UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY, Plaintiffs, v. DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA. Defendants.	**No. 2:17-cv-04540-WB**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

One year ago, this Court ruled that the federal Defendants in this action had violated the law in issuing sweeping new exemption rules that would deny women across the country access to legally protected preventive healthcare.[1] The Court found that the government had failed to follow the legal requirements of the Administrative Procedure Act in issuing the rules and had violated the clear mandate of the Affordable Care Act by allowing employers and other health plan sponsors to deny women access to contraception without imposing additional costs.[2] It further found that the rules would cause "serious and irreparable harm" to the Commonwealth of Pennsylvania and, as a result, issued a preliminary injunction preventing their further implementation.[3] Several days after this Court acted, a judge hearing a similar challenge to the rules entered a second injunction blocking them, agreeing with this Court that they were issued in violation of the APA.[4] That finding was recently affirmed.[5]

Rather than heed the direction of two federal courts, the federal Defendants chose simply to try again. Thirteen months after announcing the rules that this Court had enjoined, they issued final rules that, they claimed, reflected comments received in the interim.[6] But despite the

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[1] *See* Opinion, ECF No. 59, *Pennsylvania v. Trump*, No. 17-4540, 281 F. Supp. 3d 553 (E.D. Pa. 2018) ("PI Op."). Specifically, the Court found that the Commonwealth was "likely to succeed" on its claims that the federal Defendants had violated the law. 281 F. Supp. 3d at 585.

[2] 281 F. Supp. 3d at 576, 581.

[3] 281 F. Supp. 3d at 585.

[4] *California v. HHS*, 281 F. Supp. 3d 806 (N.D. Cal. 2017).

[5] *California v. Azar*, No. 18-15144, 2018 WL 6566752 (9th Cir. Dec. 13, 2018).

[6] *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,536 (Nov. 15, 2018) (the "final Religious Exemption Rule") (Exh. A); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (the "final Moral Exemption Rule") (Exh. B) (together, the "final Rules").

passage of time since this Court's previous decision, nothing in the final rules suggested that Defendants had seriously tried to address the deficiencies identified by this Court. They did not, for instance, withdraw the interim rules and engage in notice and comment rulemaking with respect to the final rules, as required by the APA. They did not strive to find a way to accommodate the religious beliefs of objectors while "ensuring that women . . . receive full and equal health coverage, including contraceptive coverage," as the Supreme Court had instructed. *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016) (citation and internal quotation marks omitted). And they did not grapple with the "serious and irreparable harm" that would be caused by the rules, not merely to the Commonwealth and its residents, but to women across the country.

Instead, the federal Defendants compounded their previous mistakes. They exempted more employers from the contraceptive mandate, thus ensuring that more women would lose access to essential preventive healthcare. They blithely dismissed the many serious concerns that had been raised in comments submitted on the interim rules, including comments submitted by women, medical professionals, and experts on contraception. They did, however, acknowledge one serious error in the interim rules: they admitted that their estimate that the rules would impact at least 31,700 women was wrong; instead, the correct minimum number was closer to 70,500. *Compare* 83 Fed. Reg. at 57,578, *with* 82 Fed. Reg. at 47,821. After accusing Pennsylvania of engaging in "pure speculation" for alleging that women would be harmed by the rules and that government-funded programs would be burdened as a result,[7] they now concede that their own prior estimates misjudged the harm they would cause by a factor of two. Rather than acknowledging that this error was the inevitable result of a rushed and haphazard process

[7] *See* Defs.' Mem. in Opp. to Pls.' Mot. for Prelim. Inj., ECF No. 15, at 15 (Nov. 16, 2017).

driven by political considerations, they instead decided to press ahead—and as a result, their new estimates instill little additional confidence that they have come to grips with the true scope of harm the rules will cause.

Unchanged throughout this process is the truth that, for women, contraception is necessary preventive healthcare. Contraception is necessary for women to be able to aspire, achieve, participate in and contribute to society based on their individual talents and capabilities. Indeed, in order to have equal opportunities at work, at school, and in the public sphere, women need to be able to control when and if they become mothers. For many, contraception is an economic lifeline. For some, it is lifesaving medicine. And under the Affordable Care Act, it is a legal obligation. Defendants continue to callously disregard this obligation, and women in Pennsylvania and New Jersey—and across the country—will suffer serious consequences as a result. Those consequences will cause harm to not just the women affected, but their families, their communities, and to state taxpayers who will bear the burden of providing the essential care that these women no longer receive from their employers or schools.

Because the federal Defendants still do not grasp these basic facts, the Commonwealth of Pennsylvania and the State of New Jersey respectfully request that this Court enter an injunction preventing the implementation of the final rules.

BACKGROUND

The factual and legal background of this case is set forth in the Court's earlier opinion and in the previous motion for a preliminary injunction filed on November 2, 2017. *See* Mem. of Law in Supp. of Pl.'s Mot. for Prelim. Inj., ECF No. 8-2 ("First PI Mot.") (Exh. E). Pennsylvania and New Jersey incorporate by reference the discussion and arguments made in that earlier motion, which is attached as an exhibit for the Court's convenience. This memorandum

summarizes these earlier arguments but primarily focuses on subsequent developments in this case since the issuance of the earlier interim rules and on the new legal issues presented by the final rules.

I. The Affordable Care Act and the Contraceptive Care Mandate

The Women's Health Amendment to the Affordable Care Act requires that group health plans and insurance issuers offering group or individual coverage must cover and "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 the Health Resources and Services Administration." 42 U.S.C. § 300gg-13(a)(4); PI Op., 281 F. Supp. 3d at 561. The amendment was intended to "enhance and improve women's health care" by "extend[ing] the preventive services covered by the bill to those evidence-based services for women that are recommended by the Health Resources and Services Administration." 155 Cong. Rec. S11987 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski); *id.* at S12058–59 (Dec. 1, 2009) (statement of Sen. Benjamin Cardin).

Congress did not dictate which preventive services were to be covered, but instead delegated that task to the Health Resources and Services Administration (HRSA), a component of Defendant HHS whose mission is to "improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs."[8] HRSA, in turn, commissioned the then-named Institute of Medicine (IOM) to make recommendations for appropriate preventive services to include.[9] PI Op., 281 F. Supp. 3d at 561. IOM convened a

[8] *About HRSA* (May 2018), https://www.hrsa.gov/about/index.html.

[9] IOM was renamed the National Academy of Medicine in 2015.

panel of sixteen experts, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines. *Id.*

The panel convened by IOM issued a comprehensive report that issued recommendations as to "services and screenings that could fill the identified gaps in women's preventive care." Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps* 157 (2011) (the "IOM Report") (Exh. F). Relying on recommendations from the American Academy of Pediatrics, the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, and the Association of Women's Health, Obstetric and Neonatal Nurses, the Committee recommended that HRSA's guidelines require coverage for "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id.* at 109–10. HRSA adopted the Committee's recommendations, including the recommendation to require coverage for contraceptive services and counseling (the "Contraceptive Care Mandate"). *See* PI Op., 281 F. Supp. 3d at 561; HRSA, *Women's Preventive Service Guidelines* (2011) (Exh. G) (the "2011 Guidelines").[10]

The implementing agencies attempted to accommodate plan sponsors with religious objections to certain forms of contraception. They did so in two ways. First, they exempted churches and closely related entities from the mandate in its entirety.[11] Second, they created a

[10] The Guidelines were updated in 2016, but continued to identify contraception as covered preventive care. *See* HRSA, *Women's Preventive Service Guidelines* (2016) (Exh. H) (the "2016 Guidelines").

[11] *See 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 (Aug. 3, 2011); *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8725 (Feb. 15, 2012). The definition of "religious employer" for purposes of the exemption was

separate "accommodation" process that allowed certain non-profit organizations that did not qualify for the exemption to nonetheless provide notice of their religious objections to providing contraception and shift the burden for complying with the mandate to their insurance carrier or third-party administrator.[12] As a result, individuals covered by plans that utilized the accommodation still received contraceptive coverage, whereas those employed by plans that were permitted to and did take advantage of the exemption did not.

Despite these efforts, several employers and educational institutions filed lawsuits challenging the mandate in various ways. The litigation culminated in two decisions by the Supreme Court. In *Burwell v. Hobby Lobby Stores*, 134 S. Ct. 2751 (2014), the Court held that the government violated the Religious Freedom Restoration Act, 42 U.S.C. §§ 2000bb *et. seq*. (RFRA), by requiring a closely held for-profit company to comply with the mandate while denying it the option of utilizing the accommodation. As a result, the agencies expanded the scope of the accommodation to include closely held for-profit companies. *See Coverage of Certain Preventive Services Under the Affordable Care Act*, 80 Fed. Reg. 41,318 (July 14, 2015). Then, in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), the Court addressed a RFRA challenge to the accommodation itself. The Court ultimately sidestepped the issue, instead remanding to the courts of appeals to give 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.* at 1560 (quoting Supp. Br. for Resps. at 1). However, in early

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modified slightly in a subsequent regulation. *See Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 39,870 (July 2, 2013).

[12] *See Coverage of Certain Preventive Services Under the Affordable Care* Act, 78 Fed. Reg. 39,870 (2013).

