

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

COMMONWEALTH OF
PENNSYLVANIA AND STATE OF NEW
JERSEY,

CIVIL ACTION

Plaintiffs,

NO. 17-4540

v.

DONALD J. TRUMP, ALEX M. AZAR II,
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
STEVEN T. MNUCHIN, UNITED
STATES DEPARTMENT OF THE
TREASURY, RENE ALEXANDER
ACOSTA, THE UNITED STATES
DEPARTMENT OF LABOR, AND THE
UNITED STATES OF AMERICA,

Defendants,

LITTLE SISTERS OF THE POOR
SAINTS PETER AND PAUL HOME,

Defendant-Intervenor.

OPINION

Table of Contents

I.	Background.....	3
A.	Contraceptive Mandate.....	3
B.	Regulatory Action to Accommodate Religious Objections.....	4
C.	<i>Hobby Lobby & Wheaton College</i>	6
D.	Regulatory Response to <i>Hobby Lobby & Wheaton College</i>	7
E.	<i>Zubik</i> Remand & Impasse.....	8
F.	2017 IFRs & First Preliminary Injunction.....	9
G.	2018 Final Rules & Second Motion for Preliminary Injunction.....	12
II.	Analysis.....	13
A.	Standing.....	13
1.	Special Solitude.....	15

2. Article III Standing 18

B. Venue 20

C. Preliminary Injunction 23

1. Legal Standard 23

2. Likelihood of Success on the Merits..... 24

 a. APA Procedural Claim 24

 i. Inadequate Response to Comments 25

 ii. IFRs Taint the Final Rules 27

 b. APA Substantive Claim 34

 i. The ACA..... 35

 ii. RFRA 42

3. Irreparable Harm 52

4. Balance of the Equities 55

5. Public Interest 56

D. Remedy 57

Plaintiffs, the Commonwealth of Pennsylvania and the State of New Jersey (collectively “the States”), have sued the United States of America, President Donald J. Trump, the United States Secretary of Health and Human Services Alex M. Azar II, the United States Secretary of the Treasury Steven T. Mnuchin, and the United States Secretary of Labor Rene Alexander Acosta in their official capacities, as well as each of their agencies (collectively “Defendants”), seeking to enjoin enforcement of two Final Rules that grant exemptions to the Affordable Care Act’s requirement that health plans cover women’s preventive services. The Final Rules “finalize” two Interim Final Rules, which Defendants issued in October 2017 and which this Court enjoined soon thereafter, *see Pennsylvania v. Trump*, 281 F. Supp.3d 553, 585 (E.D. Pa. 2017). On November 15, 2018, while their appeal of that preliminary injunction was pending, Defendants promulgated the Final Rules currently before the Court. The States move to enjoin enforcement of the Final Rules arguing that, like the IFRs before them, the Final Rules violate a variety of constitutional and statutory provisions. For the reasons set forth below, Plaintiffs’

Second Motion for a Preliminary Injunction shall be granted.

I. Background¹

Although the relevant factual and procedural history of this dispute has been laid out at length before, *see id.* at 560-64, that background information is recounted here for the sake of clarity.

A. Contraceptive Mandate

In March 2010, Congress enacted the Affordable Care Act. *See* Patient Protection and Affordable Care Act (“ACA”), Pub L. No. 111-148, 124 Stat. 119 (2010). A provision of the ACA, the Women’s Health Amendment, mandated that insurance providers cover preventive health services and screenings for women without cost-sharing responsibilities. Specifically, the Women’s Health Amendment requires that “[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [“HRSA”] for purpose of this paragraph.” 42 U.S.C. § 300gg-13(a)(4). This requirement applies to all health insurers offering individual or group insurance, as well as all group health plans, with an exception for certain “grandfathered” plans. 42 U.S.C. § 18011 (exempting “grandfathered” plans); *see also* 29 C.F.R. § 2590.715-1251 (2010).

Rather than enumerate the preventive services to be covered by the mandate, Congress delegated that decision to HRSA, which is an agency of Defendant Department of Health and Human Services (“HHS”). HRSA, in turn, commissioned the then-named Institute of Medicine

¹ The factual statements found here and elsewhere in the opinion constitute this Court’s findings of fact, as required under Rule 52(a) of the Federal Rules of Civil Procedure, regardless of any heading or lack thereof.

(“the Institute”), to convene a panel of experts to provide recommendations.² On July 19, 2011, the Institute issued its report, recommending that the ACA cover “the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.” Institute of Medicine, *Clinical Prevention Services for Women: Closing the Gaps*, at 109-10 (2011).

On August 1, 2011, HRSA issued its preventive care guidelines (“2011 Guidelines”), which adopted the Institute’s recommendations. See HRSA, *Women’s Preventive Services Guidelines*, available at <https://www.hrsa.gov/womens-guidelines/index.html>.³ The 2011 Guidelines hewed to the Institute’s report, defining preventive care to include all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling.” *Id.* Under the Women’s Health Amendment, “non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing.” *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). Thus these interlocking statutory and regulatory requirements created the so-called “Contraceptive Mandate.”

B. Regulatory Action to Accommodate Religious Objections

At the same time, and based on “considerable feedback,” HHS, the Department of Labor, and the Department of the Treasury (collectively “the Agencies”) found it was “appropriate that HRSA, in issuing [the 2011] Guidelines, take[] into account the effect on the religious beliefs of

² The Institute, renamed the National Academy of Medicine in 2015, is an arm of the National Academy of Sciences, an organization that Congress established for the explicit purpose of furnishing advice to the federal government. See *Pub. Citizen v. Dep’t of Justice*, 491 U.S. 440, 460 n.11 (1989).

³ The Guidelines were updated in 2016 but continue to define “preventive services” to include contraceptive services and counseling. See *Updating the HRSA-Supported Women’s Preventive Services Guidelines*, 81 Fed. Reg. 95,148, 95,149 (Dec. 27, 2016).

certain religious employers if coverage of contraceptive services were required.” *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011). The Agencies therefore provided HRSA with “additional discretion to exempt certain religious employers from the Guidelines where contraceptive services are concerned.” *Id.*

On August 1, 2011, the Agencies promulgated an interim final rule exempting certain religious employers from providing contraceptive services. *Id.* Under the exemption, a “religious employer” could be exempt from the Contraceptive Mandate only if it: (1) had the inculcation of religious values as its purpose; (2) primarily employed people who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a church, its integrated auxiliary, or a convention or association of a church exempt from taxation under the Internal Revenue Code. *Id.* On February 15, 2012, after considering more than 200,000 responses to this interim final rule, the Agencies issued a final rule adopting the “religious employer” definition. 77 Fed. Reg. at 8,725.

On March 21, 2012, the Agencies issued a notice of proposed rulemaking requesting comments on “alternative ways of providing contraceptive coverage without cost sharing in order to accommodate non-exempt, non-profit religious organizations with religious objections to such coverage.” *Certain Preventive Services Under the Affordable Care Act*, 77 Fed. Reg. 16,501, 16,503 (March 21, 2012). After receiving and considering over 400,000 comments, the Agencies issued their final rule on July 2, 2013. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 39,870, 39,871 (July 2, 2013). The final rule had two noteworthy effects.

First, the rule “eliminate[ed] the first three prongs and clarif[ied] the fourth prong of the

definition” of “religious employer” adopted in 2012. *Id.* at 39,874. Under the new definition, an entity qualified as a “religious employer” so long as it “is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii)” of the Internal Revenue Code, which applies to “churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.” *Id.*

Second, the rule established an accommodation for “eligible organizations” with religious objections to providing contraceptive coverage. *Id.* The rule defined an “eligible organization” as one that: “(1) [o]pposes providing coverage for some or all of the contraceptive services required to be covered . . . ; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria.” *Id.* An eligible organization was required to provide a copy of the self-certification to its insurance provider, which then would provide contraceptive coverage to the organization’s employees. *Id.* at 39,876. Thus an eligible organization that self-certified as such was “not required to contract, arrange, pay, or refer for contraceptive coverage,” but its “plan participants and beneficiaries [would] still benefit from separate payments for contraceptive services without cost sharing or other charge,” consistent with the Contraceptive Mandate. *Id.* at 39,874.

C. Hobby Lobby & Wheaton College

Meanwhile, a host of legal challenges to the Contraceptive Mandate progressed through the federal courts, several of which eventually reached the Supreme Court.

On June 30, 2014, the Supreme Court issued its opinion in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). There, three closely-held corporations challenged the Contraceptive Mandate. *Id.* at 2765. The Supreme Court held that the application of the Contraceptive Mandate to the organizations violated the Religious Freedom Restoration Act, 42

U.S.C. § 2000bb-1 (“RFRA”), because the Contraceptive Mandate imposed a substantial burden on the plaintiffs’ religious exercise and was not the “least restrictive means” of guaranteeing cost-free access to certain methods of contraception. 134 S. Ct. at 2780-82. The Supreme Court found the existence of the accommodation supported its conclusion that the Contraceptive Mandate was not the “least restrictive means”: “HHS itself has demonstrated that it has at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs. . . . HHS has already established an accommodation for nonprofit organizations with religious objections.” *Id.* at 2782. Nevertheless, the Supreme Court refrained from deciding “whether an approach of this type”—meaning the accommodation—“complies with RFRA for purposes of all religious claims.” *Id.*

A few days later, the Supreme Court issued an order in a related case, *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014) (per curiam). There, Wheaton College, an organization eligible for the accommodation, sought an injunction “on the theory that its filing of a self-certification form [would] make it complicit in the provision of contraceptives by triggering the obligation for someone else to provide the services to which it objects.” *Id.* at 2808 (Sotomayor, J., dissenting). The Supreme Court granted the injunction, permitting Wheaton College to “inform[] the Secretary of Health and Human Services in writing that it . . . has religious objections to providing coverage for contraceptive services”—that is, the college did not have to “use the [self-certification] form prescribed by the [g]overnment.” *Id.* at 2807 (per curiam). The Supreme Court warned, however, that the “order should not be construed as an expression of the Court’s views on the merits.” *Id.*

D. Regulatory Response to *Hobby Lobby* & *Wheaton College*

The Agencies responded to *Hobby Lobby* and *Wheaton College* by issuing a notice of

proposed rulemaking “amend[ing] the definition of an eligible organization [for purposes of the accommodation] to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered.” *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,118, 51,121 (Aug. 27, 2014). Furthermore, the Agencies issued an interim final rule, effective immediately, that provided “an alternative process” for eligible organizations to self-certify “consistent with the Wheaton order.” *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,092, 51,094-96 (Aug. 27, 2014). On July 14, 2015, the Agencies issued a rule that finalized the extended accommodation and alternative self-certification process. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 80 Fed. Reg. 41,318, 41,323-24 (July 14, 2015).

E. *Zubik* Remand & Impasse

On May 16, 2016, the Supreme Court issued its third decision regarding the Contraceptive Mandate. In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), several organizations eligible for the accommodation challenged the self-certification process on the grounds that the requirement to submit a notice either to their insurer or the federal government violated RFRA. *Id.* at 1559. The Supreme Court declined to reach the merits of the dispute, requesting instead “supplemental briefing from the parties addressing ‘whether contraceptive coverage could be provided to petitioners’ employees, through petitioners’ insurance companies, without any such notice from petitioners.’” *Id.* at 1559-60. After the parties agreed that “such an option [was] feasible,” the Supreme Court remanded to afford them “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans receive full and equal health

coverage, including contraceptive coverage.” *Id.* at 1560 (internal quotation marks omitted). Again, though, the Court “express[ed] no view on the merits of the cases,” and refrained from “decid[ing] whether petitioners’ religious exercise has been substantially burdened, whether the [g]overnment has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest.” *Id.*

Following the remand the Agencies reached an impasse. After reviewing over 50,000 comments submitted in response to a request for information, the Agencies concluded that there was “no feasible approach . . . at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” Dep’t of Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4 (2016), available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf>.

F. 2017 IFRs & First Preliminary Injunction

On May 4, 2017, President Donald Trump issued an Executive Order entitled “Promoting Free Speech and Religious Liberty.” Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017). The Order directed the Agencies to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [the Women’s Health Amendment].” *Id.* at § 3.

On October 6, 2017, aiming to be “[c]onsistent with the President’s Executive Order and the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs,” *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792, 47,799 (Oct. 13, 2017), the Agencies issued two, new IFRs, referred to as the Religious Exemption IFR and the Moral

Exemption IFR. *See id.* at 47,792 (“Religious Exemption IFR”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838, 47,838 (Oct. 13, 2017) (“Moral Exemption IFR”) (collectively, “the IFRs”).

