider factors beyond the scientific evidence in deciding whether to support a coverage mandate for particular preventive services.

Accordingly, § 300gg-13(a)(4) must be understood as a positive grant of authority for HRSA to develop the women's preventive-services guidelines and for the Agencies, as the administering agencies of the applicable statutes, to shape that development. *See* 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and is subject to the agency's general supervision. *See* 47 Fed. Reg. 38,409 (Aug. 31, 1982). The text of § 300gg-13(a)(4), thus, authorized HRSA to adopt guideline for coverage that include exemptions for certain entities (and individuals), and nothing in the ACA prevents HHS (and the other agencies) from supervising HRSA in the development of those guidelines. Indeed, since their first rulemaking on this subject in 2011, the Agencies have consistently interpreted the broad delegation to HRSA in § 300gg-13(a)(4) to include the authority to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the mandate. *See* 76 Fed. Reg. at 46,623. Plaintiffs' interpretation, on the other hand, would sweep away those exemptions as well.

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).

3. The Rules Otherwise Comply with the ACA.

Contrary to Plaintiffs' assertions, PI Mem. at 22-23, the Rules otherwise comply with the ACA's nondiscrimination requirement, 42 U.S.C. § 18116, and the prohibition on unreasonable barriers to healthcare, *id.* § 18114. If these claims had any merit, they would equally affect the longstanding exemption from the mandate for churches and their integrated auxiliaries.

i. The Rules Do Not Discriminate on the Basis of Sex.

The Rules do not discriminate on the basis of sex in violation of § 18116. Instead, the rules distinguish between employers and institutions that have religious or moral objections to (all or certain) contraceptive services, and those that do not. In other words, whether a woman has coverage under the exemptions depends on whether the woman's employer has a sincere religious

or moral objection; it has nothing to do with the fact that she is a woman. Such a distinction recognizes—and protects—the sincerely held views of those who object to facilitating the provision of some or all contraceptive services, while requiring those who have no such objection to pay for those services.

The Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing an exemption for those with religious and conscience objections. But 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 coverage of additional preventive services for women only. Moreover, any distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection by an individual’s employer to facilitating the provision of contraceptives.

No other factor reflects any invidious intent to discriminate on the basis of sex. Nor does the Agencies’ conclusion regarding the lack of a compelling interest in these circumstances demonstrate an intention to discriminate against women: The Rules explain the non-discriminatory reasons for the conclusion (addressing medical evidence in the course of doing so), *see, e.g.*, 83 Fed. Reg. at 57,546-48, and this conclusion is consistent with applicable precedent, *Hobby Lobby*, 134 S. Ct. at 2766, 2780 (noting that the Tenth Circuit held that enforcing the contraceptive mandate against objecting employers did not serve a compelling interest but “find[ing] it unnecessary to adjudicate the issue).

The Religious Exemption Rule accommodates religion by “expand[ing] exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage.” 83 Fed. Reg. at 57,540. And the Moral Exemption Rule is designed to protect sincerely held “moral convictions” by exempting those with such convictions from facilitating the provision of contraceptive services. 83 Fed. Reg. at 57,596. Indeed, Plaintiffs agree that it is legitimate to

protect non-religious moral beliefs. *See* N.J. Stat. Ann. §2A:65A1, 2 (no person or hospital facility shall be required to provide abortion services); 18 Pa. Stat. and Cons. Stat. Ann. § 3213 (conscience clause permitting medical professionals and facilities to opt out of providing abortions).

Nor do Plaintiffs cite any legal or other authority suggesting that narrowing requirements for contraceptive coverage constitutes sex discrimination.

ii. The Rules Do Not Create an Unreasonable Barrier to Medical Care.