2017, the Labor Department announced that "no feasible approach has been identified . . . that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage."[13]

II. Defendants Issue the IFRs, and this Court Enters a Preliminary Injunction

On May 4, 2017, President Donald Trump issued an Executive Order directing the agency Defendants to "consider issuing amended regulations" to address "conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of Title 42, United States Code," the Women's Health Amendment. President Donald Trump, Exec. Order No. 13798, "Promoting Free Speech and Religious Liberty" § 3 (May 4, 2017), 82 Fed. Reg. 21,675 (Exh. I). The order said nothing about the Supreme Court's instruction that the agencies ensure that women covered by health plans offered by objecting entities "receive full and equal health coverage, including contraceptive coverage." *Zubik*, 136 S. Ct. at 1560 (citation omitted).

Following the issuance of the Executive Order, the Defendant agencies issued two Interim Final Rules (IFRs).[14] The IFRs significantly expanded the scope of the existing exemption and accommodation. Among other changes, the Religious IFR allowed any entity—including a publicly traded corporation—to opt out of the Contraceptive Care Mandate on the basis of a religious objection. In addition, the agencies allowed, for the first time, entities with

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[13] Dep't of Labor, *FAQs about Affordable Care Act Implementation Part 36* (Jan. 9, 2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf (the "2017 FAQs").

[14] *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792 (Oct. 13, 2017) (Exh. C) (the "Religious Exemption IFR"); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (Exh. D) (the "Moral Exemption IFR") (together, "the IFRs").

moral objections to contraception to opt out of the mandate. Moreover, the IFRs rendered the accommodation process purely optional—thus eliminating the assurance that women who were insured by organizations that utilized the accommodation would still receive contraceptive coverage. The IFRs were issued without any prior notice or an opportunity for comment, and they went into effect immediately.

On October 11, 2017, the Commonwealth of Pennsylvania filed suit in this matter alleging that the IFRs were unlawful. ECF No. 1. It alleged that the IFRs violated numerous statutory and constitutional provisions, including the Administrative Procedure Act, the Affordable Care Act, Title VII of the Civil Rights Act on 1964, the equal protection guarantee of the Fifth Amendment to the Constitution, and the Establishment Clause of the First Amendment. *Id.* ¶¶ 141-176. The Commonwealth moved for a preliminary injunction and, following a hearing, this Court granted the Commonwealth's motion and prohibited enforcement of the IFRs. ECF No. 60 (Dec. 15, 2017).

This Court concluded that the Commonwealth had satisfied all of the necessary requirements for the issuance of a preliminary injunction: it was likely to succeed on the merits of its claims that the IFRs violated the procedural and substantive requirements of the Administrative Procedure Act, PI Op., 281 F. Supp. 3d at 570-81; it would suffer irreparable harm in the absence of an injunction, *id.* at 581-84; the balance of equities favored the issuance of an injunction, *id.* at 584-85; and an injunction was in the public interest, *id.* at 585. On the merits, the Court found that Defendants had neither express statutory authority nor "good cause" to forego notice and comment rulemaking in issuing the IFRs. *Id.* at 570-76. In addition, the Court found that the IFRs were "arbitrary, capricious, and contrary to established law" because they were inconsistent with the ACA and not justified by the Religious Freedom Restoration Act

(RFRA). *Id.* at 576-81. The Court also rejected Defendants' argument that the Commonwealth lacked standing. *Id.* at 564-69.

III. Defendant Departments Issue the Final Rules

On November 7, 2018, while the appeal of the preliminary injunction was pending before the U.S. Court of Appeals for the Third Circuit, the Defendant Departments issued two new rules that "finalize" the IFRs "with changes based on public comments." Like the Religious Exemption IFR, the Final Religious Exemption Rule allows any plan sponsor—including a large, publicly traded company—to opt out of the Contraceptive Care Mandate on the basis of "sincerely held religious beliefs." 83 Fed. Reg. at 57,537. Like the Moral Exemption IFR, the Final Moral Exemption Rule allows any plan sponsor, with the exception of publicly traded companies, to opt out of the Contraceptive Care Mandate on the basis of "sincerely held moral convictions." 83 Fed. Reg. at 57,593. And both rules, like their predecessors, render the accommodation process wholly optional. 83 Fed. Reg. at 57,537; *id.* at 57,593

There are some differences, however. In fact, the final Religious Exemption Rule goes further than the Religious IFR by allowing any employer—even one without a sincerely held religious objection to contraception—to disregard the Contraceptive Care Mandate by adopting a group health plan "established or maintained" by an objecting organization. 83 Fed. Reg. at 57,560, 57,563–64. In addition, both final rules allow an entity to claim the exemption if it objects not merely to providing contraceptive coverage itself, but to "arranging for . . . [a] plan, issuer, or third party administrator that provides or arranges such coverage of payments." 83 Fed. Reg. at 57,537; *id.* at 57,593.

ARGUMENT

In the Third Circuit, a party seeking a preliminary injunction must first satisfy two "gateway" factors: "that it can win on the merits" 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). Satisfying the first requirement "requires a showing significantly better than negligible but not necessarily more likely than not" that the movant can prevail. *Id.* Here, the States have a strong likelihood of prevailing on several of its claims, any one of which is sufficient to require that the Rules be struck down. To satisfy the irreparable harm requirement, a plaintiff must demonstrate "a significant risk that he or she will experience harm that cannot adequately be compensated after the fact by monetary damages." *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484–85 (3d Cir. 2000). The States also satisfy this requirement: if the Rules are not struck down, they will suffer direct proprietary harm as well as harm to their quasi-sovereign interests. These damages cannot be remedied after the fact.

Once a movant has satisfied these "gateway" factors, a court should then consider the possibility of harm to other interested persons and any public interest, balancing both these and the gateway factors in deciding whether preliminary injunctive relief is appropriate. *Reilly*, 858 F.3d at 176, 179. Here, these factors tip strongly in favor of the States. If the Rules remain in effect, substantial harm will result to women and families. If they are enjoined, the Defendants and others will be in no different position than they were before the rules were issued. The public interest, particularly the strong interest in promoting access to necessary preventive medicine, would be best served by granting the States' Motion.

I. The States Will Prevail in this Litigation

The Rules violate the procedural and substantive requirements of the Administrative Procedure Act (APA), as well as the Affordable Care Act (ACA).[15] For these reasons, the States will prevail in this litigation.

A. The Rules Violate the Procedural Requirements of the APA

1. Defendants Failed to Comply with the APA's Notice and Comment Requirements

The APA sets forth clear requirements that an agency must follow in issuing a new rule. It first must publish a "[g]eneral notice of proposed rule making" in the Federal Register. 5 U.S.C. § 553(b). That notice "shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id*. Then, the agency "shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). And "[a]fter consideration of the relevant matter presented," the agency "shall incorporate" within the adopted rule a "concise general statement of their basis and purpose." *Id.* An agency can avoid notice and comment only if, "for good cause," it finds the otherwise required procedures are "impracticable, unnecessary, or contrary to the public interest" and it "incorporates its reasoning into the Rules." *Id.* § 553(b)(3)(B). Rules issued without following APA procedures must be held "unlawful and set aside." 5 U.S.C. § 706(2)(D).

[15] In this memorandum, the States explain the reasons why the final Rules violate the APA. They incorporate by reference the arguments in the earlier motion relating to their other counts. *See* First PI Mot. (Exh. E) at 28–37.

Defendants indisputably issued the IFRs without first conducting notice and comment. As this Court found, they lacked independent statutory authority to do so. PI Op., 281 F. Supp. 3d at 571–72 (rejecting claim that 29 U.S.C. § 1191c, 26 U.S.C. § 9833, and 42 U.S.C. § 300gg-92 gave Defendants authority to issue the religious and moral exemptions as interim final rules). The Court also found that the Defendants lacked good cause to avoid the rulemaking process. *Id.* at 572–76. Both conclusions were correct—and Defendants cannot relitigate them in this proceeding. *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.").

Instead, Defendants claim that their subsequent review of comments cures the final Rules of any latent procedural defect. 83 Fed. Reg. at 57,552; 83 Fed. Reg. at 57,609. Not so. The "provision of post-promulgation notice and comment procedures cannot cure the failure to provide such procedures prior to the promulgation of the rule at issue." *NRDC v. EPA*, 683 F.2d 752, 768 (3d Cir. 1982); *accord Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979); *see also United States v. Reynolds*, 710 F.3d 498, 519 (3d Cir. 2013).

In *NRDC v. EPA*, the Third Circuit found that the agency violated the APA when it took regulatory action that did not allow for public comment, and that this initial defect fatally infected later rules issued after notice and comment. 683 F.2d at 767–69. There, the EPA had promulgated a number of final amendments with an effective date of March 30, 1981. *Id.* at 755. Just prior to the effective date, the EPA summarily issued an order—which the Third Circuit held to be a "rule"—that indefinitely postponed the effective date of all the final amendments. *Id.* at 760–61. Several months later, the EPA issued an NPRM seeking public comment on further postponement of the effective date. *Id.* at 757. The EPA subsequently issued a final rule that

made some of the amendments effective as of January 31, 1982, and further postponed others. *Id.* at 757. The EPA argued that the final postponement rule, taken after public comment, cured the procedural defect in the initial postponement order. *Id.* at 767.