The IFRs made several significant changes to the prior exemption and accommodation framework.⁴ For one, the Moral Exemption IFR made the exemption available to “additional entities”—including for-profit entities that are not publicly traded—that object based on “sincerely held *moral* convictions,” without any need for the objection to be grounded in a *religious* objection to contraception. 82 Fed. Reg. at 47,862 (emphasis added). Second, the Religious Exemption IFR significantly broadened the scope of the religious exemption to encompass any non-profit or for-profit entity, whether closely held or publicly traded. 82 Fed. Reg. at 47,810. Third, the IFRs “likewise” expanded eligibility for the accommodation, allowing entities with sincerely held religious or moral convictions to take advantage of the accommodation process. 82 Fed. Reg. at 47,813; 82 Fed. Reg. at 47,849. Fourth, the IFRs made “the accommodation process optional for eligible organizations,” such that entities taking advantage of the accommodation would “not be required to comply with a self-certification process.” 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850. Finally, the IFRs eliminated the requirement to provide notice of an intent to take advantage of the exemption or accommodation—entities that stop providing contraceptive care “do not need to file notices or

⁴ The following is not an exhaustive list of the changes enacted by the IFRs, and subsequently the Final Rules. For example, the IFRs also changed the level at which exemptions are to be applied. So, whereas before the availability of an exemption was to be “determined on an employer by employer basis,” the IFRs provide that an exemption “will be determined on a plan basis.” 82 Fed. Reg. at 47,810. The effect of this change, according to the States, is that an employer may disregard the Contraceptive Mandate by adopting a group health plan “established or maintained” by an objecting organization, *id.*, even if the employer itself does not hold a sincere religious or moral objection to contraception.

certifications of their exemption.” 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850. Thus the IFRs permit entities with religious or moral objections to forgo providing contraceptive coverage to employees without “fil[ing] notices or certifications of their exemption.” 82 Fed. Reg. at 47,838.⁵

The IFRs became effectively immediately. 82 Fed. Reg. at 47,815; 82 Fed. Reg. at 47,855. Rather than engage in advance notice-and-comment procedures, the Agencies requested post-promulgation comments be submitted by December 5, 2017, 60 days after the IFRs went into effect. 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838. The Commonwealth filed suit in the interim seeking to enjoin enforcement of the IFRs, arguing: (1) they failed to comply with the notice-and-comment procedures required by the APA, 5 U.S.C. § 551, *et seq.*; (2) they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in violation of the substantive provisions of the APA, 5 U.S.C. § 706(2)(A); (3) they violate Title VII of the Civil Rights Act, 42 U.S.C. § 2000e-2, *et seq.*; (4) they violate the Equal Protection Guarantee of the Fifth Amendment, U.S. Const. amend. V; and, (5) they violate the Establishment Clause, U.S. Const. amend. I.⁶ This Court granted the preliminary injunction, finding the Commonwealth was likely to succeed on its claims that the IFRs violated both the procedural and substantive strictures of the APA; it did not, however, reach the merits of the other statutory or constitutional claims. *See Pennsylvania*, 281 F. Supp.3d at 585.⁷

⁵ The IFRs note that ERISA requires certain disclosures: “[u]nder ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document.” 82 Fed. Reg. at 47,838.

⁶ The State of New Jersey was not party to the original Complaint, and thus, not a party to the first motion for a preliminary injunction either.

⁷ Following this Court’s issuance of a preliminary injunction, several other district courts issued decisions regarding the propriety of the IFRs. *See California v. Health & Human Servs.*, 281 F. Supp.3d 806, 832 (N.D. Cal. 2017) (enjoining the IFRs for violating the procedural requirements of the APA only), *aff’d in part, vacated in part*,

Defendants subsequently appealed the decision and moved to stay proceedings while the appeal was pending, which this Court granted.⁸

G. 2018 Final Rules & Second Motion for Preliminary Injunction

On November 15, 2018, while their appeal of the preliminary injunction was pending before the Third Circuit, the Agencies promulgated two new rules that “finalize[d]” the IFRs. *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,536, 57,536 (Nov. 15, 2018) (“Final Religious Exemption”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592, 57,592 (Nov. 15, 2018) (“Final Moral Exemption”). “In response to public comments,” the Agencies made “various changes” to the Final Rules “to clarify the intended scope of the language” in the IFRs. 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593. The changes, however, were largely “non-substantial technical revisions.” 83 Fed. Reg. at 57,567. Defendants assert such changes “do not alter the fundamental substance of the exemptions set forth in the IFRs.” The Final Rules were scheduled to take effect on January 14, 2019. 83 Fed. Reg. at 57,567; 83 Fed. Reg. at 57,592.

The Commonwealth then sought to lift the stay to challenge the Final Rules. The Court granted the motion,⁹ and Pennsylvania—now joined by New Jersey—filed an Amended

remanded sub nom., California v. Azar, 911 F.3d 558, 566 (9th Cir. 2018) (upholding the lower court’s conclusion on the merits, but striking down the remedy as overbroad); *Massachusetts v. Health & Human Servs.*, 301 F. Supp.3d 248, 266 (D. Mass. 2018) (finding State lacked standing to challenge the IFRs), *app. docketed*, No. 18-1514 (1st Cir. June 6, 2018).

⁸ Following the Commonwealth’s initial motion for a preliminary injunction, Defendant-Intervenor Little Sisters filed a motion to intervene. The Court denied that motion. *See Pennsylvania v. Trump*, 2017 WL 6206133, at *1 (E.D.Pa. Dec. 8, 2017). On appeal, however, the Third Circuit reversed, remanding the case to permit intervention. *See Pennsylvania v. President United States of Am.*, 888 F.3d 52, 62 (3d Cir. 2018). The Court duly vacated its prior ruling and granted Defendant-Intervenor Little Sisters’ motion.

⁹ While the filing of a notice of appeal is generally “an event of jurisdictional significance—it confers jurisdiction on the court of appeals and divests the district court of its control over those aspects of the case involved in the appeal,” *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982),—“[a]n appeal from the grant or denial of a

Complaint and a Second Motion for a Preliminary Injunction, seeking to enjoin enforcement of the Final Rules.¹⁰ The States argue the Final Rules: (1) failed to comply with the notice-and-comment procedures required by the APA; (2) are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in violation of the substantive provisions of the APA; (3) violate Title VII of the Civil Rights Act; (4) violate the Equal Protection Guarantee of the Fifth Amendment; and, (5) violate the Establishment Clause. It is to the merits of these contentions that the Court now turns.

II. Analysis¹¹

A. Standing

A threshold question is whether the States have standing. Standing is a litigant’s ticket to federal court—a constitutional requirement that “limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The States contend that they are properly before the Court because the Final Rules will imminently cause direct harm to their sovereign, quasi-sovereign and proprietary interests. Additionally, they assert that they have *parens patriae* standing to protect the health, safety and well-being of their residents in ensuring that they enjoy access to healthcare services. Defendants, on the other hand, contend that the States have not suffered any legal wrong that would allow them to get through the turnstile into federal court.

preliminary injunction does not divest the trial court of jurisdiction or prevent it from taking other steps in the litigation while the appeal is pending,” 11A Wright & Miller, Fed. Prac. & Pro. § 2962 (3d ed.); *see also In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 268 (3d Cir. 2005) (observing that the district court retains the power to “modify or grant injunctions” following an appeal).

¹⁰ The Third Circuit stayed Defendants’ appeal pending the resolution of the Second Motion for a Preliminary Injunction. *Pennsylvania v. President United States of Am.*, No. 17-3752 (3d Cir. Jan. 9, 2019).

¹¹ This section and all others afterwards includes the Court’s legal conclusions as required under Rule 52(a) of the Federal Rules of Civil Procedure.

“No principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 37 (1976). The doctrine of standing “is part of this limitation.” *Id.*; see also *Finkleman v. Nat’l Football League*, 810 F.3d 187, 203 (3d Cir. 2016). “[T]he irreducible constitutional minimum of standing contains three elements.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). First, a plaintiff must have suffered an “injury in fact,” which is “an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” *Id.* (internal quotation marks and citations omitted). Second, a plaintiff must show that there is a “causal connection between the injury and the conduct complained of”—that is, the injury must be “fairly traceable” to the “challenged action of the defendant.” *Id.* (internal quotation marks omitted). Third, a plaintiff must show that it is “likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Id.* at 561 (internal quotation marks omitted).

As “[t]he party invoking federal jurisdiction,” the States “bear[] the burden of establishing these elements.” *Id.* And, “[s]ince they are not mere pleading requirements but rather an indispensable part of the plaintiff’s case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Id.* “[A]t the preliminary injunction stage, allegations are”—without more—“not enough to support standing;” rather, the States must “adduce[] evidence demonstrating more than a mere possibility” that the elements of standing are met. *Doe v. Nat’l Bd. of Med. Exam’rs*, 199 F.3d 146, 152-53 (3d Cir. 1999).

1. Special Solitude

This standing inquiry must be made with recognition that States, like Pennsylvania and New Jersey here, “are not normal litigants for the purposes of invoking federal jurisdiction.” *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). They are “entitled to special solicitude in [the] standing analysis” if they have: (1) a procedural right that authorizes them to challenge the conduct at issue; and, (2) a “stake in protecting [their] quasi-sovereign interests.” *Id.* at 520; *see also Texas v. United States*, 809 F.3d 134, 151 (5th Cir. 2015), *aff’d by an equally divided Court*, 136 S. Ct. 2271 (2016) (per curiam).

In determining whether the States have met these conditions, both *Massachusetts v. EPA* and *Texas v. United States* are instructive. In *Massachusetts v. EPA*, Massachusetts sued the Environmental Protection Agency (“EPA”), alleging that the EPA had “abdicated its responsibility under the Clean Air Act” when it failed to issue regulations regarding the emission of certain greenhouse gases. 549 U.S. at 505. The EPA challenged Massachusetts’ standing to bring the suit, arguing greenhouse gas emissions are a widespread and generalized harm not unique to any specific plaintiff. *Id.* at 517. The Supreme Court nonetheless held that Massachusetts had special solicitude in the standing inquiry to challenge the EPA’s inaction: First, Massachusetts had a procedural right under the relevant statute, the Clean Air Act, which allowed it to “challenge agency action unlawfully withheld.” *Id.* (citing 42 U.S.C. § 7607(b)(1)). Second, Massachusetts had a quasi-sovereign interest—a “well-founded desire to preserve its sovereign territory” from the effects of global warming because Massachusetts “own[ed] a great deal of the territory alleged to be affected.” *Id.* at 519 (internal quotation marks omitted); *see also id.* at 522 (noting affidavits asserting that “rising seas have already begun to swallow Massachusetts’ coastal land.”). After concluding that Massachusetts was entitled to special

solicitude in the standing analysis, the Supreme Court ultimately held that it had Article III standing to sue the EPA based on the injury to its territory stemming from global warming. *Id.* at 526.

In *Texas v. United States*, the Fifth Circuit, relying on *Massachusetts v. EPA*, similarly concluded that Texas and a multitude of other States were entitled to special solicitude in seeking to enjoin implementation of the Deferred Action for Parents of Americans and Lawful Permanent Residents program (“DAPA”). 809 F.3d at 154-55. There, non-citizens in Texas could apply for a driver’s license if they presented “documentation issued by the appropriate United States agency that authorizes the applicant to be in the United States.” *Id.* at 155 (internal quotation marks omitted). DAPA would have permitted at least 500,000 non-citizens to qualify for these driver’s licenses. *Id.* Because Texas subsidized its licenses, it would have lost money for each license issued to a DAPA beneficiary. *Id.* Texas therefore sought injunctive relief to prevent DAPA’s implementation. *See id.* at 149.

The Fifth Circuit applied the *Massachusetts v. EPA* framework and concluded that Texas was entitled to special solicitude. First, the Fifth Circuit considered whether the States’ challenge was similar in kind to the challenge brought by Massachusetts, and concluded that it was. Both suits turned on the construction of a federal statute that specifically provided for a procedural right to judicial review, and Texas’ use of the APA to challenge an “affirmative decision” made by a federal agency was comparable to Massachusetts’ use of the judicial review provision in the Clean Air Act to challenge the EPA’s inaction. *Id.* at 152. Second, as to the quasi-sovereign interest, the Fifth Circuit held that DAPA imposed “substantial pressure” on Texas to change its laws to avoid bearing further costs from subsidizing additional driver’s licenses. *Id.* at 153. The Fifth Circuit thus concluded that Texas, and its fellow plaintiff States,

warranted special solicitude in their suit against the federal government under the APA. *Id.* at 154-55.¹²

The Fifth Circuit’s reasoning in *Texas v. United States* is persuasive here. Here as there, the States bring suit under the APA to challenge an affirmative action by the federal government. *See Texas*, 809 F.3d at 152. And, the Final Rules—like DAPA—“affect[] the [S]tates’ ‘quasi-sovereign’ interest by imposing substantial pressure on them to change their laws.” *Id.* Specifically, they put pressure on provisions of the States’ laws that provide state-funded contraceptive care to low-income citizens. As the States show, the Final Rules permit more employers to exempt themselves from the Contraceptive Mandate, which would result in more of the States’ women seeking state-funded sources of contraceptive care. The harm to the States’ fiscs are “intrusions . . . analogous to pressure to change the law,” *id.*, implicating the States’ quasi-sovereign interests. *See also Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982) (holding that a State has a “quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general.”). The States, then, meet the two conditions outlined in *Massachusetts v. EPA* and shall be accorded special solicitude in the standing analysis.

¹² Defendants here question the binding effect of *Texas v. United States* beyond the facts of that case, given that the Supreme Court summarily affirmed the Fifth Circuit’s decision “by an equally divided Court.” *United States v. Texas*, 136 S. Ct. 2271 (2016) (per curiam). While an affirmance by an equally divided Supreme Court typically does not constitute binding precedent, *see Eaton v. Price*, 364 U.S. 263, 264 (1960), where the Supreme Court is equally divided on an issue of subject matter jurisdiction, it has determined that the proper course is to remand the issue of jurisdiction to a lower court. *See Silliman v. Hudson River Bridge Co.*, 66 U.S. 582, 584-85 (1861). In other words, if the Supreme Court were equally divided on whether Texas had standing to challenge DAPA, it would have remanded that issue to the Fifth Circuit. The Supreme Court did not, and instead affirmed the Fifth Circuit, indicating that a majority of the Supreme Court decided that Texas had standing to pursue its APA claim. Certainly, if the Supreme Court had determined that Texas did not have standing, it would not have had jurisdiction to hear the case. Even if the affirmance by an equally divided Supreme Court as it relates to subject matter jurisdiction were not binding, the Court is persuaded by the reasoning of the Fifth Circuit in *Texas v. United States* as it pertains to State standing.