The Rules also do not create an unreasonable barrier to medical care in violation of § 18114. They merely narrow the scope of the mandate rather than impose 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].”). Worse, under Plaintiffs’ interpretation, § 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. In addition, Plaintiffs do not even argue that the purported barrier is unreasonable—a difficult showing given the numerous other programs providing contraception, *see* 83 Fed. Reg. at 57,548, and the continued availability of the accommodation. Finally, the need to add the Women’s Health Amendment to the ACA after both § 18116 and § 18114 were included demonstrates that neither provided an alternative mandate for coverage of additional preventive services or contraceptives. *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) (statement of Sen. Mikulski) (adding the Women’s Health Amendment).

4. The Religious Exemption Rule Is a Permissible Response to the Substantial Burden on Religious Exercise Imposed by the Mandate.

Plaintiffs also argue that RFRA does not support the Religious Exemption Rule. PI Mem. at 23-29. But even if the ACA did not permit the Agencies to establish religious exemptions to the mandate, RFRA *authorized* the Agencies to adopt the Religious Exemption Rule.

“Under RFRA, the Federal Government may not, as a statutory matter, substantially burden a person’s exercise of religion, even if the burden results from a rule of general applicability.” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2006). But a law that imposes a substantial burden on the exercise of religion is allowed under RFRA if the government “demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. § 2000bb–1(b).

“[T]he exercise of religion involves not only belief and profession but the performance of (or abstention from) physical acts that are engaged in for religious reasons.” *Hobby Lobby*, 134 S. Ct. at 2770.

“[A] substantial burden exists where (1) a follower is forced to choose between following the precepts of his religion and forfeiting benefits otherwise generally available . . . versus abandoning one of the precepts of his religion in order to receive a benefit; or (2) the government puts substantial pressure on an adherent to substantially modify his behavior and to violate his beliefs.”

Mack v. Warden Loretto, 839 F.3d 286, 304 (3d Cir. 2016) (citation omitted).

The Supreme Court held in *Hobby Lobby* that the mandate imposes a substantial burden on objecting employers absent some form of exemption or accommodation. 134 S. Ct. at 2775. And 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 the accommodation would have satisfied the objecting employers’ religious concerns in that case. *See id.* at 2780-83. But 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 alleviate the substantial burden imposed by the mandate. *See id.* at 2782. Thus, after “further consideration” and “review of the public comments . . . [t]he Departments [] determined that, in light of RFRA, an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*,” 83 Fed. Reg. at 57,544-45.

Previously, the Agencies “attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA’s requirements for imposing that burden.” 82 Fed. Reg. at 47,806. But those attempts were unsuccessful and instead led to half a decade of RFRA litigation and serial regulatory amendments, *id.* at 47,814, imposing significant costs on the Agencies, the courts, regulated entities, and plan participants, who were left uncertain about their rights and obligations. Nothing in RFRA compelled the Agencies’ novel (but ultimately unsuccessful) efforts at accommodation. Similarly, nothing in RFRA prohibits the Agencies from now 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 were required to invent the accommodation instead. Neither RFRA nor the ACA compels a different result here based merely on path dependence.

This independent ground provides a fully sufficient basis for upholding the Religious Exemption Rule. Under *Hobby Lobby*, RFRA required the Agencies to take *some* action to respond to the substantial burden imposed by the unmodified mandate. 134 S. Ct. at 2775. “[N]either RFRA nor the ACA prescribes the remedy by which the government must eliminate that burden, where any means of doing so will require departing from the ACA to some extent,” and, as the Agencies concluded, the choice “to adopt an exemption in addition to the accommodation is particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA.” 83 Fed. Reg. at 57,545. And allowing agencies to choose to respond to a substantial burden on religious exercise with an exemption rather than an accommodation is particularly appropriate here, where the Agencies have already attempted an accommodation and that accommodation has been the subject of widespread legal challenges that have divided the courts and that (at an absolute minimum) raise serious questions about its validity.