The Third Circuit disagreed, holding that *all* amendments became effective as of March 30, 1981. *Id.* at 768. It observed, first, the agency's abrupt change in position—effectively repealing the final amendments, albeit temporarily, *id.* at 763—"constitute[d] a danger signal." *Id.* at 760–61. Coupled with the absence of notice and comment, the court had to "scrutinize that action all the more closely to insure that the APA was not violated." *Id.* And, second, it found that, if "a period for comments after issuance of a rule could cure a violation of the APA's requirements, an agency could negate at will the Congressional decision that notice and an opportunity for comment must precede promulgation." *Id.* at 767–68 (quoting *Sharon Steel*, 597 F.2d at 381). Congress mandated notice and comment prior to final rule promulgation to "allow[] effective participation in the rulemaking process while the decisionmaker is still receptive to information and argument." *Id.* at 768 (quoting *Sharon Steel*, 597 F.2d at 381). Comments filed after the agency had issued a final rule, however, required a commenter to "come hat-in-hand and run the risk that the decisionmaker is likely to resist change." *Id.* (quoting *Sharon Steel*, 597 F.2d at 381).

Critical here, the Third Circuit concluded that the subsequent NPRM and final postponement rule were fatally infected with the same procedural defect. *Id.* at 768. But for the improper initial order, the amendments would have gone into effect on March 30, 1981, and "the question to be decided in the rulemaking would have been whether the amendments, which had been in effect for some time, should be suspended, and not whether they should be further postponed." *Id.* Therefore, the only remedy was to hold that all amendments went into effect as

of March 30, 1981. To hold otherwise "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." *Id.*

The same reasoning controls here. Had the Defendants not improperly issued interim final rules with immediate effect, "the question to be decided in the rulemaking" would have been whether the agencies should create new religious and moral exemptions, not whether they should be amended. *See id.* However, as a result of the procedural violation, commenters—including the Commonwealth—came to the Defendants "hat-in-hand" with the risk that the agencies were "likely to resist change." *Id.* This contravenes "the very purpose of notice and comment," which is "for agencies to 'maintain a flexible and open-minded attitude towards its [*sic*] own rules.'" *Reynolds*, 710 F.3d at 511 (quoting *Prometheus Radio Project v. FCC*, 652 F.3d 431, 449 (3d Cir. 2011)).[16]

As in *NRDC*, the remedy for an APA procedural violation must place the States "in the positions they would have been in if the APA had not been violated." *NRDC*, 637 F.2d at 768. There, this required backdating the effective date of the amendments. Here, it simply requires enjoining the final Rules. *See* 5 U.S.C. § 706(2)(D).

[16] *Ass'n of Am. Physicians & Surgeons v. Sebelius*, 746 F.3d 468, 472 (D.C. Cir. 2014), is not to the contrary. There, plaintiffs initially challenged interim final rules on procedural grounds, but the district court found that the defendant agencies had good cause to bypass notice-and-comment rulemaking. *Ass'n of Am. Physicians & Surgeons, Inc. v. Sebelius*, 901 F. Supp. 2d 19, 45–46 (D.D.C. 2012). During the pendency of the litigation, the defendant agencies issued final rules that superseded the interim final rules. *Ass'n of Am. Physicians & Surgeons*, 746 F.3d at 472. On appeal, the plaintiffs continued to attack the interim final rules on procedural grounds. *Id.* The D.C. Circuit properly rejected that claim as moot. *Id.* By contrast, the States here challenge the procedural validity of the final Rules, based on this Court's prior finding that the IFRs were issued in violation of the APA.

2. The Rules Fail to Respond to Significant Comments and Fail to Provide an Adequate Statement of Their Bases and Purposes.

That the Defendants accepted public comment prior to issuing the Rules only subjects them to additional APA obligations—obligations they failed to satisfy. The APA requires federal agencies to "consider and respond to significant comments received during the period for public comment" and provide a statement of the "basis and purpose" of each final rule. *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015) (citing 5 U.S.C. § 553(c); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971)). In this statement, the agency must answer 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 agency has an independent "obligation to remain open-minded about the issues raised and engage with the substantive responses submitted." *Prometheus Radio Project*, 652 F.3d at 453 (cleaned up).

Although Defendants have not yet produced the administrative record, the Rules themselves make clear they failed to respond adequately to comments. For example, Defendants fail to seriously address the many comments they received discussing the scientific and other evidence of the harms to the health and economic security of women that would result from the Rules. *See* 83 Fed. Reg. 57,555–56. The Defendants assert that some commenters expressed concerns about these harms, while others disputed them. *Id.* They throw their hands up in the face of these conflicting comments and argue that "it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate." *Id.* at 57,556. But of course a serious health detriment that is imposed on less than "the vast majority of women" is a cognizable and important harm that must be taken into account. "Without taking a definitive position on those evidentiary issues" the Defendants nevertheless "conclude that the

expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes." *Id.* This is far from the reasoned analysis demanded by the APA.

In other places, Defendants utterly fail to engage with the substance of the commenters. In response to comments that the broad religious and moral exemptions will cause women to lose contraceptive coverage, 83 Fed. Reg. at 57,548–49—a fact admitted by both the IFRs and the final Rules, *e.g.*, *id.* at 57,581; 82 Fed. Reg. at 47,823—the Defendants blithely note that "the final rules do not create a governmental burden; rather, they relieve a governmental burden." 83 Fed. Reg. at 57,549. In response to comments that the exemptions violate ACA prohibitions on regulations that create barriers to medical care, *id.* at 57,551–52; *see also infra* Part I.B.1, the Defendants assert that "the decision not to impose a governmental mandate is not the 'creation' of a 'barrier,' especially when that mandate requires private citizens to provide services to other private citizens." *Id.* at 57,552.

In addition, the Commonwealth, along with 15 other states and the District of Columbia, submitted comments to Defendants about the IFRs.[17] Among other things, the states noted that contraception is necessary because for some women, pregnancy "can be hazardous or life-threatening to them due to a medical condition."[18] Defendants make only a passing reference to this point—*Id.* at 57,553 (noting that some commenters "said that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death")—and then blithely decline to "take a position on the variety of empirical questions discussed above." *Id.* at 57,555. But the APA requires the Defendants to respond to comments

[17] Comment Letter on Interim Final Rules: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act, and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (Dec. 5, 2017) (Exh. X).

[18] *Id.* at 6.

pointing to these very real health risks—not least because Defendant HHS is charged with "enhanc[ing] the health and well-being of all Americans" by "fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."[19]

To satisfy the APA, the Defendants must actually conduct notice and comment rulemaking—which requires responding to "significant comments," *Perez*, 135 S. Ct. at 1203, engaging with all "vital questions[] raised by comments which are of cogent materiality," *Nova Scotia*, 568 F.2d 240, 252 (2d Cir. 1977). Having failed to do so, Defendants have violated the APA's procedural requirements. 5 U.S.C. § 706(2)(D).

B. The Rules Are Arbitrary, Capricious, and Contrary to Law in Violation of the APA.

Not only did the Defendants disregard the APA's procedural requirements, but the Rules themselves are substantively defective. "At a minimum, in adopting or modifying its rules," an agency must "'examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.'" *Prometheus Radio Project*, 652 F.3d at 469 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983)); *accord Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974). Consequentially, agency action is arbitrary and capricious if it "fail[s] to provide even that minimal level of analysis." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Agency action is also arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a

[19] HHS, *Introduction: About HHS* (Feb. 28, 2018) https://www.hhs.gov/about/strategic-plan/introduction/index.html.

difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. "[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Id.* at 50.

Agencies are "free to change their existing policies," *Navarro*, 136 S. Ct. at 2125, but they must always provide a "reasoned explanation" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). An agency must also provide "a more detailed justification" for certain policy changes, such as when "its new policy rests upon factual findings that contradict those which underlay its prior policy," or when "its prior policy has engendered serious reliance interests." *Id.* Simply demonstrating awareness of its change in policy is insufficient if the agency provides an insufficiently reasoned explanation for "why it deemed it necessary to overrule its previous position." *Navarro*, 136 S. Ct. at 2126. "[A]n agency that neglects to do so acts arbitrarily and capriciously." *Jicarilla Apache Nation v. U.S. Dept. of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010).

A change in administration does not authorize an unreasoned reversal of course. *See State Farm*, 463 U.S. at 48–51. "New presidential administrations are entitled to change policy positions, but to meet the requirements of the APA, they must give reasoned explanations for those changes and address the prior factual findings underpinning a prior regulatory regime." *State v. U.S. Bureau of Land Mgmt.*, -- .Supp.3d. --, 2017 WL 4416409, at *11 (N.D. Cal. Oct. 4, 2017) (cleaned up).

Under the APA, a reviewing court "shall . . . hold unlawful and set aside" any agency action that is "in excess of statutory jurisdiction," "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A), (C). Here, the final Rules violate the Women's Health Amendment and are therefore not in accordance with law. In addition, the final Religious Exemption Rule is not justified under RFRA, making the

Defendants' reliance (and an unexplained policy reversal) arbitrary and capricious. Finally, the Defendants provide inadequate explanations for their reversal on the importance of contraception and for the number of women likely to be affected, failing to satisfy minimum APA requirements.