2. Article III Standing

While the States are entitled to special solicitude in the standing analysis, they must nevertheless meet the “irreducible constitutional minimum of standing”—namely, injury in fact, causation, and redressability. *Lujan*, 504 U.S. at 560. In its initial challenge to the IFRs, the Commonwealth satisfied this burden, *see Pennsylvania*, 281 F. Supp.3d at 569, and the same is true of the States’ challenge to the Final Rules. *See also California*, 911 F.3d at 571 (finding another group of States had standing to challenge the IFRs).

First, the Final Rules inflict a direct injury upon the States by imposing substantial financial burdens on their coffers. An agency rule that has “a major effect on the states’ fiscs” is sufficient to find injury in fact. *Texas*, 809 F.3d at 152; *id.* at 155 (“[Texas] satisfied the first standing requirement by demonstrating that it would incur significant costs in issuing driver’s licenses to DAPA beneficiaries.”); *see also Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (holding that Wyoming had Article III standing because it undisputedly suffered a “direct injury in the form of a loss of specific tax revenues”); *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (“While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.”). If the Final Rules go into effect, the States will have to increase their expenditures for State funded programs that provide contraceptive services. This is not a speculative harm. As Defendants themselves noted in issuing the IFRs, “there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women.” 82 Fed. Reg. at 47,803. As more of the States’ women residents are deprived of contraceptive services through their insurance plans and turn to these State funded programs, the States will be pressed to make greater expenditures to ensure adequate contraceptive care. *See Mendelsohn Decl.* ¶ 15; *Steinberg Decl.* ¶¶ 24-25. And

although Defendants point out that the States have not yet identified a woman resident who has lost contraceptive coverage due to the Final Rules, the States need not sit idly by and wait for fiscal harm to befall them. *See McNair v. Synapse Group Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) (“When, as in this case, prospective relief is sought, the plaintiff must show that he is ‘likely to suffer *future* injury’ from the defendant’s conduct.”) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (emphasis added)). At bottom, just as Texas’ estimated loss due to DAPA supported a finding that Texas suffered an injury in fact, so too does the States’ estimated loss due to the Final Rules support a finding that the States have suffered an injury in fact. *See Texas*, 809 F.3d at 155.

Second, the States’ financial injury is “fairly traceable” to the issuance of the Final Rules. By their terms, the Final Rules expand the scope of the existing religious exemption rule and allow entities a new rationale for refusing to provide employees with contraceptive coverage if the refusal is “based on sincerely held moral convictions,” 83 Fed. Reg. at 57,593. Thus, the Final Rules allow more entities to stop providing contraceptive coverage, which will result in more women residents seeking contraceptive care through State-funded programs. *See Mendelsohn Decl.* ¶ 15; *Steinberg Decl.* ¶¶ 24-25. The States have thus shown a causal connection between the Final Rules and their financial injury.

As the Court previously explained, *Pennsylvania v. New Jersey*, 426 U.S. 660 (1976), is not to the contrary. *See also California*, 911 F.3d at 574 (finding *Pennsylvania* did not bar States’ challenge to the IFRs on a similar theory of standing). In that case, Pennsylvania voluntarily gave tax credits to Pennsylvania residents who paid taxes in New Jersey, and then proceeded to sue New Jersey, contending that the New Jersey tax injured Pennsylvania’s fiscs and was constitutionally impermissible. *Pennsylvania*, 426 U.S. at 662-63. The Supreme Court

found that Pennsylvania lacked standing because the injuries to its fiscs were “self-inflicted,” resulting, as they did, from a decision of its state legislature to enact a law that incorporated the legislative choices of New Jersey. *Id.* at 664. Here, by contrast, the States’ laws funding contraceptive care do not “directly and explicitly” tie the States’ finances to another sovereign’s law. *California*, 911 F.3d at 574. Rather, the States’ described injuries flow from the unilateral decision by the Agencies to issue the Final Rules. *See id.* (finding *Pennsylvania* did control in an analogous challenge); *cf. Texas*, 809 F.3d at 158 (“The fact that Texas sued in response to a significant change in the [federal government’s] policies shows that its injury is not self-inflicted.”). The States have therefore met the traceability requirement.

Finally, the States have satisfied the redressability requirement. As to the States’ procedural claims, enjoining the Final Rules could prompt the Agencies “to reconsider the program, which is all a plaintiff must show when asserting a procedural right.” *Texas*, 809 F.3d at 161; *see also Massachusetts*, 549 U.S. at 518 (noting that where, as here, a litigant is “vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant”). And, as for the States’ substantive claims, enjoining the Final Rules “would prevent [the States’] injury altogether.” *Texas*, 809 F.3d at 161.

In sum, the States have established the irreducible constitutional minimum of standing to challenge the Final Rules in federal court.¹³

B. Venue

The next question to address is whether the States’ choice of venue—the Eastern District of Pennsylvania—is proper. Notwithstanding Defendants’ argument to the contrary, it is.

¹³ Because the States have identified an imminent, direct injury to its state coffers that would result from the Final Rules, there is no need to address whether they have *parens patriae* standing.

Defendants' argument is grounded in the structure of the venue statute, Section 1391(e)(1) of which provides that in a civil action against an officer of the United States, venue lies "in any judicial district in which . . . the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1). Section 1391(c) defines a party's residence "[f]or all venue purposes," and distinguishes between three, and only three, categories of litigants: "a natural person," "an entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated," and "a defendant not resident in the United States." *Id.* at § 1391(c). Because Pennsylvania is neither a natural person nor a non-resident, Defendants argue it must be treated as an entity for purposes of determining residency. Section 1391(c)(2) provides that "if a plaintiff," an entity "shall be deemed to reside . . . only in the judicial district in which it maintains its principal place of business." *Id.* Thus, according to Defendants, Pennsylvania resides only in the Middle District—the district that encompasses Harrisburg, the state capital—because that is where Pennsylvania maintains its principal place of business.

While inventive, Defendants' interpretation of Section 1391(c) is ultimately unpersuasive. *See California*, 911 F.3d at 570 (rejecting the argument); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp.2d 1301, 1328 (N.D. Ala. 2005) (rejecting a similar argument for an earlier version of the venue statute). Defendants' argument hinges on the assumption that, because Section 1391(c) refers to only three categories of litigants and because a state is neither a natural person nor a non-resident, a state must necessarily be "an entity" for purposes of the venue statute. There are, however, several issues with that assumption.

First, the statute explicitly refers to an entity's incorporation status, indicating "that the term [entity] refers to some organization, not a state." *California*, 911 F.3d at 570. The legislative history confirms that Congress was contemplating "unincorporated associations, such

as partnerships and labor unions, and other entities with capacity to sue in their common name,” when it defined the residency of unincorporated entities in Section 1391(c). H.R. Rep. No. 112-10, at 21 (2011). There is no indication, however, that Congress intended for that provision to dictate the residency of sovereign States by equating a State with an “unincorporated association[]” like a labor union.

Second, Congress explicitly distinguishes between States and entities within Section 1391. Compare 28 U.S.C. § 1391(c) (defining the residency of an “entity”), with *id.* at § 1391(d) (“Residency of corporations in States with multiple districts”). “Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation marks and citations omitted). Thus, courts typically “refrain from concluding . . . that the differing language in [] two subsections [of a statute] has the same meaning in each.” *Id.* Here, Congress’s differentiation between “an entity” and “States” within Section 1391 indicates that Congress did not intend to include the latter within the definition of the former.

Finally, reading Section 1391 as Defendants suggest would yield an absurd result. As several courts have observed, an interpretation that “limit[s] residency to a single district in the state would defy common sense,” because “[a] state is ubiquitous throughout its sovereign borders.” *California*, 911 F.3d at 570; *Alabama*, 382 F. Supp.2d at 1329 (“[C]ommon sense dictates that a state resides throughout its sovereign borders”).¹⁴

Thus, the Court will follow the lead of the Ninth Circuit in concluding that “the statute . .

¹⁴ The unreported district court cases that Defendants rely upon are not to the contrary. See *Gaskin v. Pennsylvania*, 1995 WL 154801, at *1 (E.D. Pa. Mar. 30, 1995); *Bentley v. Ellam*, 1990 WL 63734, at *1 (E.D. Pa. May 8, 1990). Both *Gaskin* and *Bentley* discuss the residency of state agencies or officials, which is different in kind from the residency of a sovereign State itself.

. dictates that a state with multiple judicial districts ‘resides’ in every district within its borders.” *California*, 911 F.3d at 570. Venue is therefore proper in the Eastern District of Pennsylvania.¹⁵

C. Preliminary Injunction

Because the States have established standing to bring their claims into federal court and that this is a proper venue to hear those claims, the Court now turns to the merits of the preliminary injunction motion.

1. Legal Standard

A preliminary injunction is an extraordinary remedy; it “should be granted only in limited circumstances.” *American Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1426-27 (3d Cir. 1994). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v. NRDC*, 555 U.S. 7, 20 (2008). The first two are the “most critical factors: [a movant] must demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief.” *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017), *as amended* (June 26, 2017) (internal quotation marks omitted). “If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor

¹⁵ Section 1391(e) also provides that venue is proper in a civil action against an officer of the United States, where “a substantial part of the events or omissions giving rise to the claim occurred.” 28 U.S.C. § 1391(e). Because the Court finds Pennsylvania resides throughout the State, it need not address the States’ alternative argument that venue is proper because “a substantial part of the events” giving rise to their claim occurred here.

Relatedly, New Jersey’s residency does not bear on the question of because “in an action against the federal government or an agent thereof [t]here is no requirement that all plaintiffs reside in the forum district.” *Exxon Corp. v. FTC*, 588 F.2d 895, 899-90 (3d Cir. 1978); *Superior Oil Co. v. Andrus*, 656 F.2d 33, 37 n.7 (3d Cir. 1981) (“[O]nly one plaintiff need satisfy the residency requirement of [Section 1391(e)].”).

of granting the requested preliminary relief.” *Id.*

2. Likelihood of Success on the Merits

In demonstrating the likelihood of success on the merits, a plaintiff need not show that it is more likely than not that it will succeed. *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc). Instead, all a plaintiff must show is “a *likelihood* of success on the merits (that is, a reasonable chance, or probability, of winning) to be granted relief.” *Id.* (emphasis in original).

a. APA Procedural Claim

The States argue that the Final Rules should be enjoined because Defendants failed to comply with the procedural requirements of the APA.

The APA generally requires that, when promulgating regulations, administrative agencies meet a set of procedural requirements, called notice-and-comment rulemaking. *See* 5 U.S.C. § 553. Agencies must: issue a general notice of proposed rulemaking, *see id.* at § 553(b); “give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments . . .” *id.* at § 553(c); and, “[a]fter consideration of the relevant matter presented, . . . incorporate in the rules adopted a concise general statement of their basis and purpose,” *id.*

Notice-and-comment rulemaking serves two distinct purposes—it both “give[s] the public an opportunity to participate in the rule-making process,” and “enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated.” *Texaco, Inc. v. Fed. Power Comm’n*, 412 F.2d 740, 744 (3d Cir. 1969). Nevertheless, there are limited exceptions to the requirement that all rules be issued pursuant to notice-and-comment rulemaking, such as when an agency has “good cause” to

forgo the strictures of notice-and-comment rulemaking, 5 U.S.C. § 553(b), or when a subsequent act of Congress abrogates the APA's procedural requirements, *id.* at § 559.

In issuing the IFRs, the Agencies failed to meet the various requirements of notice-and-comment rulemaking. *See Pennsylvania*, 281 F. Supp.3d at 570. Defendants argued, however, that the IFRs were not procedurally invalid because they fell under one (or more) of the limited exceptions to notice-and-comment rulemaking. *Id.* at 571. The Court found otherwise and enjoined the IFRs for violating the procedural strictures of Section 553. *Id.* at 576; *see also California*, 281 F. Supp.3d at 829 (enjoining the IFRs for violating the procedural requirements of the APA), *aff'd in part, vacated in part, California*, 911 F.3d at 575 (upholding the conclusion that the IFRs violated the APA).

While Defendants continue to maintain that the IFRs were procedurally valid,¹⁶ they now argue that, even assuming the IFRs were procedurally improper, the subsequent action taken by the Agencies in promulgating the Final Rules satisfied notice-and-comment requirements, and thus the Final Rules comply with the APA. The States' response is two-fold. First, they argue that the Agencies notice-and-comment procedures fell short of the APA's requirements because the Agencies did not adequately respond to significant comments in their statement of the basis and purpose of the Final Rules. Second, the States contend that, no matter the Agencies' subsequent actions, the procedural defects that characterized the issuance of the IFRs fatally taint the Final Rules. These arguments are considered *seriatim*.

i. Inadequate Response to Comments

The States argue that the Agencies' issuance of the Final Rules failed to meet the

¹⁶ The Court, for the reasons stated in its prior opinion, again finds the Agencies' position unpersuasive, *see Pennsylvania*, 281 F. Supp.3d at 570, and therefore declines Defendants' invitation to revisit its prior holding. *See Hayman Cash Register Co. v. Sarokin*, 669 F.2d 162, 165 (3d Cir. 1982) ("Under the law of the case doctrine, once an issue is decided, it will not be relitigated in the same case, except in unusual circumstances.").

requirements of notice-and-comment rulemaking by not responding to all “vital questions[] raised by comments which are of cogent materiality.” *United States v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). The APA requires federal agencies to “consider and respond to significant comments received during the period for public comment.” *Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199, 1203 (2015). The requirement, however, is not “particularly demanding.” *Nazareth Hosp. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 747 F.3d 172, 185 (3d Cir. 2014) (quoting *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993)). All that is required is a response that “‘demonstrates that the [agency] considered and rejected’ the arguments.” *Id.* (quoting *Covad Commc’ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006)).