The contrary approach would place agencies in an impossible position. Agencies are often presented with claims that their requirements substantially burden the exercise of religion. If agencies were legally prohibited from offering an exemption unless they conclude that no other

possible accommodation would be consistent with RFRA, the result would be protracted and unnecessary litigation. In analogous contexts, the Supreme Court has recognized that an entity faced with potentially conflicting legal obligations should be afforded leeway. For example, under Title VII, an employer may “engage in intentional discrimination for the asserted purpose of avoiding or remedying an unintentional disparate impact” if the employer has “a strong basis in evidence to believe it will be subject to disparate-impact liability if it fails to take the race-conscious, discriminatory action.” *Ricci v. DeStefano*, 557 U.S. 557, 585 (2009). Critically, the Court did not require the employer to prove that it *actually would* “be subject to disparate-impact liability.” The Court explained that the more flexible standard it adopted “appropriately constrains employers’ discretion in making race-based decisions” but was not “so restrictive that it allows employers to act only when there is a provable, actual violation”—a standard that would have left employers in an untenable position. *Id.* at 583. So too here.

Plaintiffs argue that the “strong-basis-in-evidence” standard has not been met here, PI Mem. at 28 n.27, but many commenters have informed the Agencies that the mandate with the accommodation is incompatible with their religious beliefs, 83 Fed. Reg. at 57,546, and circuit courts are split on whether the mandate with the accommodation substantially burdens the religious exercise of objecting employers. *Compare Priests for Life*, 772 F.3d at 229 (accommodation does not substantially burden religious exercise), *with Sharpe Holdings*, 801 F.3d at 927 (accommodation violates RFRA). Plaintiffs also argue that leeway should be granted only when the government is put to a binary choice, PI Mem. at 28 n.27, but here the Agencies do face a binary choice of either compelling entities to violate their strongly held religious beliefs by cooperating in the provision of contraception or not. The Agencies have already tried to find a third path forward that would satisfy all, and failed. *See* FAQs at 4 (explaining that the Agencies could not find a way to amend the accommodation to both account for employers’ religious obligations and provide coverage to their employees).¹⁰

¹⁰ To be sure, if providing an exemption for an objecting religious employer would prevent the contraceptive-coverage mandate from achieving a compelling governmental interest

5. RFRA Requires the Religious Exemption Rule.

In any case, the Religious Exemption Rule is required by RFRA: the mandate as applied to those who object on sincere religious grounds to providing or arranging for contraceptive coverage imposes a substantial burden on religion, and it is not justified by a compelling government interest.

The Religious Exemption Rule reasonably concludes that the mandate, even as modified by the accommodation, imposes a substantial burden on the exercise of religion. Contrary to Plaintiffs' suggestion that they "provide no rationale," PI Mem. at 23, the Agencies fully explained their conclusion. 83 Fed. Reg. at 57,546. In *Hobby Lobby*, the Supreme Court held that forcing an entity with a religious objection to choose between abiding by the mandate or paying potentially stiff financial penalties constitutes a substantial burden on religion. 134 S. Ct. at 2779. Although the Supreme Court has not held that the accommodation—which requires provision of an opt-out notice to the health insurance issuer, third party administrator (TPA), or HHS to avoid the same potentially onerous fines, 80 Fed. Reg. at 41,318, and which provides coverage through the plan of an objecting employer—likewise imposes a substantial burden on the exercise of religion, the Agencies have reasonably concluded that it does. The accommodation requires some religious objectors to "act in a manner that they sincerely believe would make them complicit in a grave moral wrong as the price of avoiding a ruinous financial penalty." *Sharpe Holdings*, 801 F.3d at 941. It is not the role of the government "to say that their religious beliefs are mistaken or insubstantial." *Hobby Lobby*, 134 S. Ct. at 2779. The Agencies have thus reasonably concluded that "requiring certain religiously objecting entities or individuals to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA." 83 Fed. Reg. at 57,546.