1. The Final Rules Violate the ACA

As this Court recognized a year ago, the IFRs were arbitrary, capricious, and not in accordance with law because "they contradict[ed] the text of the statute that they purport[ed] to interpret." PI Op., 281 F. Supp. 3d at 576–78. The final Rules suffer from the same defect. They are contrary to the Women's Health Amendment, which guarantees no-cost preventive care and screenings, 42 U.S.C. § 300gg-13(a)(4); to the ACA provision prohibiting regulations that erect barriers to an individual's access to health care, 42 U.S.C. § 18114; and to the ACA provision guaranteeing nondiscrimination on the basis of sex, 42 U.S.C. § 18116. As a result, they must also be enjoined.

The Women's Health Amendment requires non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to "provide coverage" without "impos[ing] any cost sharing requirements" for "additional preventive care and screenings . . . provided for in comprehensive guidelines supported by the Health Resources and Services Administration [HRSA]." 42 U.S.C. § 300gg-13(a)(4). This requirement applies to coverage "with respect to women." *Id.* This affirmative grant does not authorize HRSA to determine when those services can be withheld. There is nothing in the statute suggesting that broad categories of employers, plan sponsors, issuers, or individuals can be exempt from this statutory requirement. Defendants cite nothing to the contrary.

Since 2011, HRSA Guidelines have listed "[c]ontraceptive methods and counseling" among the forms of preventive care that must be provided to women without cost sharing. 2011

Guidelines (Exh. G); 2016 Guidelines (Exh. H). The determination that contraception constitutes appropriate preventive care for women was made after the IOM commissioned sixteen professionals to examine the issue. IOM Report (Exh. F) at 11. One of those members, Dr. Carol Weisman, confirmed in testimony before this Court that IOM's conclusion is consistent with the views of numerous professional health associations. Tr. (Exh. J) at 66.17–67.24; 68.20–69.13; 73.10-17. Even Defendants acknowledge that the Guidelines remain binding. *E.g.*, 83 Fed. Reg. at 57,537 ("The rules do not remove the contraceptive coverage requirement generally from HRSA's Guidelines."); *id.* at 57,539 ("Since 2011, HRSA has exercised [its] discretion to require coverage for, among other things, certain contraceptive services."). Rather than amend the Guidelines, the final Rules provide broad exceptions to HRSA's Guidelines for "moral" and "religious" reasons—reasons never contemplated by the ACA. The language of the Women's Health Amendment is mandatory: a covered plan "shall" provide coverage for preventive services, without cost-sharing requirements.

Nothing in the ACA's text, legislative history, or purpose suggests that employers may avoid their legal obligations for religious or moral reasons. The ACA sought to facilitate access to health care, not limit it. The sole purpose of the Women's Health Amendment was to give women greater access to necessary preventive care and more control over their personal health care decisions. *See Hobby Lobby*, 134 S. Ct. 2751, 2788–89 (2014) (Ginsberg, J., dissenting) (explaining how the Amendment was intended to fill a gap that left out women's preventive services); *see also id.* at 2785-86 (Kennedy, J., concurring) ("It is important to confirm that a premise of the Court's opinion is its assumption that the HHS regulation here at issue furthers a legitimate and compelling interest in the health of female employees."). As the lead sponsor explained, the Amendment is intended to "enhance and improve women's health care." 155

Cong. Rec. S11987 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). Congress achieved this purpose by "leav[ing] the decision of which preventive services a patient will use between the doctor and the patient." *Id.* at S11988 (statement of Sen. Barbara Mikulski). This cannot be reconciled with the effect of the final Rules which allow employers—not the doctor and the patient—to decide what preventive services their insured employees may receive.[20]

The ACA is void of any conscience clause that might authorize the broad exemptions the Rules create.[21] That should be the end of the matter. No principle of law allows an agency to invent a statutory provision simply because similar provisions have been included in other statutes on the same topic, or because the final Rules tangentially touch on a myriad of issues. Even if the Guidelines impose a legally cognizable burden on certain employers, the Women's Health Amendment does not authorize deviation from its terms. Neither HHS, nor the Department of the Treasury, nor the Department of Labor, nor their sub-agencies are charged in the ACA with protecting an employer's religious beliefs or moral convictions about contraception. Instead, Congress's delegation of authority was much more discrete and much more narrow: HRSA must issue Guidelines establishing "such additional preventive care and screenings" for women that must be provided without cost-sharing. 42 U.S.C. § 300gg-13(a)(4).

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[20] Defendants argue that the exclusion of "grandfathered" plans from the scope of the mandate allows them to create additional broad exemptions. *See, e.g.*, 83 Fed. Reg. at 57541. To the contrary: "When 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). Defendants cannot rely on the existence of the exclusion for grandfathered plans to assume they are nonetheless authorized to create additional exemptions.

[21] The Senate even rejected a later effort to add such conscience protections to the ACA. S. Amdt. 1520, 112th Congress (2011-2012). In arguing that such an amendment was necessary, its sponsors fully acknowledged that the ACA did not, in fact, contain conscience protections. Rather, they admitted that the ACA "does not allow purchasers, plan sponsors, and other stakeholders with religious or moral objections to specific items or services to decline providing or obtaining coverage of such items or services." *Id.*

It has done so. Those Guidelines mandate coverage of contraceptive methods and counseling. By allowing virtually any employer to avoid this mandate, the final Rules are contrary to law.

The final Rules also violate other ACA provisions. For example, the ACA bars the Secretary of HHS from promulgating any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impedes timely access to health care services," or "limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114(1), (2), (6).[22] Here, the final Rules create a formidable barrier by preventing women who receive health insurance through their employers from receiving essential preventive healthcare based on that employer's religious or moral beliefs. Defendants' argument to the contrary, 83 Fed. Reg. at 57,552, is nonsensical. Congress mandated that health plans provide women with coverage for preventive services without cost-sharing. 42 U.S.C. § 300gg-13(a)(4). Defendants admit that the final Rules will cause some women to lose coverage for preventative care under their employer-sponsored insurance. 83 Fed. Reg. at 57,575–57,582. Under the plain language of the ACA, HHS has "create[d] . . . unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impede[d] timely access to health care services," and "limit[ed] the availability of health care treatment for the full duration of a patient's medical needs." §§ 18114(1), 18114(2), 18114(6).

[22] "Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114.

The final Rules also violate the ACA's nondiscrimination provision, which protects an individual from being "excluded from participation in," "denied the benefits of," or "subjected to discrimination" on the basis of sex under "any health program or activity" receiving federal funds. 42 U.S.C. § 18116.[23] The final Rules selectively authorize denial of coverage for women's preventive care benefits only. Indeed, the Equal Employment Opportunity Commission (EEOC) has previously held that offering coverage for preventive prescription drugs and services but not for contraception constitutes discrimination based on sex. *See* Commission Decision on Coverage of Contraception, EEOC, 2000 WL 33407187 (Dec. 14, 2000).[24]

In sum, the final Rules violate multiple provisions of the ACA. As a result, they are "not in accordance with law." *See* 5 U.S.C. § 706(2)(A).

2. Defendants' Reliance on RFRA is Arbitrary, Capricious, and Contrary to Law.

Not only are the final Rules contrary to the ACA, the final Religious Exemption Rule is "arbitrary, capricious, and contrary to established law" because it misapplies RFRA.[25] 5 U.S.C. § 706(2)(A). First, the Defendants provide no rationale for their new position that the accommodation imposes a substantial burden on the exercise of religion—the threshold requirement to implicate RFRA. "[W]here the agency has failed to provide even that minimal level of analysis, its action is arbitrary and capricious and so cannot carry the force of law."

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[23] "Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972, . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)." 42 U.S.C. § 18116.

[24] http://www.eeoc.gov/policy/docs/decision-contraception.html.

[25] Defendants do not claim that the final Moral Exemption Rule is justified by RFRA.

Navarro, 136 S. Ct. at 2125. Second, the Defendants have not "show[n] that there are good reasons" for departing from their established position that the Contraceptive Mandate furthers a compelling government interest. *See id.* at 2125–26 (quoting *Fox Television Stations*, 556 U.S. at 515). An "unexplained inconsistency in agency policy" is a reason to hold an agency regulation "to be an arbitrary and capricious change from agency practice." *Id.* at 2126 (cleaned up). And finally, the Defendants have not explained how RFRA allows them to protect sincerely held religious beliefs at the expense of women's access to federally mandated preventive services.

Contrary to pervasive characterizations by the Defendants and the Little Sisters, RFRA does not provide federal agencies with unfettered discretion to contravene federal law. Instead, RFRA applies when the Government would "substantially burden a person's exercise of religion." 42 U.S.C. § 2000bb-1(a). "[W]hether a burden is 'substantial' under RFRA is a question of law, not a question of fact." *Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 356 (3d Cir. 2017) (cleaned up). A burden is not substantial simply because the claimant says it is; instead, courts must objectively evaluate both the "*nature* of the claimed burden and the *substantiality* of that burden on the claimant's religious exercise." *Id.* (cleaned up). Even if the burden is substantial, RFRA still does not automatically allow a federal agency to contravene federal law. Instead, RFRA only blocks laws that do not further "a compelling government interest" in the "least restrictive" way possible. 42 USC § 2000bb-1(b).

Defendants rely heavily on RFRA to justify the final Religious Exemption Rule—but their explanations do not withstand scrutiny. First, the Defendants conclude that the accommodation substantially burdens religious exercise. 83 Fed. Reg. at 57,546 (affirming conclusion first set forth in the Religious Exemption IFR); *see* 82 Fed. Reg. at 47,800. This conclusion is undisputedly a change in position. *See, e.g.*, 2017 FAQs at 4–5 (concluding that the

accommodation does not substantially burden religious exercise); 78 Fed. Reg. at 39,886–88 (same). But the Defendants "offer[] barely any explanation" to support this new position. *See Navarro*, 136 S. Ct. at 2126. In *Navarro*, the Supreme Court struck down an agency's new interpretation of the Fair Labor Standards Act because the agency "said almost nothing" about why it had changed position and failed to explain why the chosen policy was more consistent with the applicable statutory provisions. *Id.* at 2127. Here, the Defendants make the same fatal error.

Defendants note that in the Religious Exemption IFR, they "revisited [their] earlier conclusions and reached a different view," which they "now reaffirm." 83 Fed. Reg. at 57,546. But the sole explanation offered in both the IFR and the final rule is the bald assertion that "the Court's analysis in *Hobby Lobby* extends" to the accommodation "either by compelling an act inconsistent with that observance or practice, or by substantially pressuring the adherents to modify such observance or practice." *Id.* As in *Navarro*, this paragraph fails to explain *why* the agencies believe the accommodation—which causes the eligible organization to play "no role whatsoever" in the provision of federally mandated contraception services, *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 438 (3d Cir. 2015), *vacated on other grounds*, *Zubik*, 136 S. Ct. at 1560—poses a *substantial* burden. *Cf. id.* at 435–44 (detailing the many reasons why the burden is not substantial). Indeed, the agencies' purported explanation actually runs contrary to the holding of *Hobby Lobby*, which found that the accommodation did not substantially burden the religious practice of closely held for-profit entities such as Hobby Lobby. 134 S. Ct. at 2782–83.

Defendants claim their new conclusion is "particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA." 83 Fed. Reg. at 57,554. But

Defendants ignore the overwhelming majority of federal appeals courts, which have held that the accommodation does not impose a substantial burden and therefore does not violate RFRA.[26] As this Court recognized previously, the Third Circuit has held that the accommodation did not substantially burden religious exercise. PI Op., 281 F. Supp. 3d at 580 (citing *Geneva Coll.*, 778 F.3d at 442). Although vacated by *Zubik*, 136 S. Ct. at 1560, the Supreme Court expressed no view on the merits of the Third Circuit's holding, which that court has subsequently reaffirmed. *Real Alternatives*, 867 F.3d at 356 ("[W]e continue to believe . . . that the regulation at issue [in *Geneva College*] did not impose a substantial burden.").

Second, even if the Defendants are correct that the accommodation imposed a substantial burden, they failed to provide "good reasons" for departing from their longstanding position that the Contraceptive Mandate serves a compelling government interest. *See Fox Television Stations*, 556 U.S. at 515. To be sure, unlike their discussion of the substantial burden, the Defendants do present an explanation, 83 Fed. Reg. at 57,546–48—but it is not "reasoned" and therefore cannot support the final Religious Exemption Rule.

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[26] *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 220 (2d Cir. 2015) (holding that the accommodation did not impose a substantial burden); *Geneva Coll.*, 778 F.3d at 442 (same); *E. Texas Baptist Univ. v. Burwell*, 793 F.3d 449, 463 (5th Cir. 2015) (same); *Michigan Catholic Conference & Catholic Family Servs. v. Burwell*, 755 F.3d 372, 390 (6th Cir. 2014) (same); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 618 (7th Cir. 2015) (same); *Little Sisters of the Poor Home for the Aged, Denver, Colo. v. Burwell*, 794 F.3d 1151, 1173 (10th Cir. 2015) (same); *Eternal Word Television Network, Inc. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 818 F.3d 1122, 1151 (11th Cir. 2016) (same); *Priests For Life v. U.S. Dep't of Health & Human Servs.*, 772 F.3d 229, 249 (D.C. Cir. 2014) (same); *but see Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, 801 F.3d 927, 943 (8th Cir. 2015) (holding that the accommodation substantially burdens religious beliefs).

Although all were vacated by (or in light of) *Zubik*, the Supreme Court's per curiam opinion expressed no view on the merits of the appellate courts' holdings. 136 S. Ct. at 1560.

The Religious Exemption IFR did acknowledge that the rule contradicted the near-unanimous conclusion of the federal appellate courts. 82 Fed. Reg. at 47,792.

For one, the agencies' about-face is foreclosed by the Supreme Court: five Justices have recognized that the government interest in guaranteeing cost-free access to contraception is compelling within the meaning of RFRA. *Hobby Lobby*, 134 S. Ct. at 2785–85 (Kennedy, J., concurring) (stating that HHS "makes the case that the mandate serves the Government's compelling interest in providing insurance coverage that is necessary to protect the health of female employees, coverage that is significantly more costly than for a male employee"); *id.* at 2799 (Ginsburg, J., dissenting) (stating, in a dissent joined by three Justices, that "the contraceptive coverage for which the ACA provides furthers compelling interests in public health and women's well being").

In addition, the Departments' purported "good reasons" are specious. That HRSA has discretion to prepare the Guidelines, 83 Fed. Reg. at 57,546–47, does not explain why the Government's interest in the Contraceptive Mandate is not compelling. Nor does the fact that Congress excluded some employers from the Mandate, *id.* at 57,547, make it any less important that the Government ensure that all covered women receive access to the full complement of preventive care. That the IOM found that some women are most at risk for unintended pregnancy, *id.* at 57,547–48, does not explain why women who work for employers with religious or moral objections are less likely to fall into this high-risk category, nor does it correlate with the ACA's mandate that preventive services be provided to all women. Nor does the ability of some women to get contraceptive services and counseling from other sources justify the change. *Id.* at 57,548. State laws mandating contraceptive coverage are neither as uniform nor as comprehensive as the Mandate, Kost. Decl. (Exh. K) ¶ 53, and ERISA bars states from regulating a significant portion of employers, 29 U.S.C. § 1144(a); Compl. ¶ 140. Moreover, the Defendants mischaracterize the impact the ACA has had on women's use of

contraceptive methods. Kost Decl. (Exh. K) ¶¶ 31–36 (showing how study cited by Defendants actually showed positive trends). Lastly, the discussion of seamlessness is a red herring, *id.*; the ACA mandates that covered health care plans "shall" provide preventive services to their female insureds without cost-sharing, 42 U.S.C. § 300gg-13(a)(4).

Finally, the Defendants fail to adequately explain, 83 Fed. Reg. at 57,544–46, how RFRA gives them broad discretion to protect sincerely held religious beliefs by categorically denying women access to the essential preventive healthcare mandated by Congress. The Supreme Court has recognized that RFRA does not permit Defendants to favor religious objectors at the expense of women's healthcare. In *Zubik*, the Court remanded the cases so that the parties could "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*." 136 S. Ct. at 1560 (cleaned up) (emphasis added).[27] Defendants have failed to comply with the second part of the Court's instruction: by design, the broad religious and moral exemptions fail to ensure that women who work for objecting entities will receive "full and equal health coverage, including contraceptive coverage." *Id.* What is more, the final Rules, like the IFRs before them, offer no evidence that they even tried.

[27] As this Court has already recognized, the only authority cited by Defendants—*Ricci v. DeStefano*, 557 U.S. 586, 585 (2009)—has never been held to apply to RFRA. Tr. (Exh. J) 47:16–50:17. But even if *Ricci*'s "strong-basis-in-evidence" standard applied to RFRA, Defendants have not met this high burden. They point only to "legal uncertainty" about the accommodation—in direct contradiction to the majority of federal appellate courts, *supra* n.26, and the Supreme Court, *Hobby Lobby*, 134 S. Ct. at 2782–83. Moreover, the strong-basis-in-evidence standard applies only to the strict binary circumstance present in *Ricci*, where the City could either certify exam results (that could have violated Title VII's disparate-impact provision) or not certify exam results (and instead violate Title VII's disparate-treatment provision). *Ricci*, 557 U.S. at 578–79. No such binary circumstance exists here.

That the prior administration was unable to identify a "feasible approach . . . that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage," is not the fatal concession Defendants treat it to be. *E.g.*, 83 Fed. Reg. at 57,544 & n.15 (quoting 2017 FAQs at 4). To the contrary, RFRA is not automatically violated whenever anyone raises a religious objection to federal law. As this Court has repeatedly recognized, the existence of a sincere or reasonable religious objection does not *per se* mean that the burden is substantial. *E.g.*, *Real Alternatives*, 867 F.3d at 356; *see* 2017 FAQs at 4–5 (identifying no substantial burden). And even if the burden is substantial, the Government policy can be enforced as long as it is the least restrictive means to further a compelling government interest. § 2000bb-1(b). The prior administration's inability, after 54,000 comments, to find an alternative to the accommodation that both "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," *Zubik*, 136 S. Ct. at 1560, demonstrates that the accommodation *is* the least restrictive means.

In sum, the Defendants fail to provide adequate explanations for their reliance on RFRA, resulting in a rule that is arbitrary and capricious and therefore "cannot carry the force of law." *Navarro*, 136 S. Ct. at 2127. For this reason alone, the final Religion Exemption Rule must be enjoined.

3. Defendants Provide Arbitrary and Capricious Explanations for the Final Rules.

In addition to violating the ACA and improperly relying on RFRA, Defendants fail to provide explanations for the final Rules that satisfy the APA's requirements. 5 U.S.C. § 706(2)(A). Defendants shift their longstanding position on the importance of women having

no-cost access to contraception, even where employers may have religious objections. They completely disregard the overwhelming scientific and medical evidence establishing the efficacy, safety, and benefits of contraception—evidence they previously accepted and incorporated into their policies and regulations. And they fail to reasonably account for the number of women who will be affected by the final Rules. As a result, the final Rules are arbitrary and capricious. *Id.*

i. Defendants' Reversal of Position on the Importance, Efficacy, and Benefits of Contraception is Arbitrary and Capricious.

Defendants fail to explain their dramatic reversal on the importance, efficacy, and benefits of contraception. As with their position on RFRA, this abrupt about-face violates the APA because Defendants fail to provide the "more detailed justification" necessary when reversing a position that rested on evidence-based factual findings or engendered serious reliance interests. *Fox Television Stations*, 556 U.S. at 515. Simply demonstrating awareness of their change in policy is insufficient if the agencies provide an insufficiently reasoned explanation for "why [they] deemed it necessary to overrule [their] previous position." *Navarro*, 136 S. Ct. at 2126. As a result, the final Rules are arbitrary, capricious, and "cannot carry the force of law." *Id.* at 2127.

Since the passage of the ACA and the adoption of the Guidelines, Defendants repeatedly reaffirmed the importance of providing women access to contraceptive services without cost-sharing.[28] This position came not from Defendants' whims, but from the evidence-based

[28] *E.g.*, 76 Fed. Reg. at 46,623 (recognizing the need to extend "any coverage of contraceptive services under the HRSA Guidelines to as many women as possible"); 77 Fed. Reg. at 8727–28 (discussing the many benefits of contraception for women and the problems with a broader exemption); *Certain Preventive Services Under the Affordable Care Act*, 77 Fed. Reg. 16,501, 16,503 (Mar. 21, 2012) (requesting comment on how to "provide women access to the important preventive services at issue without cost sharing while accommodating religious liberty interests"); *Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 8456, 8459 (Feb. 6, 2013) (same); *Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 39,870, 39,872–73 (July 2, 2013) (discussing many benefits

scientific and medical conclusions in the IOM Report, prepared by a 16-member panel of experts in preventive care, disease prevention, women's health issues, and other areas. Weisman Decl. (Exh. M) ¶¶ 14–42; IOM Report (Exh. F) at 102–10. The IOM Report specifically demonstrated—using a systematic review of voluminous evidence, studies, and expert opinions—that no-cost access to the full range of FDA-approve contraceptive methods, as well as education and counselling about contraception, is essential for alleviating adverse impacts unintended pregnancy may have on mothers and their children. Weisman Decl. (Exh. M) ¶¶ 14–42; IOM Report (Exh. F) at 102–10. The HRSA adopted these methods and findings in issuing its guidelines, 2011 Guidelines (Exh. G), and contraception remains a form of preventive care to this day, 2016 Guidelines (Exh. H).

Even as the Defendants made subsequent adjustments to the Contraceptive Mandate to respect sincerely held religious beliefs, Defendants never lost sight of the core aim: ensuring that women receive access to essential contraceptive methods and services.[29] The Supreme Court even affirmed this balance, requiring the parties on remand to "ensur[e] that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." *Zubik*, 136 S. Ct. at 1560 (cleaned up). Defendants' position was supported by the medical community, which has continued to reaffirm the benefits of contraception and the need

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of contraception for women); 2017 FAQs at 5 (stating that the government has a "compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage").

[29] *E.g.*, 76 Fed. Reg. at 46,624 ("The definition set forth here is intended to reasonably balance the extension of any coverage of contraceptive services under the HRSA Guidelines to as many women as possible, while respecting the unique relationship between certain religious employers and their employees in certain religious positions."); 77 Fed. Reg. at 8727 (stating that the Departments sought to meet two goals: "providing contraceptive coverage without cost-sharing to individuals who want it" and accommodating religious objections); 77 Fed. Reg. at 16,503 (same); 78 Fed. Reg. at 39,872 (same).

to eliminate the cost barrier. Weisman Decl. (Exh. M) ¶¶ 46–51; Chuang Decl. (Exh. L) ¶¶ 26–39; Kost Decl. (Exh. K) ¶¶ 24–36. In fact, several studies conducted after the Women's Health Amendment was implemented have shown that women are paying less for contraception and using more effective contraception as a result of mandated contraceptive coverage. Weisman Decl. (Exh. M) ¶¶ 48–49; Chuang Decl. (Exh. L) ¶¶ 26–32; Kost Decl. (Exh. K) ¶¶ 31–36; Ashley H. Snyder, *et al.*, *The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women*, 28-3 Women's Health Issues 219–223 (2018) (Exh. N).

Yet in the IFRs and the final Rules, Defendants make a dramatic reversal: women's access to contraceptive methods and counseling is now subordinate to the religious and moral objections of employers, and contraception might not be beneficial or effective anyway. This position is both contrary to prior factual findings and in spite of the significant reliance interests of women who have benefited from the Mandate. In the absence of a "more detailed justification," Defendants change in position violates the APA. *Fox Television Stations*, 556 U.S. at 515.

In the Final Rules, Defendants provide no new facts and no meaningful discussion to undercut their prior factual findings establishing the beneficial and essential nature of contraception as preventive healthcare for women. *See* 83 Fed. Reg. at 57,552–56 (discussing, in the final Religious Exemption Rule, the "Health Effects of Contraception and Pregnancy" and the "Health and Equality Effects of Contraceptive Coverage Mandates"). Instead, Defendants: (1) reproduce without analysis some public comments that question the efficacy, safety, and importance of contraception; (2) decline to "take a position on the variety of empirical issues discussed above," *id.* at 57,555; *accord id.* at 57,556 ("Without taking a definitive position on those evidentiary issues . . . ."); then (3) summarily conclude that "significantly more uncertainty

and ambiguity exists on these issues than the Departments previously acknowledged when [they] declined to extend the exemption to certain objecting organizations and individuals," *id.* at 57,555, and that the final Rules "are not likely to have negative effects on the health or equality of women nationwide," *id.* at 57,556. This is arbitrary and capricious for multiple reasons.

First, basing a major policy shift on an apparently newly discovered and poorly defined "ambiguity"—rather than a careful, rational evaluation of changes in fact or circumstance—is the very embodiment of arbitrary and capricious decision-making. *See Fox Television Stations, Inc.*, 556 U.S. at 515 (holding that an agency must provide "a more detailed justification" for certain policy changes when "its new policy rests upon factual findings that contradict those which underlay its prior policy"). *Prometheus Radio Project*, 652 F.3d at 469 (stating that an agency must "examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made" (quoting *State Farm*, 463 U.S. at 43)).

Second, basing a major policy reversal on a fabricated debate is likewise the epitome of arbitrary and capricious rulemaking. *State Farm*, 463 U.S. at 43 (holding that an agency decision was arbitrary and capricious when it "offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise"). There is no debate over the efficacy or benefits of contraception. Kost Decl. (Exh. K) ¶ 43; Chuang Decl. (Exh. L) ¶¶ 40–49; Weisman Decl. (Exh. M) ¶¶ 52–54. To the contrary: it is Defendants themselves who "provide[] the oversight to ensure that the health benefits of contraception outweigh any potential negative consequences." Kost Decl. (Exh. K) ¶ 43. All mandated contraceptive methods must be approved by the FDA—a component of Defendant HHS. *Id.* Multiple expert bodies, including the FDA, the CDC, and the

American College of Obstetricians and Gynecologists, "concur that contraception is safe and has clear health benefits that outweigh any potential risk." *Id.*

Third, the Defendants' failure to rebut the specious assertions of certain commentators with basic science further underscores the arbitrary and capricious nature of the final Rules. For example, the Final Rules discussed comments criticizing the IOM Report for citing studies asserting an "associative" rather than "causal" relationship between contraceptive use and decreases in unintended pregnancy. 83 Fed. Reg. at 57,553. Not only are associative relationship studies well-accepted—demonstrating that "smoking causes lung cancer, HIV causes AIDS, and Pap smears reduce cervical cancer"—but establishing a "causal" relationship between contraception and unintended pregnancy would require an unethical and impractical scenario. Chuang Decl. (Exh. L) ¶ 45. The final Rules also credit comments suggesting hormonal contraceptives may increase risk of venous thrombembolic disease (VTA), 83 Fed. Reg. at 57,552, when in fact pregnancy and the postpartum state—which would result from unintended pregnancies—increase VTE significantly more than hormonal contraceptives, Chuang Decl. (Exh. L) ¶ 47. The Final Rules also point to commenters who express concern over possible increased risk of certain cancers, 83 Fed. Reg. at 57,553, but the magnitude of the strong evidence that hormonal contraception reduces the risk of ovarian and uterine cancer, and some evidence that it reduces the risk of colorectal cancer, greatly outweighs any potential increased risk of breast cancer, Chuang Decl. (Exh. L) ¶ 48.

Instead of making reasoned findings based on substantive analysis of any new evidence or a change of circumstance, Defendants expressly base their revocation of women's access to contraception on factors entirely unrelated to already-settled matters of science, medicine, and the well-being of women: the notion "that some people have sincere religious [or moral]

objection to providing contraception coverage." 83 Fed. Reg. at 57,554. "[I]n this context," Defendants "believe" they "have sufficient rationale to offer expanded religious exemptions with respect to [the Contraceptive] Mandate." *Id.* But Defendant's belief does not make it so. Religious or moral objections are no substitute for the rational, detailed explanation the APA requires to justify Defendants' complete change of course, and such objections certainly do not provide the required connection between the Final Rules and a factual basis for disregarding the established evidentiary underpinning of their prior policy and regulations. *Fox Television Stations,* 556 U.S. at 515; *Bowman*, 419 U.S. at 285; *Jicarilla Apache Nation* 613 F.3d at 1112, 1119.

In sum, the Defendants fail to articulate a legitimate basis or adequate explanation for their dramatic reversal on the importance, efficacy, and benefits of contraception. As such, the Finals Rules are arbitrary and capricious and therefore invalid. 5 U.S.C. § 706(2)(A).

ii. Defendants' Explanation of Affected Women is Arbitrary and Capricious.

Finally, in estimating the number of women who will be affected by the final Rules, the Defendants fail to articulate "a rational connection between the facts found and the choice made.'" *Prometheus Radio Project*, 652 F.3d at 469 (quoting *State Farm*, 463 U.S. at 43). Although the RIA is abound with unsupported assumptions and omissions, *see infra* Part II.C, two in particular illustrate the insufficiency of the Defendants' purported explanation.

The first lies in the RIA itself. Defendants estimate that at least 70,515 and at most 126,400 women will lose contraceptive coverage when their employers take advantage of the

religious and moral exemptions.[30] 83 Fed. Reg. at 57,578; *id.* at 57,582; *id.* at 57,627. The first number estimates the number of women currently working for employers who litigated against the Mandate or who took advantage of the accommodation. The second number estimates the number of women currently working for employers who did not provide contraceptive coverage prior to the ACA. But both estimates neglect to include an estimate of the impact caused by extending the exemption to individuals—who, regardless of the policy holder's gender, will deny coverage for contraceptive services to all of his or her female dependents. Mendelsohn Decl. (Exh. P) ¶ 17.

The second lies in how the Defendants estimate the number of women working for accommodated employers. In the Religious Exemption IFR, the Defendants assumed that 209 entities were currently using the accommodation. 82 Fed. Reg. at 47,818. To determine how many employees worked for these accommodated entities, it began with a single hard number: the "576,000 plan participants and beneficiaries [who] were covered by self-insured plans that received contraceptive user fee adjustments in 201[5].[31]" *Id.* at 47,820. Defendants then multiplied by the ratio of self-insured to fully-insured plans (to account for employees working for fully insured plans that claimed the accommodation) to arrive at a total of 1,027,000 employees and beneficiaries working for 209 accommodated entities. *Id.*

In the final Religious Exemption Rule, the Defendants begin instead with the number of plan participants and beneficiaries in 2017—but the number has suddenly more than tripled. That

[30] Although the RIA requires the Defendants to calculate the annual financial impact of the final Rules, these figures have also been used to support Defendants' narrative that the Rules will not impact too many women in the States.

[31] Although the Defendants wrote "2014" here, the Defendants had early stated that "[i]n 2014, 612,000 persons were covered by plans claiming contraceptive user fees adjustments, and in 2015, 576,000 persons were covered by such plans." 82 Fed. Reg. at 47,820.

year, say the Defendants, some "1,823,000 plan participants and beneficiaries" were covered by self-insured plans that received contraceptive user fee adjustments. 83 Fed. Reg. at 57,576. Accounting for employees working for fully-insured plans,[32] the Defendants arrived at "2,907,000 persons of all ages and sexes whom the Departments estimate were covered in plans using the accommodation." *Id.* Yet the Defendants continued to use an estimate of 209 accommodated entities—as if these entities suddenly hired more than times the staff in just two years. Moreover, assuming that each policyholder has one dependent—as Defendants do, *id.* at 57,576—this means that each accommodated entity employs approximately 7,000 employees. This is not reasonable.

These two examples of faulty reasoning more than demonstrate that the Defendants' analysis is arbitrary and capricious, in violation of the APA. 5 U.S.C. § 706(2)(A).

* * *

In the APA, Congress laid out strict procedural requirements that every agency must follow when it promulgates new regulations with the binding power of law. 5 U.S.C. § 706(2)(D). Congress also provided that agency action that is arbitrary, capricious, contrary to law, and in excess of statutory authority is unlawful and must be set aside. 5 U.S.C. § 706(2)(A),

[32] The ratio of fully insured to self-insured plans appears to change dramatically from 2014 to 2015. *Compare* 82 Fed. Reg. at 47,820 & n.81 (stating that "DOL estimates that, among persons covered by employer sponsored insurance, 56.1 percent are covered by self-insured plans and 43.9 percent are covered by fully insured plans," and citing data from 2014), *with* 83 Fed. Reg. at 57,577 & n.90 (stating that "DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans," and citing data from 2015).

Instead, the Defendants erred in the IFR. The ratio there incorporated both private *and public* sector employers, even though public sector employers were ineligible for the IFR exemptions. In the final rules, Defendants use the ratio applicable to the private sector alone.

(C). The final Rules fail on both accounts. As such, the States are likely to succeed on the merits of their claims.

II. The States Will Suffer Irreparable Harm in the Absence of an Injunction.

This Court previously concluded that Pennsylvania would suffer irreparable injury if the IFRs were not enjoined. PI Op., 281 F. Supp. 3d at 581–84. Specifically, it found that Pennsylvania would suffer fiscal harm as women denied contraception would turn to Commonwealth-funded programs, and that it would also suffer injury to its interest in protecting the health and well-being of its residents. *Id.*

That conclusion holds with even more force today. Last year, the Court found that the harm from the IFRs was "not merely speculative; it is actual and imminent," and noted that Defendants own estimates found "that *at least* 31,700 women will lose contraceptive coverage" as a result of the IFRs. *Id.* at 582 (emphasis original). Defendants concede that the estimate was way off the mark: now, they say, at least 70,500 women will lose coverage. 83 Fed. Reg. at 57,578.[33] But no matter, Defendants say: even if tens of thousands of women are deprived of a legally protected right to necessary medicine, they amount to "less than 0.1%" of the women in the United States. *Id.* at 57,551 n.16. And even these women have no reason to complain, because they are not really being burdened—and if they are, it is certainly not the fault of the government. Rather, "the government has simply restored a zone of freedom where it once existed." *Id.* at 57,549. As "third parties," the women who may find their own freedom curtailed as a result of the Rules simply do not understand what has been done:

[33] In its previous motion, Pennsylvania noted that these estimates were "based on thin evidence, at best, and rest on a series of questionable assumptions" and that, based on the process that led to the IFRs, it was "unsurprising that Defendants were unable to quantify, with any degree of accuracy, the number of women who will be harmed." PI Mot. at 40 n.25

> If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits.

Id. at 57,549; *see also id.* at 57,606 (identical language).

Fortunately this Court rejected similarly specious arguments last year and found that the government does, in fact, have an obligation to require plan sponsors to provide women those preventive services identified by HRSA. And the Court further found that the harm suffered by women who are denied coverage is very real, and extends beyond the women themselves—to include the taxpayers who end up bearing the costs when employers are able to free themselves of the obligation to provide required coverage. These findings were correct.

A. Women in Pennsylvania and New Jersey Will Lose Contraceptive Coverage as a Result of the Rules

Women in the States will lose access to contraceptive coverage as a result of the rules. The Religious Exemption can be claimed by virtually anyone, and the limits on the Moral Exemption are few. Nor are there any clear standards or certifications required to claim either. And since the Rules have rendered the accommodation process optional, entities that opt out of the Contraceptive Care Mandate have no obligation to notify their insurer so that the insurer can provide coverage directly.

As a result, many women would be denied the ability to utilize the method of contraception that is best for them. *See* Kost Decl. (Exh. K) at ¶¶ 37-39. Many would be forced to pay significantly more for the same level of care. *Id.* ¶ 32 (noting that, before the ACA, "contraceptives accounted for between 30–44% of out-of-pocket health care spending for women"). Others would be forced to go without contraception entirely—and would be at greater risk of unplanned pregnancy or other potentially dangerous medical conditions. *Id.* ¶¶ 37, 42.

These risks would fall most on lower-income women, women of color, and younger women. *Id.* ¶ 45.

The previous injunction motion filed in this case discussed in detail Defendants' estimates for the number of women who will be affected by the IFRs, and the States do not repeat that discussion here. *See* PI Mot. (Exh. E) 40-42. But even under the numbers in the IFRs, which they have acknowledged were flawed, Defendants concluded that at least 31,700 women would lose coverage as a result of the IFRs. As discussed above, they now estimate that the lower bound is 70,500. There can be no serious dispute that many of these women would be citizens of the Plaintiff States. Even ignoring common sense, the evidence produced by Defendants as part of the administrative record for the IFRs identifies numerous entities located in Pennsylvania and New Jersey that Defendants themselves expect to take advantage of the Rules. *See* Exhs. V & W (spreadsheets from administrative record listing entities that potentially would utilize new exemptions); *see also* PI Mot. (Exh. E) 41–42 (discussing litigating entities in Pennsylvania); Gennace Decl. (Exh. T) ¶¶ 15-17.

Defendants' estimates, however, represent only a fraction of the women who will be harmed. Even if Defendants are correct about the number of employers claiming the exemptions, the Defendants appear to assume that no new women will enter the workforce generally, that no new women will be hired by the exempted employers specifically, and that no women will be born and become dependents of current employees of exempted employers. Defendants' estimates represent but a snapshot in time of the Rules' impact, which will continue to expand.

B. Women in Pennsylvania and New Jersey Will Be Forced to Rely on State-Funded Programs, Imposing Direct Costs on the States

The Final Rules argue that "the availability of contraceptive coverage from other possible sources—including . . . from other governmental programs for low-income women" undermines

the argument for keeping the mandate in place. 83 Fed. Reg. at 57,548; *see also* 82 Fed. Reg. at 47,803 ("[T]here are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women."). So Defendants recognize that the Rules will shift costs onto public programs, including programs funded by the States.

In Pennsylvania, women denied contraceptive coverage by their employers can seek similar coverage from a state-sponsored program. Women who are citizens of Pennsylvania with incomes up to 138% of the federal poverty level ($16,642 for an individual and $33,948 for a family of four) can enroll in Medicaid which, in Pennsylvania, is known as "Medical Assistance." *See* Allen Decl. (Exh. Q) ¶ 8. Those with incomes up to 215% of the poverty level ($25,929 for an individual and $52,890 for a family of four) can participate in the Commonwealth's Family Planning Services Program. *Id.* ¶ 9. Both programs provide contraceptive care and rely on a combination of federal and Commonwealth funding.

Similarly, New Jersey residents with incomes up to 138% of the federal poverty level, and pregnant women with incomes up to 205% of the federal poverty level ($51,624 for a family of four), can enroll in New Jersey's Medicaid program, known as "NJ FamilyCare." Adelman Decl. (Exh. S) ¶¶ 9–11. Starting in 2019, New Jersey will be rolling out a family planning benefit program called Plan First for individuals with incomes between 133% and 205% of the federal poverty limit. *Id.* ¶ 12. Both NJ FamilyCare and Plan First provide contraceptive coverage, including long-acting reversible contraception, and rely on a combination of state and federal funding.

In addition, women who lose contraceptive coverage can get some care from clinics funded under the Title X grant program. In Pennsylvania, Title X grants are administered by four non-profit organizations that provide funding to individual clinics across the Commonwealth.

These Title X clinics provide services to all women who ask, and they charge on a sliding scale based on income. They also help women who are eligible for Commonwealth-funded health care (including Medical Assistance and Family Planning Services) enroll in these programs to offset their own costs. As a result, only a small portion of the revenue for these clinics actually comes from Title X funding. *See* Steinberg Decl. (Exh. R) ¶ 13.

A full range of family planning services is also available in New Jersey through 47 Title X Family Planning Clinics run by the New Jersey Family Planning League and its ten subgrantees. Coulter Decl. (Exh. U), ¶¶ 4–5. These clinics receive funding from a variety of state and federal sources, and they serve patients Medicaid patients as well as patients with private insurance, and under a sliding fee scale, patients who self-pay. *Id.* ¶¶ 6, 8, 14. Under this sliding fee scale, lower income women who do not have insurance coverage are eligible for free or reduced-cost services contraceptive services. *Id.* ¶¶ 14, 23. Moreover, even when the women who turn to the Family Planning Clinics as a result of losing coverage are required to pay for the services they receive, the increased demand could still exceed the clinics' capacity, resulting in a need for a costly expansion of services in order for the State to continue to serve all women seeking care. *See id.* ¶ 27.

For low income women who lose access to contraception, government-funded care is likely the only available option—unless they give up contraception entirely. Therefore, because of the Rules, the Commonwealth's cost to fund the Medical Assistance and Family Planning Services, and New Jersey's cost to fund NJ Family Care, Plan First, and the Family Planning Clinics programs will increase. And women who lose access to contraceptive care will experience unplanned pregnancies and/or significant health problems as a result. Among the negative health outcomes for mothers and children associated with unintended pregnancy are

increased risk of maternal depression, increased risk of physical violence during pregnancy, reduced likelihood of breastfeeding, poorer mental and physical health during childhood, and lower rates of teenage educational attainment. Coulter Decl. (Exh. U) ¶¶ 31-32. Moreover, many mothers experiencing unintended pregnancy will turn to these same state-funded sources of care during and after pregnancy, imposing additional costs on the States. Coulter Decl. (Exh. U) ¶ 28; *see also* Butts Decl. (Exh. O) ¶¶ 56-58 (confirming that the Rules will result in some women facing unintended pregnancy and other adverse medical consequences); Steinberg Decl. (Exh. R) ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

All of these additional costs would not exist but for the Rules, and all are unrecoverable. The APA does not permit suits against the federal government for money damages, so the States will have no way of recovering the additional funds they will be forced to spend. *See* 5 U.S.C. § 702. And where a plaintiff "cannot recover damages from the defendant due to the defendant's sovereign immunity"—as is the case here—"any loss of income suffered by a plaintiff is irreparable per se." *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (citing *Bowen v. Massachusetts*, 487 U.S. 879 (1988) and *United States v. State of New York*, 708 F.2d 92, 93–94 (2d Cir.1983).

C. The States Will Suffer Injury to Their Interest in Protecting the Health and Well-Being of Their Citizens

In addition to direct pecuniary harm, the States will suffer injury to their *parens patriae* interest in protecting their own citizens. The States have "quasi-sovereign" interests that include "protecting the 'health and well-being – both physical and economic – of its residents in general.'" *In re Oxycontin Antitrust Litig.*, 821 F. Supp. 2d 591, 601 (S.D.N.Y. 2011) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 607 (1982)); *see also Snapp*, 458 U.S. at

607 ("[A] State has a quasi-sovereign interest in the health and well-being – both physical and economic – of its residents in general."). And "[i]t is unquestionable that a state, in its parens patriae capacity, does qualify as 'personally . . . suffer[ing] some actual or threatened injury." *Maryland People's Counsel v. F.E.R.C.*, 760 F.2d 318, 321 (D.C. Cir. 1985) (Scalia, J.) (quoting V*alley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (alteration in original). Not only is this harm irreparable, but it is also unquantifiable and not subject to reparation in the form of money damages. An injunction is required to address this state harm.

The States' interests are particularly relevant here, given its limited authority to regulate many of the plans covered by the Rules. The federal government, through ERISA, has taken over responsibility for regulating self-insured groups plans, which are used by the vast majority of large employers. *See* 29 U.S.C. § 1144(a). Pennsylvania and New Jersey, like all other states, "surrender[ed] certain sovereign prerogatives" when it joined the Union. *Massachusetts v. EPA*, 549 U.S. 497, 519 (2007). These prerogatives "are now lodged in the Federal Government," which, in this instance, has ordered the Defendants to enforce the provisions of the Women's Health Amendment to protect the interests of the States. *See id.* at 519 ("These sovereign prerogatives are now lodged in the Federal Government, and Congress has ordered EPA to protect Massachusetts [from certain environmental harms]."); *see also Texas v. United States*, 809 F.3d 134, 154 (5th Cir. 2015), affirmed by an evenly divided Court, 136 S. Ct. 2271 (2016) ("Both these plaintiff states and Massachusetts now rely on the federal government to protect their interests.").

III. The Public Interest and the Balance of Equities Weigh Strongly in Favor of an Injunction.

Finally, the public interest and the balance of equities strongly favor issuing a preliminary injunction. The Third Circuit has stated that "[i]f a plaintiff proves 'both' a likelihood of success on the merits and irreparable injury, it 'almost always will be the case' that the public interest favors preliminary relief." *Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 143 (3d Cir. 2017) (citing *Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1427 n.8 (3d Cir. 1994)). According to the Third Circuit, then, analyzing whether an injunction favors the public interest is "often fairly routine." *Id.* (citing *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 730 (3d Cir. 2004)).

So it is here. The public interest favors an injunction in this case because the lack of contraceptive care will cause irreparable injury, in the form of medical harm to women who rely on contraceptives for a wide range of medical reasons, increased unintended pregnancy, and widespread disruption in medical care. The public interest further favors an injunction because the Rules infringe on the sovereignty of the States, and because direct financial and other harm will befall the States and that harm, too, is irreparable. Finally, the public interest favors an injunction because the Rules are unconstitutional. *See Council of Alternative Political Parties v. Hooks*, 121 F.3d 876, 883–84 (3d Cir. 1997) ("In the absence of legitimate, countervailing concerns, the public interest clearly favors the protection of constitutional rights.").

CONCLUSION

For the reasons set forth above, the States' Motion for a Preliminary Injunction should be granted.

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