The States contend that the Agencies failed to clear this relatively low bar, pointing to several examples of comments that purportedly received an inadequate response: comments that discuss the scientific evidence of the harm to the health and economic security of women that would result from the Final Rules, 83 Fed. Reg. at 57,555-56; comments that assert the broad religious and moral exemptions will cause women to lose contraceptive coverage, *id.* at 57,548-49; comments that argue the exemptions violate the ACA prohibition on regulations that create barriers to medical care, *id.* at 57,551-52; and, specifically, a comment submitted by various States—including Pennsylvania and New Jersey—regarding the medical risks associated with pregnancy, *id.* at 57,555.

For each example, however, a review of the Final Rules demonstrates that the Agencies acknowledged the comments and provided an explanation as to why the Agencies did (or did not) amend the Final Rules based on the comment. *See* 83 Fed. Reg. at 57,548, 57,551, 57,555. While the Agencies’ explanations are not always the picture of clarity, they meet the not

“particularly demanding” requirement, *Nazareth Hosp.*, 747 F.3d at 185, that the Agencies “consider and respond to significant comments received during the period for public comment,” *Perez*, 135 S. Ct. at 1203. Put differently, the Final Rules “demonstrate [to a commenter] that the [the Agencies] considered and rejected, the arguments” put forth by a commenter, which is “all that the [APA] requires.” *Nazareth Hosp.*, 747 F.3d at 185 (internal quotation marks omitted).

Thus, the States are unlikely to succeed on the merits of their argument that, in promulgating the Final Rules, the Agencies’ actions failed to meet the requirements of notice-and-comment rulemaking.¹⁷

ii. IFRs Taint the Final Rules

The States maintain that, even if the Agencies complied with the requirements of notice-and-comment rulemaking in promulgating the Final Rules, the failure to do so in promulgating the IFRs fatally infected the process such that the Final Rules should also be held invalid.

Generally, “the period for comments after promulgation cannot substitute for the prior notice and comment required by the APA.” *Sharon Steel. Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979). The Circuit courts however, diverge on the procedural validity of a final rule that follows an IFR promulgated in a procedurally flawed manner—that is, the question of whether a “procedural defect that taints the original, interim-final rule carr[ies] over to the succeeding final rule.” Kristin E. Hickman & Mark Thomson, *Open Minds and Harmless Errors: Judicial Review of Postpromulgation Notice and Comment*, 101 Cornell L. Rev. 261, 267 (2016) (discussing various approaches taken by the Circuit courts); compare *Salman Ranch, Ltd. v. Comm’r*, 647 F.3d 929, 940 (10th Cir. 2011) (“While the . . . temporary regulations were issued

¹⁷ The States’ argument is limited to the claim that the Agencies failed to adequately respond to significant comments. The States do not argue, for example, that the notice provided was inadequate. See 5 U.S.C. § 552(b).

without notice and comment, now that the regulations have issued in final form [after notice and comment], these arguments are moot . . .”) (internal quotation marks omitted), *rev’d on other grounds, Salman Ranch, Ltd. v. Comm’r*, 566 U.S. 971 (2012), with *Air Transp. Ass’n of Am. v. Dep’t of Transp.*, 900 F.2d 369, 379 (D.C. Cir. 1990) (“Although we have suggested that there might be circumstances in which ‘defects in an original notice [could] be cured by an adequate later notice’ and opportunity to comment, we have emphasized that we could reach such a conclusion only upon a compelling showing that ‘the agency’s mind remain[ed] open enough at the later stage.’ The FAA has not come close to overcoming the presumption of closed-mindedness in this case.”) (quoting *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988)), *vacated on other grounds*, 498 U.S. 1077 (1991). For its part, the Third Circuit has evidenced a deep skepticism towards the curative powers of post-promulgation notice-and-comment procedures, *see NRDC v. EPA*, 683 F.2d 752, 767-68 (3d Cir. 1982); *United States v. Reynolds*, 710 F.3d 498, 519 (3d Cir. 2013); *accord Sharon Steel. Corp.*, 597 F.2d at 381, which warrants a conclusion that the States are likely to succeed on the claim that the procedural faults that characterized the issuance of the IFRs fatally tainted the Final Rules such that the issuance of the Final Rules violated the APA.

The Third Circuits’ decision most directly on point is *NRDC v. EPA*. There, the NRDC challenged EPA action that indefinitely postponed the effective date of certain Clean Water Act amendments. *NRDC*, 683 F.2d at 757. The EPA did not engage in notice-and-comment procedures before acting to postpone the implementation of the amendments.¹⁸ *Id.* at 756. After NRDC initiated litigation challenging the agency’s action, the EPA issued a notice of proposed

¹⁸ The EPA argued that the initial action to postpone was not a “rule” under the APA, and thus did not require notice-and-comment procedures. *NRDC*, 683 F.2d at 761. The Third Circuit rejected that argument, holding the EPA’s action postponing the effective date qualified as a rule, requiring notice-and-comment procedures. *Id.*

rulemaking, seeking comments on whether the agency should issue a rule further postponing the effective date. *Id.* at 757. After going through notice-and-comment procedures, the EPA then issued a final rule implementing some of the amendments, while further postponing the most controversial bits. *Id.* Nevertheless, NRDC maintained its challenge to the EPA's initial action to postpone the effective date. The Third Circuit rejected the EPA's argument that its notice-and-comment procedures *after* the initial action to postpone "cured" any failure to engage in such procedures *before* the initial action, and held the initial action postponing the effective date was procedurally invalid. *Id.* at 767.

Critical to this dispute, however, the Third Circuit further held that, even though the NRDC did not challenge the final rule—that is, the rule promulgated following notice-and-comment procedures—the final rule "was likewise invalid." *Id.* at 768. The court of appeals explained that the appropriate remedy for the EPA's failure to engage in notice-and-comment rulemaking before taking its initial action required holding *both* the initial action and the subsequent, final rule "ineffective." *Id.* at 767. EPA's notice-and-comment procedures "could not serve as the procedural mechanism" for the final rule because "that rulemaking [could not] replace one on the question of whether the amendments should be postponed in the first place." *Id.* That is, if the EPA had engaged in notice-and-comment procedures before initially acting to postpone the effective date, then "the question to be decided in the [subsequent] rulemaking"—the rulemaking that complied with notice-and-comment procedures—"would have been whether the amendments . . . should be suspended, and not whether they should be further postponed." *Id.* The Third Circuit warned that:

To allow the APA procedures in connection with the further postponement to substitute for APA procedures in connection with an initial postponement would allow EPA to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action

without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued. . . . We cannot countenance such a result.

Id.

That reasoning applies with equal force here. The Agencies issued the IFRs without engaging in notice-and-comment rulemaking. As in *NRDC*, the issuance of the procedurally defective IFRs fundamentally changed the “question to be decided in the [subsequent] rulemaking”—instead of asking whether substantial expansions to the exemption and accommodation should be made *at all*, the Agencies solicited comments on whether those changes should be *finalized*. Thus, the subsequent “rulemaking on [finalizing the IFRs] could not serve as the procedural mechanism,” for the Final Rules because “that rulemaking [could not] replace one on the question of whether” the Agencies should broaden the existing exemption and accommodation “in the first place.” *Id.* The Agencies are, in essence, engaging in precisely the behavior that the Third Circuit warned against in *NRDC*: “substitute[ing] post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures . . . by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued.” *Id.* The Court, like the Third Circuit, “cannot countenance such a result.” *Id.*

Defendants and Defendant-Intervenor advance several arguments to the contrary, none of which are ultimately persuasive. For one, Defendants argue that *NRDC* is not on all fours with this case and so “provides no support for the Plaintiffs’ procedural challenge.” Defendants are correct that *NRDC* differs factually from the case at hand: there the *NRDC* challenged only the initial action, here the States challenged both the IFRs and the Final Rules. But, even though the plaintiff did not challenge the final rule in *NRDC*, the Third Circuit held both the initial action to

postpone and the subsequent rule procedurally invalid. In reaching that determination, the Third Circuit rejected the notion—advanced by the Agencies here—that subsequent notice-and-comment rulemaking procedures “cured” the failure to engage in such procedures “in the first place.” *Id.* at 767-78. Both the holding and the reasoning given for that holding are binding on this Court. *See Tate v. Showboat Marina Casino P’ship*, 431 F.3d 580, 582 (7th Cir. 2005) (Posner, J.) (“[T]he holding of a case includes, besides the fact and the outcome, the reasoning essential to that outcome.”); *see also IFC Interconsult, AG v. Safeguard Int’l Partners, LLC*, 438 F.3d 298, 311 (3d Cir. 2006) (quoting Judge Posner’s definition approvingly). Because the Third Circuit’s reasoning invalidating the subsequent rule was essential to the holding, and because that reasoning applies with equal force to the promulgation of the Final Rules, that reasoning controls here.

Next, Defendants argue that the States suffered no procedural injury because they had an opportunity to submit a comment in response to the IFRs, an opportunity that the States “admit” to taking advantage of. The problem for Defendants is that the EPA made the exact argument to the Third Circuit in *NRDC*, which the court of appeals flatly rejected. *NRDC*, 683 F.2d at 768. As the Third Circuit explained, it did not matter that “notice and comment were provided in connection with the proposal that the amendments be further postponed, and NRDC was able to make all of the arguments in connection with the further postponement that NRDC would have made in connection with the initial postponement.” *Id.* The problem was that the initial, procedurally defective action fundamentally changed the question to be presented in the subsequent rulemaking, prejudicing NRDC, which ““must come hat-in-hand and run the risk that the decisionmaker is likely to resist change.”” *Id.* at 768 (quoting *Sharon Steel*, 597 F.2d at 381). Here, the procedurally invalid IFRs similarly changed the question to be presented in the

subsequent rulemaking, prejudicing the States' ability to have their comments heard by an impartial decisionmaker. *Cf. Wagner Elec. Corp. v. Volpe*, 466 F.2d 1013, 1020 (3d Cir. 1972) ("Section [553(b)] of the [APA] requires notice *before* rulemaking, not after. The right of interested persons to petition for the issuance, amendment or repeal of a rule, granted in [5 U.S.C. § 553(e)], is neither a substitute for nor an alternative to compliance with the mandatory notice requirements of [5 U.S.C. § 553(b)].") (emphasis in original).

Defendant-Intervenor's attempt to distinguish away the reasoning of *NRDC* fares no better. It argues the court of appeals' reasoning does not control because, while "unique circumstances" existed in *NRDC* "to establish prejudice," no such circumstances are present here. Specifically, Defendant-Intervenor argues that the Third Circuit invalidated the final rule in *NRDC* because of the "asymmetry between using an interim rule to repeal a rule promulgated with prior notice and comment," whereas, here, the Final Rules are not "an abrupt change in federal policy" because the Final Rules do not rescind the Contraceptive Mandate. According to Defendant-Intervenor, that makes this case "readily distinguishable from *NRDC*."

The argument is premised on a misreading of *NRDC*. The Third Circuit did not invalidate the EPA action because of the degree of change affected by the procedurally invalid action. Rather, it held that the subsequent notice-and-comment rulemaking "[could not] replace [a rulemaking] on the question of whether the amendments should be postponed in the first place." *NRDC*, 683 F.2d at 768. More fundamentally, the court of appeals did not rest its decision on the existence of any "unique circumstances," as Defendant-Intervenor suggests. Instead, the Third Circuit voiced a general admonition against the practice of using post-promulgation procedures to cure pre-promulgation procedural flaws. *Id.* As discussed, the reasoning underpinning that warning informs the result here.

Defendant-Intervenor also advances an altogether different argument. It points out that the Agencies “created the [Contraceptive] Mandate via a series of IFRs without notice and comment,” suggesting that the Final Rules are procedurally valid because the Agencies followed similar procedures in the past. The Court rejected a version of this argument last go around. *See Pennsylvania*, 281 F. Supp.3d at 573 n.8. Whether a party could have brought a successful challenge to the procedures followed in the past is not before the Court—what is at issue here is whether the procedures the Agencies followed in issuing the Final Rules violated the APA. *Id.* (explaining that the IFRs were “not identical to prior regulations” because “they make significant changes in the law, and the Supreme Court did not require immediate action”). The same flawed reasoning characterizes Defendant-Intervenor’s related argument that invalidating the Final Rules would “cast a pall on thousands of regulations,” because, according to the Government Accountability Office, 35% of all major rules were finalized with post-IFR notice-and-comment procedures. Obviously, those regulations are not currently before this Court, and, accordingly, the Court is not asked—and thus, cannot decide—whether the specific procedures employed in promulgating those regulations were defective.

The States are likely to prevail on their claim that the issuance of the Final Rules violated the procedural requirements of the APA in that the procedural defect that characterized the IFRs fatally tainted the issuance of the Final Rules. That is so, regardless of whether the procedure followed by the Agencies in the Final Rules may otherwise meet the requirements of notice-and-comment rulemaking.¹⁹

¹⁹ As noted, other courts of appeals employ other approaches when evaluating whether a procedural defect in an interim-rule fatally infects a final rule issued after notice-and-comment procedures are followed—one example being the “open mind” approach. *See, e.g., Air Transp. Ass’n of Am.*, 900 F.2d at 379 (employing the “open mind standard”). While it has never adopted this approach, the Third Circuit in *Reynolds* indicated that whether a promulgating agency “maintained a flexible and open-minded attitude towards” an interim rule is a relevant consideration in determining whether an APA violation occurred generally. 710 F.3d at 519.

b. APA Substantive Claim

The States also contend that the Final Rules violate the substantive requirements of the APA. As the Court has previously noted, the breadth of the exemptions set out in the IFRs, and now the Final Rules, is remarkable. The Final Religious Exemption allows all non-profit and for-profit entities, whether closely held or publicly traded, to deny contraceptive coverage based on sincerely held religious beliefs. The Final Moral Exemption allows any non-profit or for-profit organization that is not publicly traded to deny contraceptive coverage for its employees for any sincerely held moral conviction.

The APA's substantive requirements command that an administrative rule must be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). "It is well settled that an agency may only act within the authority granted to it by statute." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 108 (2d Cir. 2018). Because "administrative agencies may act only pursuant to authority delegated to them by Congress," an agency must "point to something" in a statute that "gives it the authority"

Even under the more flexible "open mind standard," however, the States would likely succeed on the merits of their procedural claim. As the D.C. Circuit has explained, while "defects in an original notice could be cured by an adequate later notice and opportunity to comment," the remedial measures cure the earlier lapses only if the promulgating agency makes "a compelling showing that the agency's mind remained open enough at the later stage." *Air Transp. Ass'n of Am.*, 900 F.2d at 379 (internal quotation marks omitted). That is, "it is the agency's burden to persuade the court that it has accorded the comments a full and fair hearing." *Advocates for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288, 1292 (D.C. Cir. 1994). Courts that use this approach have established that an agency can demonstrate open-mindedness by making changes to a final rule in response to public comments, or giving careful consideration to comments submitted in response to a proposed rule. *Air Transp. Ass'n of Am.*, 900 F.2d at 380; *see also Advocates for Highway & Auto Safety*, 28 F.3d at 1292.

Here, the Agencies have not made a "compelling showing" that they kept an open mind at the later stages of the rulemaking process. Most notably, while the Agencies made some changes to the Final Rules based on public comments, those rules were largely "non-substantial technical revisions," 83 Fed. Reg. at 57,567, that Defendants concede "do not alter the fundamental substance of the exemptions set forth in the IFRs." Indeed, the Final Rules and the preambles that accompany them "demonstrate[] a single-minded commitment to the substantive result reached," *Reynolds*, 710 F.3d at 519—to wit, expanding the exemption and accommodation. Because the Agencies' actions indicate closed-mindedness on "the very subject matter about which [they] w[ere] to keep an 'open mind,'" *id.*, the States would likely prevail on their procedural claim even under the more lenient open mind standard.

to take the specific action at issue. *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (internal quotation marks omitted).

Defendants cite two potential fonts of statutory authority to issue the Final Rules. First, they assert that the ACA includes a broad delegation of authority to the Agencies, permitting them to issue the Final Rules. Second, with specific regard to the Religious Exemption, Defendants assert that RFRA not only authorizes the Agencies to create a religious exemption to the Contraceptive Mandate, but in fact *requires* that the Agencies issue the broad exemption contained within the Final Religious Exemption.

As explained below, both arguments fail. The Final Rules—just as the IFRs before them—exceed the scope of the Agencies’ authority under the ACA, and, further, cannot be justified under RFRA. As a result, the Final Rules must be set aside.²⁰

i. The ACA

To reiterate for purposes of clarity, the ACA requires that group health plans and insurance issuers “shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for-- . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a). It is uncontroverted here that, pursuant to this provision, HRSA has—and by extension the Agencies have—the delegated authority to define what “preventive care” is; that in 2011, HRSA issued guidelines defining “preventive care” to include contraceptives; and that the Final Rules do not purport to remove contraceptives from the coverage mandate. 83 Fed Reg. at 57,537. In light of these provisions, *what* must be provided under the ACA’s “preventive care”

²⁰ Defendants argue that any finding that they lack statutory authority to enact the Final Rules necessarily calls into doubt their ability to enact the 2011 religious exemption, which extended to religious entities such as churches and their auxiliaries. Whatever the merits of that argument, the 2011 religious exemption is not before this Court.

requirement is clear—all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling,” 77 Fed. Reg. at 8,725—as is *who* must provide it—any “group health plan” or “health insurance issuer offering group or individual health insurance coverage,” 42 U.S.C. § 300gg-13(a).

The Agencies, however, contend that the authority to define *what* preventive care will be covered includes a congressional delegation of authority to carve out exceptions to *who* must provide preventive coverage. More specifically, Defendants argue that the Women’s Health Amendment necessarily grants them the authority to exempt employers and healthcare plan sponsors from the coverage requirement, based on religious or moral objections to the Mandate. Thus, the precise question at issue is whether the ACA permits the Agencies to develop the exemptions set forth in the Final Rules.

When the scope of the authority delegated to an agency is challenged, that challenge is generally addressed under the analytical framework prescribed by *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). That is because, “[n]o matter how it is framed, the question a court faces when confronted with an agency’s interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority.” *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (emphasis removed); *see also Am. Farm Bureau Fed’n v. EPA*, 792 F.3d 281, 295 (3d Cir. 2015) (applying *Chevron* framework to resolve “[w]hether an [agency] interpretation falls within the scope of authority that Congress has delegated”) (internal punctuation omitted).

There are two steps to the *Chevron* analysis. Step One asks “whether Congress has directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842. “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give

effect to the unambiguously expressed intent of Congress.” *Id.* at 842-43. But, “[i]f the statute is ambiguous on the point,” Step Two requires “defer[ence] . . . to the agency’s interpretation so long as the construction is ‘a reasonable policy choice for the agency to make.’” *National Cable & Telecomm. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron*, 467 U.S. at 845).

Here, as noted, the ACA provides that any “group health plan” or “health insurance issuer offering group or individual insurance coverage *shall*, at a minimum provide coverage for” “preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a) (emphasis added). On its face, the Women’s Health Amendment does not contemplate exceptions or exemptions to the “preventive care” coverage mandate—much less delegate authority to the Agencies to create such exemptions.²¹ Rather, the statute directs that all specified health plans and insurance issuers “shall” cover “preventive care,” however defined. “Shall” is a mandatory term that “normally creates an obligation impervious to judicial [or agency] discretion.” *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Thus, by stating that the specified plans “shall” provide coverage for “preventive care,” the statute sets forth who is bound by the coverage mandate (any “group health plan” or “health insurance issuer offering group or individual insurance coverage”), while delegating to the Agencies the task of defining what counts as “preventive care.” The statute further underscores the importance of the Contraceptive Mandate, by stipulating that the specified health plans must provide preventive care coverage “at a minimum” and without “any cost sharing requirements.”

²¹ As discussed further *infra*, the ACA, in sections outside the Women’s Health Amendment, does provide one very specific exception to its broader coverage mandate, for grandfathered health plans. *See* 42 U.S.C. § 18011. The ACA insurance requirements also do not apply to employers with fewer than 50 employees. *See* 26 U.S.C. § 4980H(c)(2).

Nonetheless, the Agencies assert that they hold the authority to issue the far-reaching exemptions to the Contraceptive Mandate set out in the Final Rules. They argue that the statement “as provided for in comprehensive guidelines supported by [HRSA]” contemplates a broad delegation of authority, that permits the Agencies not only to define preventive care, but also the manner and reach of “preventive care” coverage. 42 U.S.C. § 300gg-13(a). Effectively, the Agencies’ argument is that the statute authorizes them to carve out, contrary to the express remits of the statute, categories of entities who need not provide preventive care coverage. But such a grant of authority is inconsistent with the statute’s text. Congress has already answered *who* must provide preventive care coverage: any “group health plan” or “health insurance issuer offering group or individual insurance coverage.” To permit the Agencies to disrupt this mandate contradicts the plain command of the text.

There are further textual reasons to doubt that the phrase “as provided for in comprehensive guidelines supported by [HRSA]” permits such an extensive delegation. True enough, the statute speaks to “*comprehensive* guidelines,” which suggests a broad scope. But the delicate term *support* undermines this contention: it strains credulity to say that by granting HRSA the authority to “support” guidelines on “preventive care,” Congress necessarily delegated to HRSA the authority to subvert the “preventive care” coverage mandate through the blanket exemptions set out in the Final Rules.

MCI Telecommunications Corp. v. American Telephone & Telegraph Co., 512 U.S. 218 (1994), is instructive. In that case, the Supreme Court rejected an agency’s assertion of authority—similar to the assertion here—to create exceptions to statutory requirements. *Id.* at 234. There, the statutory scheme at issue required that “[e]very common carrier . . . shall . . . file” tariffs, and also granted the Federal Communications Commission (“FCC”) the authority to

“modify any requirement made by or under the authority of this section.” *Id.* at 224 (quoting 47 U.S.C. § 203). The FCC asserted that the grant of authority to “modify” the statutory requirements permitted it to eliminate the filing requirement for certain entities altogether. The Supreme Court firmly rejected this view, finding that the FCC’s authority to “modify” statutory requirements did not allow the FCC to make “basic and fundamental changes” to the command of the statute. *Id.* at 225. In a passage particularly on point here, the Supreme Court reasoned that “[i]t is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to ‘modify’ rate-filing requirements.” *Id.* at 231.

The logic of *M.C.I.* compels the conclusion that Congress’s limited delegation to the Agencies does not include authority to create broad exemptions to the Contraceptive Mandate. In *M.C.I.*, the Court held that the agency could not create exceptions for statutorily mandated filing requirements—despite the fact that, there, the text explicitly authorized the agency to “modify” statutory requirements. Here, the statute presents no authority at all to “modify” or waive statutory requirements. As in *M.C.I.*, if Congress intended to grant the Agency such broad authority, it has the means available to it to do so. *See Whitman v. Am. Trucking Ass’n*, 531 U.S. 457, 468 (2001) (“Congress . . . does not . . . hide elephants in mouseholes.”).

Defendants argue to the contrary that the text and structure of the ACA permit the Agencies to issue the Final Rules, primarily thanks to the use of the word “as” in the Women’s Health Amendment. They note that the Women’s Health Amendment follows immediately after—and differs slightly from—another subsection of the ACA that speaks to preventive care coverage, for children. Specifically, the Women’s Health Amendment mandates coverage for

“preventive care and screenings . . . *as provided for in* comprehensive guidelines supported by [HRSA],” while the subsection pertaining to children mandates coverage for “preventive care and screenings *provided for in the* comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a)(3)–(4) (emphasis added). Proceeding from the statutory maxim that statutes “must be interpreted, if possible, to give each word some operative effect,” *Walters v. Metro. Educ. Enter., Inc.*, 519 U.S. 202, 209 (1997), Defendants conclude that the inclusion of the word “as” in the women’s subsection means that HRSA may determine not only the services covered by the ACA, but also the manner or reach of that coverage.

The impact of the word “as” in this instance can be determined by “look[ing] to dictionary definitions to determine the ordinary meaning of a word,” while bearing in mind that “statutory language must be read with reference to its statutory context.” *Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 200 (3d Cir. 2015) (internal quotation marks omitted). The term “as” in this context could mean “[u]sed in comparisons to refer to the extent or degree of something,” “[u]sed to indicate that something happens during the time when something else is taking place,” or “[u]sed to indicate by comparison the way that something happens or is done.” *As*, Oxford English Dictionary Online (January 2018), <https://en.oxforddictionaries.com/definition/as>.

Defendants argue for either the first or third of these definitions, asserting that the “as” here means something like “as you like it.” However, the statutory context indicates that the second definition is the most appropriate. When Congress passed the ACA, HRSA had already promulgated guidelines defining children’s preventive care. HRSA had not yet promulgated such guidelines for women’s preventive care. Thus, the ACA requires coverage “provided for in *the*” preexisting HRSA guidelines for children’s care. The use of the article “the” demonstrates that Congress referred to particular, extant guidelines governing children’s preventive care.

Giving effect to the use of the word “as” with regard to the Women’s Health Amendment leads to the conclusion that Congress used “as” here to indicate that the HRSA guidelines would be *forthcoming*, *i.e.* in anticipation of HRSA issuing guidelines—not to the conclusion that the ACA implicitly provides the Agencies with the authority to create exemptions.

Further, even if the word “as” is read to “indicate by comparison” the “extent,” “degree” or “way” the Agencies may promulgate guidelines, that definition does not help Defendants, for the following reason. The most natural comparison available in the statute—as Defendants recognize—would be to the pre-ACA children’s health preventive services guidelines. And comparing the children’s guidelines to the women’s guidelines ultimately undermines Defendants’ reading of the statute. That is because the children’s guidelines simply define a list of “preventive care” services—that is, *what* must be covered. *See* HHS, *Preventive Care Benefits for Children*, available at <https://www.healthcare.gov/preventive-care-children>. They do not include any exemptions to that coverage; indeed, the children’s guidelines do not speak at all to *who* must provide that coverage. And that makes sense because Congress already defined the *who*: any “group health plan” or “health insurance issuer offering group or individual insurance coverage”—the same plans that “shall” cover women’s preventive services without cost sharing. Thus if Congress employed “as” here to create a comparison to the children’s care guidelines, then Congress assuredly did not intend to permit HRSA to craft exemptions to the types of preventive care that would be required. Rather, Congress intended that HRSA would create a parallel set of guidelines, setting forth the types of “preventive care” to be covered, without exception.