The compelling interest element "requires the Government to demonstrate that the

as to that employer, then RFRA would not authorize that exemption. *See Hobby Lobby*, 134 S. Ct. at 2779-80. But, as explained below, the Agencies expressly found that application of the mandate to objecting entities neither serves a compelling governmental interest nor is narrowly tailored to any such interest.

compelling interest test is satisfied through application of the challenged law ‘to the person’—the particular claimant whose sincere exercise of religion is being substantially burdened.” *Hobby Lobby*, 134 S. Ct. at 2779 (internal citations omitted). Here, the Government does not assert any compelling interest in requiring objecting employers to provide the contraceptives at issue.¹¹ That, in itself, is dispositive: the Government is not aware of any case in which any court has found a government policy to advance a compelling interest where the Government itself does not claim a compelling interest. And, in any event, even where the Government does assert a compelling interest, courts “loo[k] beyond broadly formulated interests” and “scrutiniz[e] the asserted harm of granting specific exemptions to particular religious claimants.” *Id.* The existence of numerous exceptions to a law can undercut the conclusion that it furthers a compelling interest. See, e.g., *Williams-Yulee v. Fla. Bar*, 135 S. Ct. 1656, 1668 (2015); *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 1143-33 (10th Cir. 2013); *Legatus v. Sebelius*, 988 F. Supp. 2d 794, 810 (E.D. Mich. 2013) (“But in this context, given the multiple tens of millions of Americans that are simply exempt from the HRSA mandate, the court is dubious that the Government would be able to prove a *compelling* interest.”).

The Religious Exemption Rule reasonably concludes that there is no compelling interest in imposing the contraceptive-coverage mandate on the small percentage of employers with sincere religious objections to it. 83 Fed. Reg. at 57,546-48.

First, Congress has a history of flexibility concerning contraceptive coverage and has never required private employers to offer contraceptive coverage. *Id.* Contraceptive services are absent from 42 U.S.C. § 300gg-13(a)(4), and from any part of the ACA’s provisions defining required benefits. That Congress left open the possibility that contraceptive services would not be covered at all undermines any argument that the government has a compelling interest to require a small subset of employers to provide such coverage over their sincere religious objections. And the fact

¹¹ Contrary to Plaintiffs’ argument, PI Mem. at 25, *Hobby Lobby* assumed without deciding that the mandate served a compelling interest, and such assumptions do not bind future courts. *Hobby Lobby*, 134 S. Ct. at 2759, 2780; *id.* at 2785 (Kennedy, J., concurring).

that Congress left it up to HHS (acting through HRSA) to decide whether contraceptive services should be covered *at all* indicates that HHS's judgment about whether the inclusion of those services meets the extremely high compelling-interest standard warrants particular deference.

Second, the underinclusiveness of the mandate undermines any claim of a compelling interest. 83 Fed. Reg. at 57,547. The ACA did not extend the mandate to employees covered by grandfathered plans, though it did require grandfathered plans to comply with other health reform provisions that provide what HHS has described as "particularly significant protections." 75 Fed. Reg. at 34,540. And, the Agencies have already exempted from the mandate churches and their integrated auxiliaries. 78 Fed. Reg. 34,538, 39,873-74 (June 17, 2010). Moreover, objecting entities that participated in self-insured church plans were effectively exempt because the government lacks the authority to require the TPA of a self-insured church plan provide contraceptive services through the accommodation. *Roman Catholic Archbishop of Wash. v. Sebelius*, 19 F. Supp. 3d 48, 82-83 (D.D.C. 2013), *aff'd in part, vacated in part sub nom. Priests for Life*, 772 F.3d 229, *vacated and remanded sub nom. Zubik*, 136 S. Ct. at 1557. These already significant exemptions were broadened when the Supreme Court recently held that a self-insured church plan can include a plan that is not established or maintained by a church (or by a convention or association of churches), but is maintained by "an organization . . . the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches." *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1656-57 (2017). A requirement might serve a compelling interest even if it is subject to exemptions. But this more limited application of the mandate, as compared to other "reform provisions, suggests that the need for cost-free contraceptive coverage is not a compelling interest when weighed against specific concerns, such as those of the small subset of employers with religious objections. *See Hobby Lobby*, 134 S. Ct. at 2780; *Legatus*, 988 F. Supp. 2d at 810; *see also Williams-Yulee*, 135 S. Ct. at 1668.

Third, the Agencies have now determined, in their expert judgment, that the administrative record in support of the mandate does not contain adequate evidence to meet the high standard of demonstrating a compelling interest having objecting employers provide cost-free contraceptive coverage. The Agencies explained that the evidence regarding the effect of the mandate on women’s health is significantly more “uncertain[] and ambigu[ous] . . . than the Departments previously acknowledged.” 83 Fed. Reg. at 57,555; *see also* 83 Fed. Reg. at 57,547, 57,552-55. For example, a recent study by the Guttmacher Institute to determine whether the mandate changed contraceptive use patterns concluded that “[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,” and “there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012-2014) excepting small increases in implant use.” 83 Fed. Reg. at 57,548 (quoting M.L. Kavanaugh et al., *Contraceptive methods use in the United States: trends and characteristics between 2008, 2012 and 2014*, 97 *Contraception* 14, 14-21 (2018) (available at [https://www.contraceptionjournal.org/article/S0010-7824\(17\)30478-X/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/fulltext))). The Agencies did not take the view that contraceptive coverage has no benefits at all, but simply that the evidence of its benefits is not strong enough, given the scope of the exemption, to meet the compelling interest standard’s high evidentiary bar. The Agencies’ view of this medical evidence is accorded deference because it falls within the ambit of HHS’s expertise. *N.J. Env’tl. Fed’n*, 645 F.3d at 228 (highest deference is owed to agency conclusions about scientific matters within their area of expertise).

Fourth, contraceptives are available from other sources, including through Title X funding, Medicaid, and other programs. 83 Fed. Reg. at 57,548.

There is no compelling interest, then, in applying the mandate to those employers that will qualify for the expanded religious exemption.¹²

¹² And, contrary to Plaintiffs’ argument, PI Mem. at 29, even if there is a compelling interest, there are not other equally “least restrictive” means that better advance that interest. After reviewing

Plaintiffs argue that the Agencies “fail to adequately explain . . . how RFRA gives them broad discretion to protect sincerely held religious beliefs by categorically denying women access to” contraceptives. PI Mem. at 28. Contrary to Plaintiffs’ implication, RFRA *requires* that the Agencies avoid substantially burdening religious exercise, subject to certain constrained exceptions. And, in meeting this obligation, the Agencies have not “categorically den[ied]” anyone access to anything, just as the original exemption did not “deny” contraception to individuals employed by churches or their integrated auxiliaries; the Agencies have simply narrowed the group of entities required to facilitate the provision of contraceptive coverage. Neither RFRA nor any other statute requires the Agencies to affirmatively provide the benefit of cost-free contraceptive coverage to all individuals. *Cf.* 83 Fed. Reg. at 57,549. And, contrary to Plaintiffs’ assertion that there is “no evidence that [the Agencies] even tried” to both provide greater access to contraceptives for women and not burden the sincere religious beliefs of objecting entities, PI Mem. at 28, the Agencies did try after *Zubik* was remanded, but were unable to arrive at a solution that would satisfy all. FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).