The conclusion that the Women’s Health Amendment does not grant HRSA the power to create exemptions is bolstered by other provisions of the ACA. Congress created only a single

exemption from the ACA’s statutory mandate to cover women’s preventive care, for “grandfathered health plans.” 42 U.S.C. § 18011(e)(3). In accordance with the *expressio unius est exclusio alterius* principle, “[w]hen Congress provides exceptions in a statute . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth.” *United States v. Johnson*, 529 U.S. 53, 58 (2000). The fact that there is no religious or moral exemption in the explicit text of the statute, while there is an exemption for grandfathered health plans, militates against finding that Congress authorized the Agencies to create any additional exemptions. Indeed, that interpretation is supported by the legislative history, given that, in 2012, Congress explicitly rejected an attempt to add to the ACA an exemption similar to that contained in the Final Rules. *See* 158 Cong. Rec. S1165 (Mar. 1, 2012); *see also Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147 (2000) (rejection of an agency’s interpretation by Congress is a factor courts consider when determining the meaning of a statute).

For these reasons, the ACA prohibits HRSA from exempting entities from providing such coverage as set forth in the Final Rules. Accordingly, the Final Rules violate the APA and fail at *Chevron*’s Step One.

ii. RFRA

Defendants argue that, even if the ACA does not grant the Agencies authority to issue the Final Rules, RFRA independently enables the Agencies to issue the Final Religious Exemption.²² They assert that the Contraceptive Mandate cannot be brought into accord with RFRA by anything less than the provisions contained in the Final Religious Exemption, and that, as such,

²² It should be noted at the outset that Defendants specifically do not propound this argument with respect to the Final Moral Exemption. Nor could they. RFRA protects a person’s “exercise of religion,” and does not speak to broader moral convictions. 42 U.S.C. § 2000bb-1(a). Thus, because neither the ACA nor RFRA grant the Agencies the authority for it, the Final Moral Exemption must be invalidated.

RFRA “required” the promulgation of the rule. But it is the courts, not the Agencies, that determine RFRA’s reach. And the Final Religious Exemption goes far beyond RFRA’s command.

Congress enacted RFRA in 1993 following the Supreme Court’s decision in *Employment Div., Dep’t of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990). In *Smith*, the Supreme Court held that “the Constitution does not require judges to engage in a case-by-case assessment of the religious burdens imposed by facially constitutional laws,” and thus strict scrutiny did not apply to Free Exercise challenges to laws of general applicability. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2000). Prior to *Smith*, in decisions such as *Sherbert v. Verner*, 374 U.S. 398 (1963), courts employed “a balancing test that took into account whether the challenged action imposed a substantial burden on the practice of religion, and if it did, whether it was needed to serve a compelling government interest,” *Hobby Lobby*, 134 S. Ct. at 2760. With RFRA, Congress sought to restore the pre-*Smith* judicial standard. See 42 U.S.C. § 2000bb(b)(1) (stating that a purpose of the statute is “to restore the compelling interest test as set forth in *Sherbert v. Verner*, 374 U.S. 398 (1963) and *Wisconsin v. Yoder*, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened”); see also *Gonzales*, 546 at 424, 430-31.

In accordance with this goal, RFRA provides that the “Government shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability,” unless “it 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(a)-(b). Accordingly, RFRA has two components. First, the government is prohibited from placing a substantial

burden on religious exercise. If government action does not impose a substantial burden on religion, then RFRA is not implicated. However, if it does, the government action must be struck down unless it is the least restrictive means of furthering a compelling interest.

Despite Defendants' contention that the Agencies may determine what RFRA demands with respect to the ACA, RFRA provides, to the contrary, that it is the courts that are charged with determining RFRA's application. RFRA "explicitly provides a private cause of action," *Mack v. Warden Loretto FCI*, 839 F.3d 286, 301 (3d Cir. 2016), which permits an aggrieved individual to obtain "Judicial Relief," and contemplates them doing so in a "judicial proceeding," 42 U.S.C. § 2000bb-1(c). More specifically, RFRA states that, "[a] person whose religious exercise has been burdened . . . may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." *Id.* RFRA thus commits to the courts the task of determining whether generally applicable laws violate a person's religious exercise: "RFRA . . . plainly contemplates that *courts* would recognize exceptions—that is how the law works. . . . RFRA makes clear that it is the obligation of the courts to consider whether exceptions are required under the test set forth by Congress." *Gonzales*, 546 U.S. at 434 (emphasis in original).

Nevertheless, the Agencies contend that they are independently required to assess how RFRA bears on the Contraceptive Mandate and that their authority to promulgate the Final Religious Exemption flows from that obligation. In years past, the Agencies asserted that the accommodation did not impose a substantial burden on any entity's religious exercise and that guaranteeing cost-free contraceptive coverage did serve several compelling government interests. The Agencies now take the obverse positions: that the accommodation constitutes a substantial burden on the religious exercise of objecting employers and that the contraceptive mandate does

not serve “any compelling interest.” Indeed, they go further—arguing that this new set of views “in itself, is dispositive,” as a matter of law. In essence, they have taken on the quintessentially judicial tasks of determining whether the application of the Contraceptive Mandate to objecting entities constitutes a substantial burden, whether any burden was in furtherance of a compelling government interest, and whether the accommodation was the least restrictive means of accomplishing contraceptive coverage. Having taken on those tasks, the Agencies—based on their independent assessments of these legal questions—now claim that RFRA “requires” the Final Religious Exemption.

Their position is unsustainable for a number of reasons, the foremost being that administrative agencies may not simply formulate a view of a law outside their particular area of expertise, issue regulations pursuant to that view, claim that the law requires those regulations, then seek to insulate their legal determination from judicial scrutiny. It is axiomatic that under our constitutional system, “[i]t is emphatically the province and duty of the judicial department to say what the law is.” *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). Nothing about RFRA warrants departure from this general maxim. To the contrary, RFRA specifically provides only for “Judicial Relief,” 42 U.S.C.A. § 2000bb-1(c), thereby committing interpretative authority to the courts—not to agencies. *See Gonzales*, 546 U.S. at 434; *see also Real Alternatives, Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338, 356 (3d Cir. 2017) (“[I]t is for the reviewing court to determine whether a burden is ‘substantial.’”). Indeed, in the *Hobby Lobby* decision, the Supreme Court found that agency action violated RFRA, without ever suggesting that the agency’s interpretation was entitled to deference. *See Hobby Lobby*, 134 S. Ct. at 2775-85 (analyzing whether the Contraceptive Mandate violated RFRA, without discussion of deference to agency view); *see also* Thomas W. Merrill, *Step Zero After*

City of Arlington, 83 Fordham L. Rev. 753, 759 (2014) (“[T]he [Supreme] Court has never suggested that trans-substantive statutes like the Administrative Procedure Act (APA) or the Religious Freedom Restoration Act (RFRA) should be interpreted by giving deference to agency interpretations.”).

Nevertheless, Defendants cast their new legal contentions as reasonable policy decisions within their ambit of expertise. Of course, where a statute leaves gaps for an agency to fill, the agency may change its interpretation so long as it provides a “reasoned explanation for the change.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). However, what Defendants attempt to do here is not a change of interpretation regarding an ambiguous statute they are tasked with administering. Rather, Defendants are baldly asserting—with respect to a statute that does not explicitly delegate them any authority—what RFRA “requires.” Defendants have no expertise in administering RFRA. *See Gonzales*, 546 U.S. at 434; *see also Real Alternatives*, 867 F.3d at 356; *Iglesia Pentecostal Casa De Dios Para Las Naciones, Inc. v. Duke*, 718 F. App’x 646, 653 (10th Cir. 2017) (holding that the question of whether a RFRA violation exists is “a legal determination that Congress has not exclusively entrusted to” agencies) (internal quotation marks omitted). While Defendants may change course in their legal assessment of what RFRA commands, this is not the final word. Ultimately, it is up to the courts to decide.

It is true, as Defendants point out, that there is a great deal of “legal uncertainty” about RFRA’s precise application to the Contraceptive Mandate. But on the specific question presented here—whether RFRA “requires” the Final Religious Exemption—the law is clear.

To set out Defendants’ position in greater detail, yet another review of *Hobby Lobby* is in order. There, the Supreme Court held that “[t]he contraceptive mandate, as applied to closely

held corporations, violates RFRA.” 134 S. Ct. at 2785. The Supreme Court reasoned that the Contraceptive Mandate imposed a substantial burden on the religious exercise of the plaintiffs—closely held corporations—and that the burden was not the least restrictive means of providing contraceptive coverage to women. With specific regard to the least restrictive means element, the Supreme Court explained that the Agencies had already created a less restrictive means to both ensure women had contraceptive coverage and reduce the burden on religious objectors: the accommodation. *Id.* at 2781-82. As noted, the accommodation allowed eligible religious objectors to notify their healthcare administrator of their religious objection, and the administrator would then have to provide the legally required contraceptive services directly to women covered under the employer’s plan. Because the accommodation “[did] not impinge on the plaintiffs’ religious belief that providing insurance coverage for the contraceptives at issue here violates their religion,” and still accomplished the government’s goal of providing contraceptive coverage, the Supreme Court found that the Contraceptive Mandate, as applied to the plaintiffs, was not the least restrictive means, and thus violated RFRA. *Id.* at 2782. Importantly, the Supreme Court reserved on the question of “whether an approach of this type complies with RFRA for purposes of all religious claims.” *Id.* Following *Hobby Lobby*, in *Zubik*, the Supreme Court declined to decide the question of whether the accommodation itself imposed a substantial burden on plaintiff nonprofits’ religious exercise; instead, it remanded so that the parties might come to a resolution on their own, whereby the plaintiffs’ employees could receive contraceptive coverage without the plaintiffs’ having to submit the form required by the accommodation. 136 S. Ct. at 1559-60.

Based on these rulings, Defendants assert that RFRA “requires” the Religious Exemption, because their previous attempts to satisfy RFRA with the accommodation failed.

This theory rests on three legal conclusions: (1) a blanket exemption from the Contraceptive Mandate for religious objectors strays no further than RFRA demands; (2) the accommodation did not relieve the substantial burden identified by the Supreme Court in *Hobby Lobby*; and, (3) the contraceptive mandate imposes a substantial burden on publicly traded corporations. But each of these views is either incorrect under the law—as previously determined by precedential rulings—or a significant extension of existing doctrine. Accordingly, Defendants have stepped beyond the demands of RFRA, and the Final Religious Exemption cannot be justified as a “requirement” of RFRA.

As to the first conclusion—that a blanket exemption for religious objectors goes no further than RFRA demands—a close read of *Hobby Lobby* demonstrates that the Agencies’ conclusion is incorrect. There, the Supreme Court explained that an exemption akin to the Final Religious Exemption goes beyond RFRA’s requirements. 134 S. Ct. at 2775 n.30. More specifically, prior to enacting the ACA, Congress had considered but ultimately voted down a ‘conscience amendment,’ which, like the Final Religious Exemption, enabled an employer or insurance provider to deny coverage based on its asserted religious beliefs. *Id.* The *Hobby Lobby* majority concluded it was “reasonable to believe that” Congress rejected the amendment because such a “blanket exemption” for religious objectors “extended more broadly than the . . . protections of RFRA.” *Id.* That is because “it would not have subjected religious-based objections to the judicial scrutiny called for by RFRA, in which a court must consider not only the burden of a requirement on religious adherents, but also the government’s interest and how narrowly tailored the requirement is.” *Id.* Thus, as the *Hobby Lobby* Court recognized, the blanket exemption the Agencies have set forth “extend[s] more broadly than the . . . protections of RFRA.” Plainly then, RFRA cannot “require” such a rule, which creates precisely this blanket

exemption.

As to the second conclusion—that the accommodation imposes a substantial burden on the religious exercise of objecting entities—Defendants are incorrect under the law of this circuit. While the Supreme Court has not resolved this precise issue, Third Circuit authority demonstrates that, contrary to the Agencies’ view, the accommodation does *not* impose a substantial burden. See *Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015), *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam); see also *Real Alternatives*, 867 F.3d at 356 n.18. The accommodation has been specifically upheld against a RFRA challenge by the Third Circuit, first, and directly, in *Geneva Coll.*, 778 F.3d at 442, and second, by implication, in *Real Alternatives*, 867 F.3d at 356 n.18. Defendants argue that *Geneva* is no longer good law because it was vacated by the Supreme Court in *Zubik*. But the Supreme Court in *Zubik* specifically declined to decide the merits of the RFRA challenge to the accommodation, by explicitly refraining from “decid[ing] whether petitioners’ religious exercise has been substantially burdened.” 136 S. Ct. at 1560. Instead, the Supreme Court vacated *Geneva* (and related decisions from other Circuit courts) and remanded for the express purpose of allowing the parties “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans receive full and equal health coverage, including contraceptive coverage.” *Id.*

Following *Zubik*, the Third Circuit reiterated in *Real Alternatives* that it “continue[s] to believe . . . that the regulation at issue”—the accommodation—“did not impose a substantial burden.” *Real Alternatives*, 867 F.3d at 356 n.18. Defendants characterize this statement as dicta, and indeed, the issues in the two cases were slightly distinct. In *Geneva*, nonprofits

eligible for the accommodation asserted that filling out the accommodation form “facilitated” or “triggered” the provision of contraceptives, thereby substantially burdening their religious exercise. 778 F.3d at 427. In *Real Alternatives*, employees of a secular employer similarly asserted that the Contraceptive Mandate violated RFRA because their purchase of insurance enabled the provision of contraceptives. 867 F.3d at 359. What Defendants overlook is that in *Real Alternatives* the Third Circuit reaffirmed and reapplied the reasoning of *Geneva*. In both cases, the Third Circuit found that there was no substantial burden on the plaintiffs’ religious exercise because their actions were insufficiently related to the provision of contraceptives and “an independent obligation on a third party can[not] impose a substantial burden on the exercise of religion in violation of RFRA.” *Id.* at 364 (quoting *Geneva*, 778 F.3d at 440-41).

Accordingly, applying the law of this circuit as announced in *Real Alternatives*, the accommodation does not impose a substantial burden on religious exercise.

The third conclusion—that the Contraceptive Mandate imposes a substantial burden on the religious exercise of publicly traded corporations—goes considerably beyond existing jurisprudence. In *Hobby Lobby*, the Supreme Court found that the Contraceptive Mandate imposed a substantial burden on the specific plaintiffs in that case: “closely held corporations, each owned and controlled by members of a single family.” 134 S. Ct. at 2774. It explicitly declined to extend its holding to publicly traded corporations, suggesting that publicly traded corporations would be unlikely to hold a singular, sincere religious belief:

These cases, however, do not involve publicly traded corporations, and it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable. In any event, we have no occasion in these cases to consider RFRA’s applicability to

such companies.

Id. Defendants assert that it is reasonable to include publicly traded corporations in the Religious Exemption. But, as *Hobby Lobby* makes clear, RFRA does not “require” this expansion.

Thus, even if the Agencies are correct that the accommodation imposes a substantial burden on religious employers, and that they must act, through regulation, to relieve that burden,²³ the Final Religious Exemption sweeps further than RFRA would require. The Agencies’ willingness to exceed the bounds of existing case law demonstrates that the Agencies have cast aside RFRA’s mandate for “judicial scrutiny . . . in which a *court* must consider not only the burden of a requirement on religious adherents, but also the government’s interest and how narrowly tailored the requirement is.” *Id.* at 2775 n.30 (emphasis added). Accordingly, the

²³ Defendants contend that the Final Rules—like earlier rules that created the exemption and accommodation framework—are merely the Agencies’ attempts to respond to the Supreme Court’s decisions in *Hobby Lobby*, *Wheaton College*, and *Zubik*. After each of those decisions, the Agencies promulgated generally applicable regulations that expanded or modified the exemption and accommodation framework in an attempt to bring the Agencies’ actions in line with what the Supreme Court said RFRA commands. According to Defendants, that is all that is happening here, the only difference being the States have now challenged the Agencies’ authority to do so.

Fair enough. Nonetheless, this challenge raises a fundamental question: whether RFRA grants agencies independent authority to issue regulations of general applicability, like the Final Religious Exemption. It is worth noting that the scope of affirmative authority, if any, that RFRA grants to agencies to issue regulations of general applicability—whether in response to judicial interpretations of RFRA or based on their own assessments of RFRA’s application—is distinctly undetermined. Neither *Hobby Lobby*, nor *Wheaton College*, nor *Zubik* resolved this question—nor, does it appear, has any other court. The statutory language does not provide a clear answer. On the one hand, RFRA “applies to all Federal law, and the implementation of that law, whether statutory or otherwise,” which could possibly be read to grant agencies some authority to promulgate regulations on a generalized basis. 42 U.S.C. § 2000bb-3(a) (emphasis added). However, RFRA is fundamentally a remedial measure, that by its terms “provide[s] a claim or defense to persons whose religious exercise is substantially burdened by government,” *id.* at § 2000bb(b)(2), in a “judicial proceeding” in order to “obtain appropriate relief against a government,” *id.* at § 2000bb-1(c) (emphasis added). See also *Hobby Lobby*, 134 S. Ct. at 2775 n.30; *Gonzales*, 546 U.S. at 430-31, 434. Indeed, quite recently, the federal government suggested that RFRA does not permit an agency to create exemptions to regulations absent a judicial determination, albeit in a case that did not focus on this issue in great depth. See *Iglesia Pentecostal*, 718 F. App’x at 653 (recounting federal government’s position that “[a]bsent a judicial finding that the regulation violates RFRA, neither the director of USCIS nor the AAO has any discretion to set aside any provision of those regulations.”) (brackets omitted).

Put simply, it is not clear what, if any, affirmative authority RFRA grants to agencies to issue regulations of general applicability. The parties do not point to any authority that resolves this question. Nor has independent research yielded definitive answers. While this large question looms in the background, the Court need not decide it here. Whatever the extent of an agency’s authority under RFRA, the Agencies here have exceeded it in promulgating the Final Religious Exemption.

Religious Exemption cannot be justified under RFRA.

Because neither the ACA nor RFRA confer authority on the Agencies to promulgate the Religious Exemption, the rule is invalid.²⁴

* * *

In light of these conclusions, the States have demonstrated an adequate likelihood of success on the merits in support of their motion for preliminary relief.

3. Irreparable Harm

The second factor to consider in deciding the States' motion is whether they have demonstrated that they are likely to suffer irreparable harm in the absence of a preliminary injunction. The Supreme Court's "frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original); *see id.* ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with the characterization of injunctive relief as an extraordinary remedy that may be awarded only upon a clear showing that the plaintiff is entitled to such relief."). The States assert that they will suffer two forms of irreparable harm in the absence of an injunction: (1) significant damage to the States' fiscal integrity; and (2) harm to the health, safety, and wellness of the women of Pennsylvania and New Jersey. The Court finds both sufficient to justify preliminary relief.

As to the harm to the States' fiscal integrity, the States' evidence demonstrates that it is likely that the Final Rules will cause direct and irreparable harm. The States will become

²⁴ Given its holding that Defendants violated the procedural and substantive provisions of the APA in issuing the Final Rules, and in view of the admonition that "courts should be extremely careful not to issue unnecessary constitutional rulings," *American Foreign Serv. Ass'n v. Garfinkel*, 490 U.S. 153, 161 (1989) (per curiam), it is unnecessary to proceed to the constitutional issues. Similarly, because the Final Rules violate the substantive provisions of the APA for the reasons given, there is no need to reach the States' other statutory challenges to the Final Rules.

obligated to shoulder much of the burden of providing contraceptive services to women who lose contraceptive care because their health plans take advantage of the expanded exemptions contained in the Final Rules. *See* Steinberg Decl. ¶¶ 27-29 (discussing Pennsylvania); Geenace Decl. ¶¶ 15-17 (discussing New Jersey). Such women will seek contraceptive services elsewhere and, as Defendants noted in issuing the IFRs, may turn to “multiple . . . State[] and local programs that provide free or subsidized contraceptives for low-income women” for alternative coverage. *See* 82 Fed. Reg. at 47,803. In Pennsylvania, these state funded programs include: Medicaid, called “Medical Assistance;” the Family Planning Service Program; and the Commonwealth’s network of clinics funded under the Title X grant program. *See* Allen Decl. ¶¶ 3-18; Steinberg Decl. ¶ 16. New Jersey funds similar programs through Medicaid, known as “NJ Family Care,” and the State’s Plan First Program. Adelman Dec. ¶¶ 9-14. As women in the States lose contraceptive coverage through their health insurance plans and turn to state-funded programs, it is likely that the States will bear the added financial burden occasioned by the increase in women who need contraceptive care coverage. *See* Mendelsohn Decl. ¶¶ 15-18; Allen Decl. ¶ 23; Geenace Decl. ¶¶ 15-18.

The States’ harm is not merely speculative; it is actual and imminent. The Final Rules estimate that at least 70,500 women will lose coverage. *See* 83 Fed. Reg. at 57,578.²⁵ Thus, the only serious disagreement is not whether the States will be harmed, but *how much*. Though Defendants argue that the States have not identified any individual who has lost coverage already, there is no need to wait for the axe to fall before an injunction is appropriate, particularly where Defendants have estimated that it is about to fall on thousands of women—and, as a corollary, on the States. *See Texas*, 809 F.3d at 186 (granting relief based on predicted

²⁵ The States argue that there is reason to believe the number is significantly higher because organizations taking advantage of the exemption need not inform the Agencies of their plan to do so.

harm to States' fiscs).

While “loss of money” is generally insufficient to merit a preliminary injunction, *see Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989), here, the harm to the States' fiscs is irreparable because they will not be able to recover any economic damages that result from the Final Rules. That is because a party—like the States here—which alleges an APA violation may not recover monetary damages from the federal government on that claim. *See* 5 U.S.C. § 702 (permitting relief “other than money damages”); *California*, 911 F.3d at 581 (finding irreparable harm in APA case on similar grounds). Therefore, if the Final Rules are ultimately struck down as violative of the APA, the States will not be able to recoup any money they expend on contraceptive care in the interim. In such circumstances, a preliminary injunction is appropriate. *See, e.g., N.J. Retail Merchants Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012) (holding that a preliminary injunction is appropriate where a movant could not recover damages from a State due to sovereign immunity).

In addition to pecuniary harm, the States also stand to suffer injury to their interest in protecting the safety and well-being of their citizens. *See Alfred L. Snapp*, 458 U.S. at 607 (observing that a State has a “quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general”). The States' witnesses explained that employers taking advantage of the Final Rules will result in more women losing no-cost contraceptive coverage. Mendelsohn Decl. ¶¶ 14-15; Adelman Decl. ¶ 20. As a result, women will likely forgo contraceptive services or seek out less expensive and less effective types of contraceptive services in the absence of no-cost insurance coverage. Weisman Decl. ¶¶ 45-48; Chuang Decl. ¶¶ 36-39; *see also* Adam Sonfield, *What is at Stake with the Federal Contraceptive Coverage Guarantee?*, 20 Guttmacher Policy Review 8, 9 (2017) (reporting that women cite cost as a

significant factor in determining whether to purchase contraceptive services and which contraceptive services to use). Disruptions in contraceptive coverage will lead to women suffering unintended pregnancies and other medical consequences. Butts Decl. ¶¶ 57-59; Institute of Medicine, *Clinical Prevention Services* at 107 (explaining that contraceptive services are used to treat menstrual disorders, acne, hirsutism, and pelvic pain, in addition to assisting family planning and birth spacing).²⁶ The negative effects of even a short period of decreased access to no-cost contraceptive services are irreversible.

The States have therefore showed that they are likely to suffer irreparable harm as a result of the Rules' impact on both the States' fiscs and the welfare of the States' citizens.

4. Balance of the Equities

The third factor is that the balance of the equities tips in favor of granting a preliminary injunction. “Balancing the equities” is jurisprudential “jargon for choosing between conflicting public interests.” *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1943) (Frankfurter, J., concurring). Here, Congress has already struck the balance: the Women’s Health Amendment was intended to ensure women received no-cost coverage for preventive services, which includes contraceptives. As lead sponsor of the Women’s Health Amendment, Senator Barbara Mikulski, explained: the amendment “leaves the decision of which preventive services a patient will use between the doctor and the patient.” 155 Cong. Rec. S11988 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). Congress enacted the Women’s Health Amendment to guarantee that “the decision about what is medically appropriate and medically necessary is between a woman and her doctor.” *Id.* Where “Congress itself has struck the balance, [and] has

²⁶ Increased unplanned pregnancies will also inflict additional pecuniary harm on the States. See Steinberg Decl., ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

defined the weight to be given the competing interests, a court of equity is not justified in ignoring that pronouncement under the guise of exercising equitable discretion.” *Youngstown Sheet*, 343 U.S. at 609-10.

Here, given the States’ clear interest in securing the health and well-being of women residents and limiting their costs for contraceptive services, the balance of the equities weighs in their favor. Defendants will not be substantially prejudiced by a preliminary injunction. If the Final Rules were issued in violation of applicable law, they will have suffered no harm. If Defendants ultimately prevail, then a preliminary injunction will have merely delayed their preferred regulatory outcome.

5. Public Interest

“If a plaintiff proves both a likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interests favors preliminary relief.” *Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 143 (3d Cir. 2017) (internal quotation marks omitted). So it proves here. A preliminary injunction is unquestionably in the public interest because it maintains the status quo pending the outcome of this litigation. The Final Rules permit any entity to opt out of coverage after 30 to 60 days’ notice to plan members. This litigation will not conclude in that short span. A preliminary injunction will maintain the status quo: those eligible for exemptions or accommodations prior to October 6, 2017 will maintain their status; those with injunctions preventing enforcement of the Contraceptive Mandate will maintain their injunctions;²⁷ those alleging RFRA violations may pursue “Judicial Relief;” and those with coverage will maintain their coverage as well.

²⁷ For example, Defendant-Intervenor has secured a permanent injunction, preventing enforcement of the Contraceptive Mandate against it. *See Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611, Dkt. 82 (D. Colo. May 29, 2018). Nothing in this Court’s ruling will disturb that order.

D. Remedy

Before concluding, an additional word is required on the scope of the preliminary injunction to be issued. When the IFRs were initially before this Court, they were enjoined generally, without any specific geographic or temporal limitation. *See Pennsylvania*, 281 F. Supp.3d at 585.

Since then, however, much has been made about the propriety (or impropriety) of so-called nation-wide injunctions. *See, e.g., Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring); Zayn Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. 2095 (2017); Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev. 417 (2017). In light of this increased focus on the proper exercise of district courts' remedial powers, it is prudent to explain in some detail why a nation-wide injunction is appropriate here.

First, it is well established that a district court sitting in equity has the *authority* to enter a nation-wide injunction. *See Lemon v. Krentler-Arnold Hinge Last Co.*, 284 U.S. 448, 451 (1932) (holding district court's order "binding upon the respondent, not simply within the District of Massachusetts, but throughout the United States"); *Texas*, 809 F.3d at 188 ("[T]he Constitution vests the District Court with 'the judicial power of the United States.' That power is not limited to the district wherein the court sits but extends across the country.") (quoting U.S. Const. art. III, § 1); *McLendon v. Cont'l Can Co.*, 908 F.2d 1171, 1182 (3d Cir. 1990) (holding "[f]ull relief required a nationwide injunction"). The issue, then, is whether a nation-wide injunction is appropriate here, given the facts of this specific case.

"In shaping equity decrees, the trial court is vested with broad discretionary power." *Lemon v. Kurtzman*, 411 U.S. 192, 200 (1973) (plurality opinion). That is because crafting

equitable remedies is an inexact science; instead, “equitable remedies are a special blend of what is necessary, what is fair, and what is workable.” *Id.*; *see also Trump v. Int’l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (“Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents.”). As Justice Douglas succinctly put it seventy-five years ago: “[t]he essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it.” *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944).

The Supreme Court articulated the relevant standard for determining the proper scope of a preliminary injunction in *Califano v. Yamasaki*, 442 U.S. 682 (1979), stating that “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.” *Id.* at 702 (emphasis added). Subsequent Supreme Court and lower court decisions have treated the “no more burdensome than necessary” rubric as the “general rule” for determining whether an injunction is overbroad. *Madsen v. Women’s Health Center, Inc.*, 512 U.S. 753, 765 (1994); *see also Trump*, 137 S. Ct. at 2090 (Thomas, J., concurring in part and dissenting in part); *see also McLendon*, 908 F.2d at 1182 (“In granting injunctive relief, the court’s remedy should be no broader than necessary to provide full relief to the aggrieved plaintiff.”).²⁸

The *Califano* standard requires district courts to balance the competing principles of providing complete relief to meritorious plaintiffs against a defendant’s right to be free from overly burdensome injunctions. The complete relief requirement reflects the “well-settled principle that the nature and scope of the remedy are to be determined by the violation.”

²⁸ In *Califano*, the Court indicated that the “no more burdensome than necessary” standard is a general rule of injunctions, regardless of whether a nation-wide class-action is certified. *See* 442 U.S. at 702.

Milliken v. Bradley, 433 U.S. 267, 281-82 (1977). Where a violation has been found, “the remedy does not ‘exceed’ the violation if the remedy is tailored to cure the ‘condition that offends [the law.]’” *Id.* at 282 (quoting *Milliken v. Bradley*, 418 U.S. 717, 738 (1974)).

The complete relief principle explains why, in APA cases, “when a reviewing court determines that agency regulations are unlawful, the *ordinary result* is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Nat’l Min. Ass’n v. U.S. Army Corps of Eng’rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (internal quotation marks omitted and emphasis added). Where “agency action . . . consist[s] of a rule of broad applicability” that violates the strictures of the APA, *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 913 (Blackmun, J., dissenting),²⁹ a remedy “tailored to cure the condition that offends [the law]” may be correspondingly broad, *Milliken*, 433 U.S. at 282 (internal quotation marks omitted). Thus, when an individual challenges agency action and prevails, “the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual.” *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting).³⁰ Put differently, the national character of an APA violation “ordinar[ily]” demands a national remedy. *Nat’l Min. Ass’n*, 145 F.3d at 1409.

At the same time, the Supreme Court has warned that injunctions should be “no more burdensome to the defendants than necessary.” *Califano*, 442 U.S. at 702. Over fifty years ago, Justice Fortas cautioned:

[A]rming each of the federal district judges in this Nation with power to enjoin enforcement of regulations and actions under the federal law designed to protect the people of this Nation. . . is a general hunting license; and I respectfully submit, a license for mischief because it authorizes aggression

²⁹ In *Nat’l Min. Ass’n*, the D.C. Circuit explained that, while Justice Blackmun’s observations came in a dissent, they “apparently express[ed] the view of all nine Justices on this question.” 145 F.3d at 1409.

³⁰ Indeed, at least one scholar has argued that the language of the APA—providing that a reviewing court “shall . . . hold unlawful and set aside” agency action that is arbitrary or capricious, 5 U.S.C. § 706—requires courts to vacate all unlawful agency actions. See Brian S. Prestes, *Remanding Without Vacating Agency Action*, 32 Seton Hall L. Rev. 108, 110 (2001).

which is richly rewarded by delay in the subjection of private interests to programs which Congress believes to be required in the public interest.

Toilet Goods Ass'n v. Gardner, 387 U.S. 167, 183 (1967) (Fortas, J., dissenting). More recently, the Supreme Court has warned that overbroad injunctions “have detrimental effect[s] by foreclosing adjudication by a number of different courts and judges,” which “often will be preferable in order to gain the benefit of adjudication by different courts in different factual contexts.” *Califano*, 442 U.S. at 701-02; *California*, 911 F.3d at 583 (raising same concern). In addition, courts worry that overly broad injunctions invite “forum shopping, which hinders the equitable administration of laws.” *California*, 911 F.3d at 583 (citing Bray, *Multiple Chancellors*, 131 Harv. L. Rev. at 458-59).

The concerns about overbroad injunctions carry into APA cases. Courts have, at times, resisted granting nation-wide relief, even where “agency action . . . consist[s] of a rule of broad applicability.” *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting); *see, e.g., California*, 911 F.3d at 584 (finding an APA violation, but concluding “the scope of the preliminary injunction is overbroad”); *Baeder v. Heckler*, 768 F.2d 547, 553 (3d Cir. 1985) (holding regulation invalid, but determining district court did not have “the authority to issue an injunction aimed at controlling [Agency’s] behavior in every . . . case in the country”). Thus, while an APA violation may “ordinar[ily]” result in a nation-wide remedy, the potential dangers of an overbroad injunction must still be weighed when crafting a remedy for an APA violation.

The upshot is that striking the appropriate balance between providing complete relief to meritorious plaintiffs, on the one hand, and protecting defendants from overly burdensome injunctions, on the other, is necessarily a difficult line-drawing exercise, even in APA cases.

To see why, recall the injury the States stand to suffer from enforcement of the Final Rules: both Pennsylvania and New Jersey complain that, because enforcement of the Final Rules

will result in “numerous insureds—and their female dependents—[losing] the medical coverage for contraceptive care required by the Affordable Care Act,” the States will suffer “significant, direct and proprietary harm” in the form of increased use of state-funded contraceptive services as well as increased costs associated with unintended pregnancies. Affording complete relief to the States would require the Court to enjoin enforcement of the Final Rules as to all entities that “offer[] and arrange[]” health insurance to insureds residing in Pennsylvania or New Jersey.³¹

But drafting—much less enforcing—a preliminary injunction that runs only to those entities is nigh impossible. Neither the Court nor the parties can readily ascertain what those entities are or whether they intend to take advantage of the exemption, given that providing notice to the Agencies is only optional under the Final Rules. At the same time, the Court cannot, consistent with Rule 65 of the Federal Rules of Civil Procedure simply and broadly enjoin “all entities that offer and arrange health insurance to insureds residing in Pennsylvania or New Jersey.” That is because “[e]very order granting an injunction . . . must . . . state its terms specifically and describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained.” Fed. R. Civ. P. 65 (internal punctuation omitted).

Given the challenges associated with crafting a “perfect” injunction, district courts tend to rely on geographic proxies when tailoring a remedy. For example, the Ninth Circuit—hearing an appeal from a district court decision that also enjoined the enforcement of the IFRs nationwide—held that “an injunction that applies only to the plaintiff states would provide complete relief to them.” *California*, 911 F.3d at 584; *see also California v. Health & Human Servs.*, ---

³¹ Even that may not provide complete relief because a non-resident that lost contraceptive coverage may try to take advantage of the States’ programs. *Cf. Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2304 (2016) (explaining that, following the enactment of a Texas regulation that would force the closure of abortion clinics in west Texas, “the Court of Appeals said that women in El Paso wishing to have an abortion could use abortion providers in nearby New Mexico”).

F. Supp. ---, No. 17-cv-5783, ECF No. 234 (N.D. Cal. 2019) (enjoining enforcement of Final Rules within plaintiff States only). Defendants similarly argue that, if the Final Rules are to be enjoined, then the injunction should be limited to Pennsylvania and New Jersey.

The problem with the Ninth Circuit’s approach, however, is that it simply does not afford the meritorious plaintiffs—the States—complete relief. Hundreds of thousands of the States’ citizens travel across state lines—to New York, Ohio, Delaware, Maryland, West Virginia and even further afield—to work for out-of-state entities. *See Amici Curiae Brief of Massachusetts, et al. in Support of Plaintiffs’ Motion for a Preliminary Injunction*, at 13-14 (2019) (noting that “548,040 New Jersey residents, or 14% of the workforce, and 299,970 Pennsylvania residents, or 5.4% of the workforce” travel to jobs in other states) (citing U.S. Census Bureau, *Out-of-State and Long Commutes: 2011, American Community Survey Reports*, at 10 (Feb. 2013), available at <https://www2.census.gov/library/publications/2013/acs/acs-20.pdf>). Furthermore, with their many universities and educational institutes, the States take in tens of thousands of out-of-state students each year. *Id.* at 14 (noting that Pennsylvania takes in 32,000 out-of-state students alone) (citing Nat’l Ctr. for Education Statistics, *Residence and Migration of All First-Time Degree/Certificate-Seeking Undergraduates* (2017), available at https://nces.ed.gov/programs/digest/d17/tables/dt17_309.20.asp?current=ye).

An injunction limited to Pennsylvania and New Jersey would, by its terms, not reach Pennsylvania and New Jersey citizens who work for out-of-state employers. Despite residing in the States, those out-of-state workers could lose contraceptive coverage if the out-of-state employers took advantage of the exemptions included in the Final Rules, resulting in proprietary harm to the States. Nor would an injunction limited to the States cover out-of-state students attending school in Pennsylvania and New Jersey, who may not be considered “residents” of the

States. Such students, by remaining on their parents' out-of-state employer-based health plans or other health insurance through their State of "residency," could lose contraceptive coverage but still turn to in-state publicly-funded clinics for contraceptive coverage. Put differently, "an injunction that applies only to the plaintiff states" *would not* "provide complete relief to them" because it *would not* "prevent the economic harm extensively detailed in the record." *California*, 911 F.3d at 584.

Injunctions that are intermediate in geographic scope—that is, applicable beyond the States but not nation-wide—encounter the same problems in ensuring "complete relief to the plaintiffs." *Madsen*, 512 U.S. at 765. An injunction limited to the Third Circuit, for example, would fail to account for the thousands of Pennsylvania and New Jersey citizens that commute to neighboring or nearby states outside the Third Circuit for work. Similarly, an injunction covering the surrounding states would not account for the fact that the States draw out-of-state students from across the nation.

At the same time, the Court recognizes that, on the record before it, a nation-wide injunction may prove "broader than necessary to provide full relief" to the States. *McLendon*, 908 F.2d at 1182. The States concede, for example, that there is no evidence that any citizen of the States physically commutes to New Mexico, so an injunction that covers the Land of Enchantment appears "broader than unnecessary." Nor have the States presented evidence of a New Mexican that currently attends a Pennsylvania or New Jersey institute of higher learning, who may lose her contraceptive coverage through her out-of-state insurance. The same can be said for a host of other states.

Ultimately, crafting a remedy that provides "complete relief to the plaintiffs," while being "no more burdensome to the defendant than necessary" would require empirical data—the

working conditions of each and every citizen of the States—that is simply not ascertainable.³² In the absence of such information, the Court must exercise “discretion and judgment,” *Trump*, 137 S. Ct. at 2087, in balancing the competing risks and uncertainties associated with either a potentially under- or over-inclusive remedy, bearing in mind the maxim that “[w]e should not allow the infeasible perfect to oust the feasible good.” *Resorts Int’l Hotel Casino v. NLRB*, 996 F.2d 1553, 1558 (3d Cir. 1993) (internal quotation marks and alternations omitted).

On balance, the Court finds that, in this case, potential over-inclusiveness is the more prudent route. For one, anything short of a nation-wide injunction would likely fail to provide the States “complete relief.” *Cf. Texas*, 809 F.3d at 188 (“[T]here is a substantial likelihood that a geographically-limited injunction would be ineffective because DAPA beneficiaries would be free to move among states,” which would leave Texas open to potential injury); *see also Siddique, Nationwide Injunctions*, 117 Colum. L. Rev. at 2146-47 (“If one agrees with the district court that Texas suffers some injury from having deferred action beneficiaries within its territorial boundaries, the only way to afford *complete* relief to Texas and prevent any deferred action beneficiaries from making their way to Texas is by enjoining the grant of deferred action nationwide.”). While a nation-wide injunction may prove overbroad, there is no more geographically limited injunction that protects the States from potential harm.

Second, it is far from clear how burdensome a nation-wide injunction would be on Defendants, given that when “agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Nat’l Min. Ass’n*, 145 F.3d at 1409.

³² This is neither an explicit or implicit critique of the parties. Rather, it is the frank observation that crafting a perfect remedy would require information that would be insurmountable to gather and maintain.

Third, one of the risks associated with a nation-wide injunction—namely, “foreclosing adjudication by a number of different courts,” *Califano*, 442 U.S. at 701-02—is not necessarily present here, as the parallel litigation in the Ninth Circuit evidences. *See also* Spencer E. Amdur & David Hausman, *Nationwide Injunctions and Nationwide Harm*, 131 Harv. L. Rev. F. 49, 53 n.27 (2017) (noting that “in practice, nationwide injunctions do not always foreclose percolation,” and giving several recent examples).

Fundamentally, given the harm to the States should the Final Rules be enforced—numerous citizens losing contraceptive coverage, resulting in “significant, direct and proprietary harm” to the States in the form of increased use of state-funded contraceptive services, as well as increased costs associated with unintended pregnancies—a nation-wide injunction is required to ensure complete relief to the States.

An appropriate order follows.

January 14, 2019

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.