Plaintiffs cite *Geneva*, but that case has, of course, been vacated by the Supreme Court, *Zubik*, 136 S. Ct. at 1560, and as the Third Circuit has recognized, is no longer controlling. In any event, it was wrongly decided because the *Geneva* panel erred in substituting its own view of the plaintiffs’ religious doctrine to conclude that the act of notifying the insurance issuers of the objection would not violate the plaintiffs’ religious beliefs. *See Geneva*, 778 F.3d 422, 435-42 (3d Cir. 2016). It is not the role of the government “to say that [the plaintiffs’] religious beliefs are mistaken or insubstantial.” *Hobby Lobby*, 134 S. Ct. at 2779. And, contrary to Plaintiffs’ suggestion that the Third Circuit “reaffirmed” that the accommodation does not impose a substantial burden in *Real Alternatives, Inc. v. Secretary*, 867 F.3d 338 (3d Cir. 2017), PI Mem. 25-26, that is *dicta* because *Real Alternatives*

over 54,000 public comments on the June 22, 2016 request for information and considering various options, the Agencies could not find a way to amend the accommodation so as to both account for employers’ religious objections and provide contraceptive coverage to their employees. *See* FAQs.

required the panel to decide only whether the accommodation substantially burdened *employees*—not objecting employers or schools. *See id.* at 355 & n.17 (noting that the relevant question “is distinct from an *employer’s* RFRA claim objecting to the mandated provision of contraceptive services that was found to be meritorious in [*Hobby Lobby*]”).

V. PLAINTIFFS HAVE NOT SHOWN THAT PRELIMINARY RELIEF IS NEEDED TO PREVENT IRREPARABLE HARM.

Even if Plaintiffs could show they were likely to succeed on the merits, they are not entitled to injunctive relief because they have not shown a likelihood of irreparable harm. To secure an injunction, “[t]he irreparable harm alleged must be actual and imminent, not merely speculative.” *Macchione v. Coordinator Adm’r in Wash., D.C.*, 591 F. App’x 48, 49 (3d Cir. 2014). When economic harm unrecoverable due to sovereign immunity is at issue, the showing of loss must be both concrete and “sufficiently severe to warrant emergency relief.” *Save Jobs USA v. Dep’t of Homeland Sec.*, 105 F. Supp. 3d 108, 115 (D.D.C. 2015); *see also In re N. Am. Refractories Co.*, 542 B.R. 350, 358 (Bankr. W.D. Pa. 2015) (explaining that “[t]he key inquiry” in determining whether unrecoverable economic injury will support entry of a preliminary injunction “is whether the . . . injury is of such nature or magnitude that it will cause serious or special harm to the plaintiff, for example by threatening the plaintiff’s solvency or requiring it to undergo substantial changes in its operations”).¹³ Plaintiffs assert that they will suffer irreparable harm if the Rules go into effect because (1) women in Pennsylvania and New Jersey will lose contraceptive coverage;¹⁴

¹³ *N.J. Retail Merchants Ass’n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012), is not to the contrary; the plaintiffs there were ordered to pay money directly to the state that they could not later recover. Plaintiffs’ claims of economic losses are far more conjectural.

¹⁴ Plaintiffs rely on lawsuits filed in Pennsylvania five years ago by employers impacted by the contraceptive-coverage mandate as a means of arguing that many entities will exercise the exemptions. *See* PI Mem. at 40; Ex. E at 41-42, Ex. W. But these examples crumble under close scrutiny. Most of the lawsuits filed in Pennsylvania (including *Zubik*, *Brandt*, *Catholic Charities of Philadelphia*, *Trauman*, and *Persico*) were not even included in HHS’s estimates of impacted individuals because the “Government argued [in *Brandt*] that these and all similar Catholic diocese-sponsored self-insured plans and entities . . . likely qualify to be church plans exempt from ERISA” and thus need not rely on the exemption. Ex. V at 2 (discussing *Brandt*); *id.* at 6, 8 (noting similar treatment for *Zubik* and *Persico*). Still others were dismissed because employers were satisfied with the accommodation, *id.* at 8 (*Valley Forge College*), or found to have no impact

(2) those women will be forced to rely on state-funded programs, imposing costs on the states; and
(3) Pennsylvania and New Jersey will suffer harm to their quasi-sovereign interests if the Rules go into effect. But because Plaintiffs fail to establish standing on these grounds for the reasons discussed earlier, they necessarily fail to satisfy the more demanding irreparable harm standard.

VI. THE BALANCE OF EQUITIES AND PUBLIC INTEREST MAKE INJUNCTIVE RELIEF INAPPROPRIATE.

The balance of hardships and the public interest weigh against issuing an injunction here. Where the federal government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Plaintiffs have not demonstrated that any harm to them outweighs the public interest. Plaintiffs assert that they are all but automatically entitled to a preliminary injunction because they believe they have an irreparable harm and a likelihood of success on the merits. *See* PI. Mem. at 45. For numerous reasons already discussed, this position is wrong. Plaintiffs' speculative allegations of injury are not sufficient to establish standing, *see supra* Part II, let alone the kind of likely, imminent, and irreparable harm necessary to support a preliminary injunction. *See Winter v. NRDC*, 555 U.S. 7, 22 (2008). The government, on the other hand, suffers irreparable institutional injury whenever its laws and regulations are set aside by a court. *See Maryland v. King*, 133 S. Ct. 1, 3 (2012) (Roberts, C.J., in chambers). Moreover, the government and the public at large have a substantial interest in protecting religious liberty and conscience. *See Kikumura v. Hurley*, 242 F.3d 950, 963 (10th Cir. 2001) (allegation of RFRA violation satisfies irreparable-harm requirement); *Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996) (same). The Supreme Court confirmed the relevance and weight of such conscience injuries when on four occasions it took the extraordinary step of issuing interim injunctions to ensure that objecting organizations would not be required to violate their sincere religious beliefs while they challenged the accommodation,

because all of the affected employees shared their employer's objections, *id.* at 7 (*Real Alternatives*). Finally, cases brought by Geneva College and the Little Sisters of the Poor have resulted in permanent injunctions that excuse those entities from compliance with the regulations, regardless of whether the Rules provide an exemption. *Geneva College*, ECF No. 153; *Little Sisters of the Poor Home for the Aged v. Azar*, No. 1:13-cv-02611, Order Reopening Case and Granting Permanent Injunction, ECF No. 82 (D. Colo. May 29, 2018).

despite expressing no view on whether the accommodation actually violated RFRA. *See Zubik v. Burwell*, 135 S. Ct. 2924 (2015); *Wheaton Coll. v. Burwell*, 134 S. Ct. 2806, 2807 (2014); *Little Sisters of the Poor Home for the Aged v. Sebelius*, 134 S. Ct. 1022 (2014); *see also Zubik*, 136 S. Ct. at 1560-61. The institutional and conscience injuries set forth above outweigh the State’s speculative injuries.

VII. EVEN IF PLAINTIFFS PREVAIL, A LIMITED INJUNCTION IS THE APPROPRIATE REMEDY.

If the Court rules in Plaintiffs’ favor, any injunction should be no broader than necessary to provide Plaintiffs complete relief, and should therefore enjoin only the application of the Final Rules in Pennsylvania and New Jersey.¹⁵

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). The Supreme Court recently applied this principle to hold that a set of voters had not demonstrated standing to challenge alleged statewide partisan gerrymandering beyond the legislative districts in which they resided, reasoning that a “plaintiff’s remedy must be limited to the inadequacy that produced his injury in fact” and that “the Court’s constitutionally prescribed role is to vindicate the individual rights of the people appearing before it.” *Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018) (internal quotation omitted). The Third Circuit similarly has recognized that a plaintiff lacks “standing to seek an injunction” beyond what is necessary to “provide [it] full relief.” *Ameron, Inc. v. U.S. Army Corps of Eng’rs*, 787 F.2d 875, 888 (3d Cir. 1986).

Equitable principles likewise require that “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs” before the court. *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979); *see also Meyer v. CUNA Mut. Ins. Soc’y*, 648

¹⁵ For that reason, no injunction should run against the portion of the Rules that permits issuers and plan sponsors to offer plans to individuals that account for sincerely held objections the individual may have; Plaintiffs do not demonstrate any harm from that aspect of the Rules. Any injunction also should not interfere with the Agencies’ ability to resolve other existing litigation challenging the prior accommodation rules. *See Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 585 (E.D. Pa. 2017).

F.3d 154, 170-71 (3d Cir. 2011). The equitable jurisdiction of federal courts is grounded in historical practice, *see Grupo Mexicano de Desarrollo, S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 318 (1999), yet nationwide injunctions are a modern invention, *see* Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev. 417, 428-37 (2017).

Moreover, nationwide injunctions “take a toll on the federal court system—preventing legal questions from percolating through the federal courts, encouraging forum shopping, and making every case a national emergency for the courts and for the Executive Branch.” *Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring). That concern has already materialized in the context of challenges to the IFRs. *See* Order, *Washington v. Trump*, No. 2:17-cv-1510 (W.D. Wash. Jan. 19, 2018), ECF No. 52m (staying litigation in light of nationwide injunction in this case).

Nationwide injunctions also create an inequitable “one-way-ratchet” under which any prevailing party obtains relief on behalf of all others, but a victory by the government would not preclude other potential plaintiffs from “run[ning] off to the 93 other districts for more bites at the apple.” *City of Chicago v. Sessions*, 888 F.3d 272, 298 (7th Cir. 2018) (Manion, J., concurring in the judgment in part and dissenting in part), *reh’g en banc granted*, Order of June 4, 2018 (vacating panel judgment “insofar as it sustained the district court’s decision to extend preliminary relief nationwide”), *reh’g en banc vacated as moot*, Order of Aug. 10, 2018; *cf. United States v. Mendoza*, 464 U.S. 154, 158-62 (1984) (holding that nonparties to an adverse decision against the federal government may not invoke the decision to preclude the government from continuing to defend the issue in subsequent litigation). Indeed, the Third Circuit has repeatedly held that nonparty injunctions should not be used as an end-run around the class-action procedure. *Ameron*, 787 F.2d at 888; *Meyer*, 648 F.3d at 170.

That concern is fully actualized here, given another district court’s rejection—on Article III standing grounds—of Massachusetts’s challenge to the IFRs. *See Massachusetts v. HHS*, 301 F. Supp. 3d 248 (D. Mass. 2018), *appeal docketed*, No. 18-1514 (1st Cir. June 6, 2018). Issuing a nationwide injunction would effectively grant Massachusetts the relief that the district court in

Massachusetts refused to provide.

That the Plaintiffs raise claims under the APA does not justify a different conclusion. The APA expressly provides that “to the extent necessary to prevent irreparable injury,” a court “may issue all necessary and appropriate process . . . to preserve status or rights pending conclusion of the review proceedings.” 5 U.S.C. § 705. In allowing preliminary injunctions only “to the extent necessary to prevent irreparable injury,” *id.*, the APA codifies the principle that preliminary injunctions are designed to remedy the specific harms allegedly suffered by plaintiffs themselves.

For these reasons, the Ninth Circuit recently held that a district court abused its discretion in enjoining the IFRs nationwide, because “an injunction that applies only to the plaintiff states would provide complete relief to [plaintiffs].” *California v. Azar*, 2018 WL 6566752, at *15-17. The Ninth Circuit noted that “such broad relief must be *necessary* to give prevailing parties the relief to which they are entitled” and that “[t]he Supreme Court has repeatedly emphasized that nationwide injunctions have detrimental consequences to the development of law and deprive appellate courts of a wider range of perspectives.” *Id.* at *15 (internal quotation marks and citations omitted).

CONCLUSION

Accordingly, the Court should deny Plaintiffs’ motion for a preliminary injunction.

DATED: January 3, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on January 3, 2019, a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

DATED this 3rd day of January, 2019.

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG