Nos. 17-3752, 18-1253, 19-1129, 19-1189

United States Court of Appeals for the Third Circuit

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY,
Plaintiffs-Appellees,

v.

PRESIDENT, UNITED STATES OF AMERICA et al.,
Defendants-Appellants,

and

LITTLE SISTERS OF THE POOR, SAINTS PETER AND PAUL HOME,
Intervenor-Defendant-Appellant.

On Appeal from the United States District Court for the
Eastern District of Pennsylvania, No. 17-cv-4540

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Regulations

Constitutional Provisions

INTRODUCTION

This case is a challenge to two rules issued by the federal government that permit employers to disregard a legal obligation to provide their female employees with coverage for contraceptive services. The district court, on two separate occasions, found that the government had failed to follow the necessary procedures in issuing the rules and that the rules themselves were inconsistent with the Affordable Care Act. The court further found that the state plaintiffs had shown that they would be irreparably harmed by the rules, as women who were denied coverage inevitably turned to other sources of care, including government-funded programs. As a result, it blocked the federal government from enforcing the rules.

The district court acted well within its discretion. It relied on evidence submitted by the states—including declarations from key government officials—establishing that the rules would impose additional costs on already burdened state programs. It assessed the obligations of federal agencies under the Administrative Procedure Act and concluded that the government's justifications for failing to comply with those obligations were sorely lacking. And it reviewed the plain language of the Affordable Care Act and rightly concluded that a statutory requirement that insurers "shall, at a minimum" provide coverage for certain services did not give federal agencies *carte blanche* to excuse insurers from actually doing so.

Issues relating to the mandate under federal law to provide contraceptive coverage have been the subject of litigation for years. Employers and others have raised a number of challenges to the application of this mandate and to earlier regulations implementing it, leading to two significant Supreme Court decisions. But this case is not about those earlier disputes. It is not about the legality of regulations issued years ago, nor is it about questions that were resolved in earlier litigation. It is about the legality of the sweeping exemption rules issued by three federal agencies and whether these agencies have the authority to issue them using the process they employed.

Despite the many complex questions relating to aspects of this case, the core issues are reasonably straightforward. Congress required covered employers and others to provide cost-free coverage for preventive services for women, and it delegated the task of identifying which preventive services should be included to a specific federal agency with the mission of improving access to care. That agency identified contraceptive services as one of eight health services that should be covered. But now, if the rules at issue in this case are allowed to go into effect, a woman employed by an organization—including a large, publicly traded company—may lose contraceptive coverage on the basis of her employer's religious objections, and the government will do nothing to see to it that she otherwise receives the coverage she is entitled to. In addition, for the first time, an

employer with a vague moral objection—which could include, as the district court found, a belief that women are better off not working—could choose to deny contraceptive coverage to his female employees, without so much as being required to notify them or the government of the nature of his objections.

It is not necessary to resolve all of the difficult questions that have previously arisen in litigation in this area to decide this case. Rather, it is simply necessary to acknowledge that these rules sweep too far, and that the process the agencies followed here fell short of what the law requires. The district court focused on these issues and found that the rules were unlawful. A second district judge in California reached the same conclusion. These courts reached the right result: the rules are unlawful; the states have standing to challenge them; and preventing the harm they threaten requires injunctive relief. The decision of the district court should be affirmed.

STATEMENT OF JURISDICTION

The district court has jurisdiction over this lawsuit under 28 U.S.C. § 1331. This Court has appellate jurisdiction over No. 19-1189 pursuant to 28 U.S.C. § 1292(a)(1), because it involves an appeal from an order granting a preliminary injunction.

The other three consolidated appeals should all be dismissed. Nos. 17-3752 and 18-1253 are moot, because the interim rules that are the subject of that injunction are no longer at issue. The appeal in No. 19-1129 should be dismissed because the Little Sisters of the Poor as Appellant in that case are not affected by the injunction and therefore lack appellate standing. *See infra* Argument Part III.

STATEMENT OF THE ISSUES

1. Whether the district court correctly concluded that the States have Article III standing (J.A. 71–81).
2. Whether the district court abused its discretion in granting the States' motion for preliminary injunction (J.A. 81–114).
3. Whether the district court erred in concluding that the States are likely to succeed on the merits of their claims that:
    a. Defendants violated the procedural requirements of the APA (J.A. 25–35, 85–91).
    b. The final rules violate the Affordable Care Act (J.A. 93–100).
    c. The final rules are not required or permitted by the Religious Freedom Restoration Act (J.A. 100–10).
4. Whether the district court committed clear error in concluding that the States will suffer irreparable harm absent an injunction (J.A. 110–13).
5. Whether the district court committed clear error in concluding that the balance of the equities and public interest favor an injunction (J.A. 113–14).
6. Whether the district court abused its discretion in granting a nationwide injunction (J.A. 115–23).
7. Whether Intervenor has appellate standing (J.A. 114 n.27).

STATEMENT OF RELATED CASES

The States agree with the Statement of Related Cases in Defendants' brief.

The Statement of Related Cases in the brief of Intervenor Little Sisters of the Poor lists a number of cases that are unrelated to this action. All cases except the first two challenge prior rules not before this Court. Moreover, cases listed under the headings "Cases resulting in permanent injunctions issued prior to October 2017 against prior versions of the rules" and "Cases resulting in permanent injunctions issued since October 2017 against prior versions of the rules" are wholly irrelevant. The permanent injunctions in all 60 of these cases resulted from (a) consent injunctions entered by the prior administration pursuant to the Supreme Court's holding in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), (b) concessions by the current administration that the contraceptive mandate and accommodation violate the Religious Freedom Restoration Act, and/or (c) the current administration's voluntarily dismissal of pending appeals.

STATEMENT OF THE CASE

I. The Women's Health Amendment

In an effort to counter gender discrimination in healthcare, the Senate passed the "Women's Health Amendment" during consideration of the Affordable Care Act.[1] *See* S. Amdt. 2791, 111th Congress (2009–2010). The amendment required health insurance providers to offer coverage for "additional preventive care and screenings" for women without imposing cost-sharing requirements. I*d.*; 42 U.S.C. § 300gg-13(a)(4). Supporters of the amendment argued that it was necessary to address the "fundamental inequity in the current system" and to stop the "punitive practices of insurance companies" toward women. *See* 155 Cong. Rec. S12027 (Dec. 1, 2009) (statement of Sen. Gillibrand); *id.* S11987 (Nov. 30, 2009) (statement of Sen. Mikulski).[2] The Women's Health Amendment was included in the final version of the ACA, which became law on March 23, 2010.

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[1] Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18001 *et seq.* (2010).

[2] Senator Barbara Mikulski, the lead sponsor of the Amendment, stated:

> "Women are often faced with the punitive practices of insurance companies. No. 1 is gender discrimination. Women often pay more and get less. For many insurance companies, simply being a woman is a preexisting condition. Let me repeat that. For many insurance companies, simply being a woman is a preexisting condition."

155 Cong. Rec. at S11987.

In the amendment, Congress did not mandate which specific "additional preventive care and screenings" for women were to be covered. Rather, it left that decision to the Health Resources and Services Administration (HRSA), a unit of the Department of Health and Human Services that "has as its goal to improve access to primary and preventive care services to uninsured and underinsured individuals" and which "strives to develop 'best practices' and create uniform standards of care." 155 Cong. Rec. S12058–59 (Dec. 1, 2009) (statement of Sen. Cardin). Yet while Congress did not dictate to HRSA the full list of "care and screenings" to be covered, the amendment's supporters made clear that they expected certain services would be included. Among these were cancer screenings, well-women visits, domestic violence screenings, and family planning services.[3]

[3] *See* 155 Cong. Rec. S12025 (Dec. 1, 2009) (statement of Sen. Boxer) ("[Covered] health care services include annual mammograms for women at age 40, pregnancy and postpartum depression screenings, screenings for domestic violence, annual women's health screenings, and family planning services."); *id.* at S12027 (statement of Sen. Gillibrand) ("With Senator Mikulski's amendment, even more preventive screening will be covered, including for post-partum depression, domestic violence, and family planning."); *id.* at S12028 (statement of Sen. Mikulski) ("It also provides family planning…."); *id.* at S12059 (statement of Sen. Cardin) ("General yearly well-women visits would be covered; pelvic examinations, family planning services, pregnancy, and post partum depression screenings, chlamydia screenings for all women over 25."); *id.* (statement of Sen. Feinstein) ("This may include mammograms, pap smears, family planning, and screenings to detect heart disease, diabetes, or postpartum depression-in other words, basic services that are a part of every woman's health care needs at some point in life."); *id.* at S12275 (Dec. 2, 2009) (statement of Sen. Murray) ("Women will have improved access to well-women visits-important for all women; family

II. The Institute of Medicine Report

Following passage of the ACA, HRSA commissioned the Institute of Medicine (IOM), a widely respected organization of medical professionals, to issue recommendations identifying the preventive services for women to be covered by the Women's Health Amendment. The IOM, in turn, convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. After conducting an extensive study, the IOM committee issued a comprehensive report identifying eight evidence-based preventive health services that it recommended be included. *See* J.A. 1007–11 (Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* 8-12 (2011)); *see also* J.A. 280–85 (Declaration of IOM Committee Member Carol S. Weisman, Ph.D.).

The IOM Committee recommended that HRSA include "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education" as a required preventive service for women. *See* J.A. 1034–35. In making this recommendation, the IOM cited evidence that "contraception and contraceptive counseling are effective at reducing unintended

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planning services; mammograms, which we have all talked about so many times, to make sure they maintain their health.").

pregnancies" and observed that "[n]umerous health professional associations and other organizations recommend the use of family planning services as part of preventive care for women." J.A. 1034, 1029.[4]

In choosing to include contraception on the list of recommended preventive services, the IOM Committee relied on the following considerations:

Unintended Pregnancy Is Prevalent in the United States. The IOM report found that, in 2001, "an estimated 49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception" and that "1 in 20 American women has an unintended pregnancy each year." J.A. 1027 (all citations omitted). These unintended pregnancies disproportionately impact certain groups, including "women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group." J.A. 1027.

Unintended Pregnancies Have Negative Health Consequences. The IOM report found that "women with unintended pregnancies are more likely

[4] The IOM Report specifically identified the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the American Academy of Pediatrics (AAP), the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, the Association of Women's Health, Obstetric and Neonatal Nurses, and the March of Dimes as organizations that recommended family planning services as preventive care for women. J.A. 1029.

than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy." J.A. 1028. Babies born as a result of unintended pregnancies face "significantly increased odds of preterm birth and low birth weight" and are "less likely to be breastfed or are breastfed for a shorter duration." J.A. 1028.

Contraception Promotes Healthy Spacing of Pregnancies. The IOM found that contraceptives promote medically recommended spacing between pregnancies. Spacing is important because of the "increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)." J.A. 1028. Specifically, the report found that "[S]hort interpregnancy intervals" were "associated with low birth weight, prematurity, and small for gestational age births." J.A. 1028.

For Some Women, Pregnancy Is Especially Dangerous. While pregnancy always carries some health risks, the IOM report found that these risks were particularly high for certain women. It concluded that pregnancy "may be contraindicated for women with serious medical conditions," including pulmonary hypertension, cyanotic heart disease, and Marfan Syndrome. J.A. 1028. In addition, "women with certain chronic medical conditions," including diabetes and obesity,

"many need to postpone pregnancy until appropriate weight loss or glycemic control has been achieved." J.A. 2018.

Contraceptives Are Effective at Preventing Unintended Pregnancies and Reducing Abortion Rates. The IOM also found that contraceptives are, in fact, effective at preventing unintended pregnancies. It concluded, "greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally." J.A. 1030. The report highlighted a study showing that, as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, their rates of unintended pregnancy and abortion declined. J.A. 1030. Other studies show that increased rates of contraceptive use by adolescents were associated with a "decline in teen pregnancies" and, conversely, that "periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use." J.A. 1030.

Contraceptives Have Other Significant Health Benefits. In addition, the IOM recognized that contraceptives have other significant health benefits unrelated to preventing unintended pregnancy. The report stated that these "non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain." J.A. 1032. Long-term use of oral contraceptives has also been shown to "reduce a woman's risk of endometrial

cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases." J.A. 1032.

Cost Is A Meaningful Barrier to Contraceptive Use. The IOM found that cost is a meaningful barrier to contraceptive access. It concluded that "[d]espite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years" and that "cost-sharing requirements, such as deductibles and copayments, can pose barriers to care and result in reduced use of preventive and primary care services, particularly for low-income populations." J.A. 1034.

Reducing Costs Promotes the Use of More Effective Methods of Contraception. The IOM report reviewed evidence on the effectiveness of different methods of contraception, concluding that "long-acting, reversible contraceptive methods and sterilization" were the "most effective contraceptive methods," but that these methods have "high up-front costs."[5] The report concluded that reducing costs

[5] Long-acting reversible contraception methods—often referred to as LARCs—include intrauterine devices and subdermal implants. The IOM Report found that these methods had failure rates (defined as the percentage of users who become pregnant during the first year of use) of less than one percent. J.A. 1031. By comparison, other methods had much higher failure rates, because users often failed to use them properly. For instance, the report found that, under "typical use," birth control pills had a failure rate of eight percent, and male condoms had a failure rate of fifteen percent. J.A. 1031. When used "consistently and correctly,"

for contraception leads to increased use of more effective methods, citing a Kaiser Permanente study finding that "when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods." J.A. 1034.

* * *

The IOM report was released July 19, 2011. On August 1, 2011, HRSA adopted the recommendations of the report and issued its first "Women's Preventive Services Guidelines," as required by the Women's Health Amendment. J.A. 984–86. Consistent with the recommendations of the IOM committee, the guidelines required health plans to cover "All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." J.A. 985. This became known as the "contraceptive mandate."[6]

III. The Agencies Work to Accommodate Religious Objections to Contraception

In July 2010—one year before completion of the IOM report—the Departments of Health and Human Services, Labor, and the Treasury ("the

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the failure rates for these methods dropped to 0.3 percent and two percent, respectively. J.A. 1031.

[6] In 2016, HRSA updated the Guidelines but retained the contraceptive mandate. J.A. 979.

Agencies") issued interim final rules on the Women's Health Amendment and other provisions of the ACA relating to preventive medicine. 75 Fed. Reg. 41,726 (July 19, 2010). These interim rules noted the ACA's requirement that plans cover preventive services for women pursuant to guidelines issued by HRSA and stated that HHS was "developing these guidelines and expects to issue them no later than August 1, 2011."

A. The Church Exemption

Shortly after the completion of the IOM report and the adoption of its recommendations by HRSA, the Agencies issued amendments to the July 2010 interim rules. *See* 76 Fed. Reg. 46,621 (Aug. 3, 2011). Based on the "considerable feedback" received "regarding which preventive services for women" should be covered under the Women's Health Amendment, *id.* at 46,623, the Agencies amended the guidelines to state that certain religious employers were exempt from the obligation to cover contraceptive services (the "church exemption").

To qualify as an exempt "religious employer," an organization had to satisfy four criteria set forth in the regulation. *See id.* at 46,626. Two years later, the Agencies simplified the definition to cover any "organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986." 78 Fed. Reg. 39,870, 39,896 (July 2, 2013). These two sections refer to "churches, their integrated auxiliaries, and

conventions or associations of churches" and "the exclusively religious activities of any religious order." 26 U.S.C. § 6033(a)(3)(A)(i) & (iii).

B. The Accommodation

Six months later, the Agencies issued a final rule adopting the amended interim rules without change. 77 Fed. Reg. 8725 (Feb. 15, 2012). At the same time, the Agencies also announced that they planned to further consider how to address entities that did not qualify for the church exemption but nonetheless objected to providing contraception. *Id.* at 8727. Specifically, the Agencies said that they "plan[ned] to develop and propose changes … that would meet two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit organizations' religious objections to covering contraceptive services." *Id.* In order to facilitate this process, they announced a temporary "safe harbor" from enforcement of the mandate for certain organizations. *Id.* at 8728.

Over the next fifteen months, the Agencies issued an Advanced Notice of Proposed Rulemaking (ANPRM),[7] a Notice of Proposed Rulemaking (NPRM),[8] and ultimately a Final Rule.[9] The result was the "accommodation," which was

[7] 77 Fed. Reg. 16,502 (March 21, 2012).

[8] 78 Fed. Reg. 8456 (Feb. 6, 2013).

[9] 78 Fed. Reg. 39,870 (July 2, 2013).

distinct from the church exemption provided to organizations that qualified under the definition of "religious employers." The accommodation was initially available to any nonprofit entity that "holds itself out as a religious organization" and that had religious objections to "providing coverage for some or all of any contraceptive services required" by the Women's Health Amendment.[10]

An organization that qualified for the accommodation could opt out of providing contraceptive coverage directly by submitting a standard form to its insurance company if fully insured, or third-party administrator if self-insured, informing it of its objections.

An insurance company receiving such notification from an objecting fully insured organization was required to "[e]xpressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan," and instead "[p]rovide separate payments for any contraceptive services required to be covered … for plan participants and beneficiaries for so long as they remain enrolled in the plan." *Id.* at 39,893. The insurance company was further required to "segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services." *Id.* Finally, the insurer was required to provide written notice to plan

[10] *Id.* at 39,874.

participants and beneficiaries of the fact that "the eligible organization does not administer or fund contraceptive benefits" but that such benefits were available directly from the insurer. *Id.*

Under this system, fully insured objecting organizations could opt out of providing it directly, but their plan participants and beneficiaries would still receive the benefits they were entitled to under the ACA. Shifting the burden to the insurer to provide the services directly was not expected to impose additional costs on the insurer, because "[c]overing contraceptives … yields significant cost savings," in the form of lower "direct medical costs of pregnancy" as well as lower "indirect costs, such as employee absence." *Id.* at 39,872. As a result, the insurance company would expect to see lower expenses from providing coverage to the organization's participants and beneficiaries for all other services.

Unlike fully insured employers, self-insured employers directly pay for the health expenses they elect to cover, typically with the administrative assistance of an outside organization known as a third-party administrator (TPA).[11] Under the accommodation, self-insured objecting organizations could submit the standard form to their TPA, noting their objection to providing such coverage. *Id.* at 39,892–93. The TPA then assumed the obligation to provide contraceptive

[11] Many TPAs are insurance companies, but they do not act as insurers in serving as TPAs.

coverage to plan participants and beneficiaries, either by paying for contraceptive services directly or by contracting with another entity to do so. *Id.* at 39,893. And the TPA was obligated to provide the same notice that insurers were required to provide, stating that the organization did not provide contraceptive benefits, but that such benefits were available from the TPA. *Id.*

In these respects, the accommodation functioned in precisely the same manner for self-insured and fully-insured organizations. However, because TPAs for self-insured plans do not bear the costs for other benefits provided to plan participants and beneficiaries, they would not be expected to save money by providing contraceptive coverage. *Id.* at 39,882–86. As a result, the regulations created a mechanism whereby these TPAs could obtain reimbursement from HHS for the cost of providing the coverage, as well as an allowance for administrative expenses and profit. *Id.*[12]

IV. Litigation over the Contraceptive Mandate and Its Implementing Regulations

Numerous employers and colleges filed lawsuits challenging aspects of the mandate and, on two occasions, the Supreme Court heard argument in cases raising

[12] The payment mechanism operated through the Federally-Facilitated Exchange (FFE) user fee paid by companies that participate in federally-administered healthcare exchanges, and was referred to as the "FFE user fee adjustment." *Id.* at 39,882.

claims that the government had violated the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb, *et seq*., through its actions in carrying out the mandate.

A. Burwell v. Hobby Lobby Stores

Several closely held, for-profit corporations challenged the application of the mandate to them, arguing that being required to provide contraception violated their religious beliefs. Following the creation of the accommodation, many of these plaintiffs argued that the accommodation (for which for-profit corporations were not eligible) showed that the government could achieve the same benefits without requiring them to provide contraceptive services directly. Two of these challenges were consolidated before the Supreme Court in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014).

In *Hobby Lobby*, the Court held, 5-4, that the imposition of the mandate on for-profit closely held corporations violated RFRA. Under that statute, the government may not "substantially burden a person's exercise of religion," unless it can establish that "that application of the burden to the person … is in furtherance of a compelling governmental interest" and "is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb–1(a)-(b). *Hobby Lobby* held that, for purposes of RFRA, a closely held for-profit corporation was a "person." 573 U.S. at 708. It further held that requiring objecting

closely held for-profit corporations to comply with the mandate constituted a "substantial burden," and that the existence of the accommodation—which for-profit corporations were not eligible for—showed that requiring direct compliance with the mandate was not the "least restrictive means" of achieving the government's interest. *Id.* at 731.

Three days after its decision in *Hobby Lobby*, the Court issued an unsigned order in *Wheaton Coll. v. Burwell*, 573 U.S. 958 (2014), another challenge to the contraceptive mandate. Over the dissent of three justices, the Court ruled that Wheaton College could not be forced to comply with the mandate if it "inform[ed] the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services." *Id.* at 958. The Court stressed, however, that "[n]othing in [the] interim order affects the ability of the applicant's employees and students to obtain, without cost, the full range of FDA approved contraceptives" as the government could rely on the notice provided by Wheaton to "facilitate the provision of full contraceptive coverage under the Act." *Id.*

Shortly after these decisions, the Agencies initiated a formal rulemaking process using a NPRM to amend the eligibility criteria for the accommodation in light of *Hobby Lobby*. 79 Fed. Reg. 51,118 (Aug. 27, 2014). On the same day, the Agencies issued an interim final rule to address the Court's order in *Wheaton*

College. The interim rule created an alternate mechanism by which objecting entities could establish eligibility for the accommodation by notifying HHS—rather than their third-party administrator—of their objection to providing contraception coverage. 79 Fed. Reg. 51,092 (Aug. 27, 2014). Both sets of rules were finalized one year later. 80 Fed. Reg. 41,318 (July 1, 2015).

B. Zubik v. Burwell

While *Hobby Lobby* involved a challenge to the mandate filed by plaintiffs that were not eligible for the accommodation, several additional cases were filed by plaintiffs that were eligible for the accommodation but alleged that it violated their rights under RFRA. Many of these cases were ultimately consolidated before the Supreme Court in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

Prior to *Zubik*, the majority of courts of appeals had addressed the critical question raised by that case: whether requiring an objecting entity to comply with the accommodation "substantially burden a person's exercise of religion" such that RFRA applied. 42 U.S.C. § 2000bb–1(a). *Zubik* itself involved a decision of this Court rejecting the argument that the accommodation imposed a substantial burden. *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422 (3d Cir. 2015), *vacated and remanded sub nom. Zubik*, 136 S. Ct. 1557. Similarly,

Intervenor the Little Sisters of the Poor (hereinafter "Intervenor")[13] had filed a similar action in Colorado challenging the accommodation; in that case, both the district court and the Court of Appeals rejected the argument that the accommodation imposed a substantial burden on their exercise of religion. *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151 (10th Cir. 2015), *vacated and remanded sub nom. Zubik*, 136 S. Ct. 1557.

In fact, prior to *Zubik*, eight of the courts of appeals had rejected similar arguments. *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207 (2d Cir. 2015); *E. Texas Baptist Univ. v. Burwell*, 793 F.3d 449, 452 (5th Cir. 2015); *Michigan Catholic Conference & Catholic Family Servs. v. Burwell*, 807 F.3d 738 (6th Cir. 2015); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 618 (7th Cir. 2015); *Eternal Word Television Network, Inc. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 818 F.3d 1122 (11th Cir. 2016); *Priests For Life v. U.S. Dep't of Health & Human Servs.*, 772 F.3d 229 (D.C. Cir. 2014). Only the Eighth Circuit had ruled in favor of plaintiffs in a case alleging that the accommodation imposed a substantial burden. *Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015).[14]

[13] Defendants and Intervenor together are called "Appellants."

[14] All of these decisions were vacated in *Zubik* or shortly thereafter.

Six days after argument in *Zubik*, the Court issued an order directing the parties to submit supplemental briefing to "address whether and how contraceptive coverage may be obtained by petitioners' employees through petitioners' insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees." *Zubik v. Burwell*, 194 L. Ed. 2d 599 (Mar. 29, 2016). The order proposed one such arrangement, but added that "[t]he parties may address other proposals along similar lines." *Id.*

After the parties submitted supplemental briefing on the topic, the Court issued a brief per curiam decision. *Zubik*, 136 S. Ct. 1557. Finding that the option it had proposed was "feasible," the Court decided that the parties should be "afforded 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. The Court added:

> Nothing in this opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by petitioners' health plans "obtain, without cost, the full range of FDA approved contraceptives."

Id. at 1560–61 (citations omitted).

In early 2017, the Agencies 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," Dep't of Labor, *FAQs about Affordable Care Act Implementation Part 36*, at 4–5 (Jan. 9, 2017)[15] (the "2017 FAQs")—confirming that the accommodation was the least restrictive means of furthering the government's compelling interest in providing contraceptive coverage without cost sharing. The Agencies also reaffirmed their view that the accommodation does not violate RFRA. *Id.* As a result, *Zubik* and its companion cases remained pending in the courts of appeals.

V. The Interim Final Rules

On May 4, 2017, President Donald Trump issued an Executive Order directing the Agencies 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. J.A. 977. The order said nothing about the Court's instruction in *Zubik* that the Agencies ensure that women covered by health plans offered by objecting entities "receive full and equal health coverage, including contraceptive coverage." 136 S. Ct. at 1560 (citation omitted).

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

Several months after the Executive Order was issued, federal defendant agencies (the "Defendants") published two interim final rules. J.A. 804–847 (82 Fed. Reg. 47,792 (Oct. 13, 2017) (the "Religious Exemption IFR")); J.A. 848–872 (82 Fed. Reg. 47,838 (Oct. 13, 2017) (the "Moral Exemption IFR")) (together, "the IFRs"). The IFRs were issued without any prior notice or an opportunity for comment, and they went into effect immediately. The IFRs imposed a number of sweeping changes to the Mandate, the church exemption, and the accommodation:

Publicly Traded Corporations. For the first time, the IFRs provided that publicly traded for-profit corporations could opt out of the Mandate based on sincerely held religious views. The Religious IFR justified this expansion by arguing "in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character." J.A. 822. It continued, "Thus we consider it possible, though very unlikely, that a religious publicly traded company might have objections to contraceptive coverage." J.A. 822–23.

Moral Objection. As a result of the Moral IFR, entities with "sincerely held moral convictions" could also opt out of providing contraceptive coverage. J.A. 856. The Moral IFR did not explain what type of belief would qualify as a

"sincerely held moral conviction" that would allow an entity to avoid having to provide coverage. In most respects, the Moral IFR functioned in the same manner as the Religious IFR, with one exception: publicly traded companies were not eligible for the Moral IFR; instead, it was only available to nonprofit entities and closely held corporations.

***No Mandatory Accommodation*:** In perhaps their most sweeping change, the two IFRs rendered the accommodation entirely optional. Any organization that claimed a religious or moral objection to providing contraceptive coverage could opt out entirely. As a result, the organization's plan participants and beneficiaries would no longer receive the contraceptive coverage to which they were legally entitled. The IFRs did not create any mechanism for women who were denied coverage to obtain it from other sources, and it did not suggest that the Agencies would work to ensure that such women had coverage—perhaps by reaching out to insurance companies to have them provide it directly.

***No Notice Requirement*:** The IFRs provided that "exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them." J.A. 860. Rather, the only notice plans were required to provide to participants was that already mandated by ERISA. So long as plans that did not provide contraception indicated

that fact somewhere in their plan documents, they were in full compliance with the IFRs.

* * *

The Agencies justified the IFRs on the basis that "[t]he United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions." J.A. 804.

While conceding that they had little specific information to rely on, the Agencies attempted to estimate the number of women who would lose access to contraceptive coverage as a result of the IFRs, ultimately concluding that the IFRs would affect anywhere from 31,715 to 120,000 women. J.A. 833, 836, 868. They argued that the harm to women denied coverage would be limited, because they had other options—specifically, other government-funded options—for receiving contraceptive care:

> Moreover, there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families.

J.A. 815.

On October 11, 2017, the Commonwealth of Pennsylvania filed suit in this matter alleging that the IFRs violated numerous statutory and constitutional

provisions. J.A. 165–97. The Commonwealth moved for a preliminary injunction, which the district court granted on December 15, 2017. J.A. 7–52. The 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; it would suffer irreparable harm in the absence of an injunction; the balance of equities favored the issuance of an injunction; and an injunction was in the public interest. J.A. 23–50. On the merits, the district court found that Defendants had violated the Administrative Procedure Act in failing to provide notice and an opportunity to comment before issuing the IFRs. J.A. 23–50. In addition, the district court found that the IFRs were "arbitrary, capricious, and contrary to established law" because they were inconsistent with the ACA and not justified by RFRA. J.A. 35–43.

VI. The Final Rules

On November 7, 2018, while the appeal of the final preliminary injunction was pending before this Court, the Defendants issued two new rules that "finalize" the IFRs "with changes based on public comments" J.A. 882–936 (83 Fed. Reg. 57,536 (Nov. 15, 2018) (the "final Religious Exemption Rule")); J.A. 937–76 (83 Fed. Reg. 57,592 (Nov. 15, 2018) (the "final Moral Exemption Rule")) (together, the "Final Rules" or "Rules"). The Final Rules made few substantive changes to

the IFRs: they continued to allow publicly traded companies to claim the religious exemption; they kept the moral exemption in essentially the same form; and they did not require objecting entities to utilize the accommodation. The Final Rules were to become effective January 14, 2019.

As in the IFRs, the Agencies attempted to estimate the number of women who would lose access to contraceptive coverage. In the Final Rule, they estimated that anywhere from 70,515 to 126,400 women would be affected. J.A. 924, 926, 972. The lower estimate had more than doubled (from 31,700 in the IFRs) notwithstanding the fact that the Agencies removed from their calculations women covered by plans that, like Intervenor, had obtained preliminary injunctions. J.A. 921–22.[16]

The Final Rules discussed many of the objections commenters had raised to the IFRs. In particular, the Final Rules rejected concerns that the expanded

[16] The estimate increased primarily because the Agencies had seen a significant increase in requests for FFE user fee adjustments pursuant to the accommodation. *See supra note* 12 (discussing user fee adjustments). In the IFRs, the Agencies estimated 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." J.A. 832. In the Final Rules, they estimated that they had received user fee adjustment requests "for plans covering approximately 1,823,000 plan participants and beneficiaries of all ages, male and female," although data for the year was not yet complete. J.A. 922. The volume of user fee adjustment requests provided one of the few pieces of hard data the agencies could use to estimate the number of individuals affected by the accommodation—although it was necessarily incomplete, as it did not account for fully-insured plans.

exemption would burden women who were denied contraceptive coverage. Such concerns were beside the point, the Rules claimed, because any harm that women would suffer was not the government's fault:

> If some third parties do not receive contraceptive coverage from private parties whom the government chooses 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.

J.A. 951.

Finally, the Final Rules—like the IFRs—stressed that women who lost coverage would not necessarily be harmed at all, because they could receive coverage from other government programs. In particular, the Final Rules noted that HHS had recently issued a proposed rule providing that women denied coverage because of an employer's objections would be considered to be from a "low income family" and therefore eligible for "free or low cost contraceptive services" at Title X clinics. J.A. 897.

On December 14, 2018, Pennsylvania—joined by the State of New Jersey—filed an amended complaint challenging the Final Rules. Three days later, the States filed a motion for a second preliminary injunction. Shortly before the scheduled injunction hearing, the Ninth Circuit issued a decision affirming the preliminary injunction of the IFRs issued by the Northern District of California.

California, et al. v. Azar, et al., 911 F.3d 558, 579 (9th Cir. 2018). That court found that the plaintiff states had standing and had shown a likelihood of success on their claim that the IFRs were issued in violation of the procedural requirements of the APA and otherwise satisfied the requirements for an injunction. The court also considered whether the injunction of the IFRs would become moot once the Final Rules went into effect, but concluded that it did not need to address that question because that date had not yet arrived. *Id.* at 569.

The district court held a hearing on January 10, 2019, and, on January 14, 2019—the day the Final Rules were scheduled to go into effect—issued a second nationwide preliminary injunction blocking them. J.A. 124–25. The district court specifically noted that the injunction would not affect Intervenor because it had secured its own separate injunction. Nevertheless, Intervenor filed a notice of appeal the same day, and Defendants filed one soon thereafter.

SUMMARY OF ARGUMENT

1. The district court correctly found that the States have Article III standing. The Rules will injure the States' proprietary interests through the increased use of state-funded programs that provide contraceptive and medical services, and the district court was well within its discretion in crediting the States' evidence on this point. In addition, the Rules will injure the States' quasi-sovereign interests through harm to their residents' well-being and denial of their residents' full enjoyment of federal benefits.

2. The district court did not abuse its discretion in granting the States' motion for preliminary injunction of the Final Rules:

   a. Defendants violated the procedural requirements of the APA. They lacked both statutory authority and "good cause" to dispense with these requirements, and their solicitation of post-promulgation comments did not cure their error.

   b. The Rules violate the Women's Health Amendment to the Affordable Care Act, which imposes a mandatory obligation on insurers and does not authorize the Agencies to create broad exceptions from this obligation.

   c. The Rules were neither required nor authorized by RFRA. Courts, not agencies, are responsible for enforcing RFRA, and any analysis under

RFRA requires an individualized assessment. RFRA does not authorize blanket exemptions of the type created by the Rules. Furthermore, there is no justification for the Agencies' determination that the accommodation imposes a substantial burden on the exercise of religion.

d. The district court did not err in finding that the States had shown they would suffer irreparable injury in the absence of injunctive relief, and that the balance of equities and the public interest also warranted issuance of an injunction.

3. The district court did not abuse its discretion in entering a nationwide injunction. To the contrary, the court considered all relevant facts and correctly concluded that granting the States full relief required issuance of an injunction that was not geographically scope.

4. Intervenor lacks appellate standing because the district court explicitly excluded it from the scope of the preliminary injunction. Therefore, it is not harmed by the order on appeal here.

ARGUMENT

I. The District Court Correctly Found that the States Have Standing.

Standard of Review

The district court's "legal conclusions related to standing" are subject to de novo review, while "the factual elements underlying the District Court's determination of standing" are reviewed for clear error. *Edmonson v. Lincoln Nat. Life Ins. Co.*, 725 F.3d 406, 414 (3d Cir. 2013) (quoting *Gen. Instrument Corp. v. Nu–Tek Elecs. & Mfg.*, 197 F.3d 83, 86 (3d Cir. 1999)).

Discussion

A plaintiff has standing to sue if it can "show that [it] personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, and that the injury fairly can be traced to the challenged action and is likely to be redressed by a favorable decision." *Pub. Interest Research Grp. of New Jersey, Inc. v. Powell Duffryn Terminals Inc.*, 913 F.2d 64, 70 (3d Cir. 1990) (cleaned up). The Rules injure the States in two ways: they will harm the States' proprietary interests through the increased use of state-funded programs that provide contraceptive and medical services, and they will injure the States' quasi-sovereign interests through harm to their residents' well-being and denial of their residents' full enjoyment of federal benefits. Either provides a

sufficient basis for affirming the district court's conclusion that the States have standing.

A. The Final Rules Will Injure the States' Proprietary Interests.

The district court found that "the Final Rules inflict a direct injury upon the States by imposing substantial financial burdens on their coffers." J.A. 76. Relying on evidence submitted by the States as well as Defendants' own admissions, the Court concluded that female residents of the States would be deprived of cost-free coverage for contraception and that some number of these women would turn to state-funded programs for coverage. J.A. 76 ("If the Final Rules go into effect, the States will have to increase their expenditures for State funded programs that provide contraceptive services."). This conclusion was not clearly erroneous.

The States submitted eleven separate declarations discussing the harm that would result from the Rules. Those declarations explained that women who lost contraceptive coverage as a result of the Final Rules would seek it elsewhere, including from State-funded programs. For instance:

- Dr. Samantha F. Butts, M.D., MSCE, stated that "as a result of the Rules, some women will lose insurance coverage for preventive contraceptive care" and that "under the new Rules, cost will, again, become a barrier to women's access to and use of the contraceptive that is medically recommended for them." J.A. 295–96 (¶¶ 53–55).
- Seth Mendelsohn, the Executive Deputy Director Insurance Commissioner for Pennsylvania, stated that the Pennsylvania Insurance Department "anticipates that women who lose contraceptive coverage through their employer's plans may seek contraceptive coverage from other sources,

including state-funded programs, or face the financial burden of paying for the full cost of contraceptives themselves." J.A. 299 (¶ 15).

- Leesa Allen, the Acting Executive Deputy Secretary for the Pennsylvania Department of Human Services, explained the eligibility criteria for Medical Assistance (Pennsylvania's Medicaid) and the Commonwealth's Family Planning Services Program, both of which provide contraceptive services. She concluded that "some eligible women who require contraceptive care but who work for employers that choose to opt out under the new exemption rules will likely seek out other coverage options, including [these] Commonwealth-funded programs." J.A. 305–06 (¶ 23).
- Sarah Adelman, Deputy Commissioner for the New Jersey Department of Human Services, explained the operation of "NJFamilyCare," New Jersey's combined state-funded Medicaid and Children's Health Insurance Program. According to Ms. Adelman, the New Jersey Division of Medical Assistance and Health Services "anticipates that some women, particularly low-income women, who lose contraceptive coverage through their employer's plans may seek coverage from other sources, such as NJ FamilyCare, Plan First, and Title X," which would "result in additional costs to New Jersey." J.A. 317 (¶ 19).
- Ms. Adelman added: "The expanded exemptions are to result in greater financial expenditures by both the State of New Jersey and women in New Jersey on contraceptive coverage and on healthcare generally for women and infants." J.A. 318 (¶ 24); *see also* J.A. 319–23 (Declaration of Philip Gennace, Assistant Commissioner of Life and Health in the New Jersey Department of Banking and Insurance).
- Elizabeth Coulter, Deputy Director of the Office of Women's Health for the New Jersey Department of Health stated that she "expect[ed] that many women in New Jersey who lose their contraceptive coverage will seek care from one of the 47 New Jersey Family Planning Clinics," which rely on state funding. J.A. 328 (¶ 25).

The States also submitted evidence on the eligibility requirements for various state programs that fund contraception. For instance, in Pennsylvania, Family Planning Services are available to those with incomes of up to 215% of the poverty level and Medical Assistance is available to those with incomes up to

138% of the federal poverty level. New Jersey has similar income thresholds. J.A. 315–16 (Declaration of Sarah Adelman). And both states have networks of state-funded Title X clinics, which serve patients at every income level. J.A. 307–13, 324–30. As a result, many women who lose coverage as a result of the Rules will be eligible for state-funded programs.

The state officials who testified on the anticipated impact of the Rules on state-funded programs were all senior executives who are responsible for overseeing those same programs or who regulate the insurance industry in their states. They based their conclusions on their experience and their detailed understanding of the market for healthcare in their states. Their testimony was buttressed by that of medical professionals who publish extensively on issues relating to contraception and who regularly treat patients. The district court was well within its discretion to credit the testimony of the States' declarants in finding that the Rule "inflict a direct injury upon the States by imposing substantial financial burdens on their coffers." J.A. 76.

Defendants chose not to present any evidence to counter these assertions. To the contrary, Defendants' own assertions in the Rules confirm that the States will suffer injury. In attempting to minimize the harm to women as a result of the Rules, they argued that those who lost coverage could easily turn to other programs:

> [T]here are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families.

J.A. 815. Intervenor agrees: it argues that employees of companies that opt out "may 'obtain coverage . . . through Medicaid or another government program.'" Int. Br. 33.

In the Final Rules, Defendants highlight an anticipated rule change will make all women who lose employer-sponsored coverage eligible for free or reduced services at Title X clinics. J.A. 897. This assertion, it turned out, was incorrect—HHS later disagreed with its interpretation of its own rule. But the point was clear: the Agencies expect women who lose coverage to seek it from government programs. Their assertions to the contrary now cannot erase the clear statements they made in the Rules.

Defendants similarly try to hide from their own estimates as to the number of women who are likely to be harmed. As explained above, Defendants estimated in the IFRs that the Rules would affect anywhere from 31,715 to 120,000 women; in the Final Rules, the increased their estimate to 70,515 to 126,400 women. *Supra* Statement Parts V & VI. But they now dismiss these estimates, arguing that "the agencies' analysis does not show that it is likely rather than speculative that there is even a single woman who resides in Pennsylvania or New Jersey who would

wish to use the particular contraceptive method to which her employer objects, and would seek and qualify for state assistance." Def. Br. 31–32. In other words, despite estimating that tens if not hundreds of thousands of women will lose coverage, the Agencies suggest that it is possible that none of these women will reside in Pennsylvania or New Jersey—or, at the very least, if some of these women do reside in the States, not one of them will chose to receive care from a state-funded program. This suggestion is absurd on its face.

Defendants also argued that "[t]he States merely speculate that an employer that uses the exemption will choose not to cover the contraceptive method that a particular employee would otherwise choose," noting that plaintiffs in *Hobby Lobby* were willing to provide coverage for 14 of the 18 FDA-approved methods. Def. Br. 29. But the four methods Hobby Lobby objected to "are among the most effective forms of pregnancy prevention and also have among the highest up-front costs." J.A. 252–53 (¶ 38). Declarants from both States discussed the importance of encouraging the use of more effective methods of contraception, and explained why the States have made a concerted effort to encourage women to utilize methods that have been proven more effective. And the States introduced evidence that the Mandate had been effective in promoting the use of more effective methods. J.A. 1036–39. Defendants simply ignore this evidence.

Defendants' argument rests on the belief that the district court and the Ninth Circuit should have given more weight to the Agencies' own professions of ignorance. They emphasize, for instance, that "the *agencies* lacked specific data as to which entities would make the switch [from the accommodation to the expanded exemption] and did not identify any such entities." Def. Br. 28 (emphasis added). Similarly, they assert that the Ninth Circuit "ignored the *agencies'* lack of specific data about how many—or which—employers might use the expanded exemption instead of the accommodation." *Id.* 34 (emphasis added).

Defendants' "lack of specific data" is due, at least in part, to their decision to push the Rules through without engaging in a formal notice-and-comment process. By comparison, when they initially created the accommodation, the Agencies went through an extended formal rulemaking process with multiple rounds of comments. And ultimately their claims of ignorance prove too much. Because while claiming to profess extremely limited knowledge as to which employers (with the exception of those that filed lawsuits) will take advantage of the new exemption, the Agencies simultaneously argue that the need to protect these unknown employers is so great that it warrants ignoring the procedural requirements of the APA.

Furthermore, while Defendants are correct that their estimates are just that, they downplay one significant piece of data they do have. As discussed above, the Agencies have the ability to track user fee adjustments on behalf of TPAs that

provide contraceptive coverage for an accommodated entity. In the IFR, they determined that fee adjustments were sought by plans covering 576,000 individuals. J.A. 832. In the Final Rule, they put this number at 1,823,000 for 2017. J.A. 923. Extrapolating to account for fully-insured employers (who cannot seek user fee adjustments), they estimate that nearly 3 million individuals were covered by accommodated plans. J.A. 923.

A plaintiff making "an allegation of future injury" may establish standing "if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (cleaned up). Defendants would twist this requirement into an obligation to quantify the injury with precision. That neither the Agencies nor the States know precisely how many women will lose coverage (and of those women, how many will impose additional costs on the States) does not defeat the States' showing of a "substantial risk" of injury. In *Massachusetts v. EPA*, the Court found that Massachusetts had established injury because "one Massachusetts official believes that a significant fraction of coastal property will be 'either permanently lost through inundation or temporarily lost through periodic storm surge and flooding events.'" 549 U.S. 497, 523 (2007). The evidence presented by the States here was

far more comprehensive that the considered by the Court in *Massachusetts v. EPA*, and the district court was well within its discretion to credit it.[17]

The evidence from the States' declarations and the admissions from the Rules themselves was more than enough to establish injury from the Rules. This is especially true because "the injury required for standing need not be actualized." *Constitution Party of Pennsylvania v. Aichele*, 757 F.3d 347, 361 (3d Cir. 2014) (quoting *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008)). Rather, "a party facing prospective injury has standing to sue where the threatened injury is real, immediate, and direct." *Id.* (quoting *Davis*, 554 U.S. at 734). Here, the district court correctly found that the States faced such a "real, immediate, and direct" threat as a result of the Rules, and there is no basis for disturbing that determination.

B. The States Have *Parens Patriae* Standing Because the Interim Final Rules Will Injure Their Quasi-Sovereign Interests.

The States may also assert standing under the long-established *parens patriae* doctrine, which allows states to sue based on an invasion of their quasi-sovereign interests. *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 607, 607–

[17] Intervenor claims that this injury is "self-inflicted." But the law is clear that an injury "cannot be deemed 'self-inflicted' when a party faces only two options: full compliance with a challenged action or a drastic restructure of a state program." *Texas v. United States*, 86 F. Supp. 3d 591, 619 (S.D. Tex.), *aff'd by an evenly divided Court*, 136 S. Ct. 2271 (2016).

08 (1982); *see also Massachusetts v. EPA*, 549 U.S. at 518–26 ; *Georgia v. Tenn. Copper Co.*, 206 U.S. 230, 237–38 (1907); *Missouri v. Illinois*, 180 U.S. 208, 241 (1901). Here, the Rules threaten the States' quasi-sovereign interests in the general physical and economic "well-being of [their] populace" and in "ensuring that the State[s] and [their] residents are not excluded from the benefits that are to flow from participation in the federal system." *Snapp*, 458 U.S. at 602, 608. Because these injuries are caused by Defendants and redressible by a court, the States have standing.

Only a decade ago, the Supreme Court reaffirmed a state's standing to protect its quasi-sovereign interests. *Massachusetts v. EPA*, 549 U.S. at 518–26. There, Massachusetts sought to challenge the EPA's refusal to regulate greenhouse gases as required by the Clean Air Act. *Id.* at 514. The Court recognized that Massachusetts surrendered "certain sovereign prerogatives" when it joined the Union: it could not "invade" or "negotiate a [] treaty with" a federal agency to ensure its compliance with federal law. *Id.* at 519. But Massachusetts "did not renounce the possibility of making reasonable demands on the ground of [its] still remaining quasi-sovereign interests." *Georgia v. Tenn. Copper Co.*, 26 U.S. at 237. As a result, "the special position and interest of Massachusetts" as a "sovereign State" was of "considerable relevance," entitling it to "special solicitude in our standing analysis." *Massachusetts v. EPA*, 549 U.S. at 515, 520.

Here, the States proceed under the procedural right afforded by the APA[18] and allege that Defendants issued the final Rules in violation of the APA and the ACA. The final Rules will cause women in the States to lose access to cost-free contraceptive coverage, with the resultant harms to their physical and economic well-being. J.A. 1027–35 (IOM Report). The final Rules will also cause women to no longer enjoy the cost-free preventive care guaranteed by the Women's Health Amendment. In light of the States' position in the federal system, filing a lawsuit is their only recourse to force Defendants to comply with federal law and there are entitled to special solicitude in doing so. *See Massachusetts v. EPA*, 549 U.S. at 515, 520; *Georgia v. Tenn. Copper Co.*, 206 U.S. at 237.

That the States do not assert an invasion of their sovereign territory, Def. Br. 38, is of no moment.[19] The Court granted Massachusetts special solicitude based

[18] The APA creates a cause of action for any "person" who is "adversely affected or aggrieved by agency action." 5 U.S.C. § 702. The States are "'person[s]' entitled to enforce" the APA. *E.g.*, *Texas v. United States*, 809 F.3d at 152 (allowing states to sue under APA), *aff'd by equally divided Court*, 136 S. Ct. 2271.

[19] Whether the holding of *Massachusetts v. EPA* ultimately rested on *parens patriae* standing is open to debate. The Court identified a legally sufficient injury in Massachusetts's ownership of coastal property, *id.* at 522, but supported its holding by referencing a state's well-established right to bring a *parens patriae* suit, *id.* at 519–20 & n.17 (citing R. Fallon, D. Meltzer, & D. Shapiro, *Hart & Wechsler's The Federal Courts and the Federal System* 290 (5th ed. 2003)). This Court need not decide the precise holding of that case, however, because it nevertheless supports the proposition that states do have the right to bring *parens patriae* suits to protect their quasi-sovereign interests. *See id.*

on its "stake in protecting its *quasi-sovereign interests*," *Massachusetts v. EPA*, 549 U.S. at 520 (emphasis added), which is the established basis of *parens patriae* standing, *Snapp*, 458 U.S. at 602. Nor is the standing analysis "especially rigorous," Def. Br. 39 (quoting *Raines v. Byrd*, 521 U.S. 811, 819 (1997)) when the States only challenge, for the purpose of this appeal, the federal government's compliance with statutory law.

Massachusetts v. Mellon, 262 U.S. 447, 484–86 (1923), is not to the contrary. *Mellon* stands for the limited proposition that, under principles of prudential standing, a state cannot ordinarily bring a *parens patriae* suit to "protect her citizens from the operation of federal statutes." *Massachusetts v. EPA*, 549 U.S. at 520 n.17 (quoting *Georgia v. Pa. R.R. Co*, 324 U.S. 439, 447 (1945)); *id.* at 539–40 & n.1 (Roberts, C.J., dissenting) (referring to state's inability to bring a *parens patriae* suit against a federal statute as a "prudential requirement"); *Md. People's Counsel v. FERC*, 760 F.2d 318, 321–22 (D.C. Cir. 1985) (Scalia, J.) (holding that *Mellon* imposed prudential limitation on state *parens patriae* standing). Here, however, the States seek to *enforce* existing federal statutes—specifically, the APA and the ACA—in the same way Massachusetts was allowed to enforce the Clean Air Act over a decade ago. *Massachusetts v. EPA*, 549 U.S. at 520 n.17 (finding that a state has standing "to assert its rights under federal law"). All counts brought by the States proceed under the APA, which allows a claim to

challenge agency action that is "not in accordance with law" or "contrary to [a] constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2). They do not allege that the Rules have usurped any state power, nor that the ACA or APA are unconstitutional.

Because the States seek only to ensure that a federal agency complies with a duly-enacted law of Congress, no prudential limitation bars their assertion of *parens patriae* standing here.

II. The District Court Did Not Abuse its Discretion in Granting the Preliminary Injunction.

Standard of Review

The party moving for preliminary equitable relief must first "demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017); *see also Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Once the movant satisfies these "gateway factors," the district court then considers the balance of the equities and the public interest. *Reilly*, 858 F.3d at 179. Ultimately, the district court "determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief." *Id.*

Although the standard applied by the district court is "stringent," the "standard of appellate review is simply whether the issuance of the injunction, in the light of the applicable standard, constituted an abuse of discretion." *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931–32 (1975). "An abuse of discretion occurs only if the decision reviewed rests upon a clearly erroneous finding of fact, an errant conclusion of law, or an improper application of law to fact." *Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 131 (3d Cir. 2017). "Ultimately, this Court's review is "narrow because 'the grant or denial of a preliminary injunction is almost always based on an abbreviated set of facts, requiring a delicate balancing that is the responsibility of the district judge.'" *Lanin v. Borough of Tenafly*, 515 F. App'x 114, 117 (3d Cir. 2013) (cleaned up) (quoting *Frank's GMC Truck Center, Inc. v. General Motors Corp.*, 847 F.2d 100, 101–02 (3d Cir. 1988)).

Discussion

A. The District Court Did Not Err in Finding the States Demonstrated a Likelihood of Success on the Merits.[20]

1. The Interim Final Rules Violated the APA Because They Did Not Go Through Notice and Comment Rulemaking.

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

[20] Intervenor presents jurisdictional and merits arguments against the States' Title VII, Equal Protection, and Establishment Clause claims. Int. Br. 30–31; 56–

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).

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59. But those claims were not briefed below and the District Court expressly declined to reach them. J.A. 110 n.24. If the Court determines that the States are unlikely to succeed on the merits of their procedural and substantive APA claims, the Court should remand the case to the district court so it can review the States' other claims in the first instance. *Singleton v. Wulff*, 428 U.S. 106, 120 (1976) ("It is the general rule, of course, that a federal appellate court does not consider an issue not passed upon below."). To that end, the district court has scheduled a preliminary pretrial conference on April, 4, 2019, to discuss resolving the States' remaining claims. *Commonwealth, et al. v. Trump et al.*, No. 17-4540, ECF No. 156 (Mar. 13, 2019).

a. No Statutory Authority Allowed Defendants to Avoid Notice and Comment.

The district court correctly found that Defendants lacked express statutory authority to dispense with the APA's procedural requirements. J.A. 21–23. The Ninth Circuit agreed. *California*, 911 F.3d at 579.

Defendants point to three provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to argue that they have such statutory authority. Those provisions provide, in their entirety:

> The Secretary, consistent with section 104 of the Health [Insurance] Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this chapter. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this chapter.

26 U.S.C. § 9833; *see also* 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92.

As the Ninth Circuit recognized, these provisions "are silent as to any required procedure for issuing an IFR." *California*, 911 F.3d at 579. And the APA is clear: "Subsequent statute may not be held to supersede or modify this subchapter … except to the extent that it does so expressly." 5 U.S.C. § 559. Nothing in the HIPAA provision Defendants rely on discusses the steps necessary

for the agency to issue IFRs, much less "expressly" modifies the procedural requirements of the APA.[21]

Defendants' argument was squarely rejected in *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18–19 (D.D.C. 2010), which Defendants ignore. That case involved a claim by the same Agencies that the same statutory provisions gave them authority to dispense with the notice-and-comment requirements of the APA. Coalition for Parity recognized that the three statutory provisions cited by the Agencies in that case (and here) "do not mention notice and comment or any other aspect of the APA." *Id.* at 18. Therefore, the "relevant standard [is] 'whether Congress has established procedures so clearly different from those required by the APA that it must have intended to displace the norm.'" *id.* at 18 (quoting *Asiana Airlines v. FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998)).

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[21] Defendants argue that the district court's reading would render the authorization to issue IFRs superfluous. The Ninth Circuit addressed and rejected this argument as well:

> The first sentence of the quoted provisions authorizes the issuance of regulations "consistent with section 104 of the Health [Insurance] Portability and Accountability Act of 1996." Section 104 of HIPAA, entitled "Assuring Coordination," generally requires the three Secretaries to coordinate their regulations and policies. Notably, the second sentence of the quoted provisions does not contain the same consistency requirement; each Secretary is authorized to issue IFRs without ensuring consistency with the rules of his or her partner Secretaries.

California, 911 F.3d at 579–80 (cleaned up).

In justifying their argument in *Coalition for Parity*, Defendants relied on the same two cases they cite here: *Asiana Airlines* and *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225 (D.C. Cir. 1994). *See Coalition for Parity*, 709 F. Supp. 2d at 18. That court distinguished those cases, finding that "[i]n both *Methodist Hospital* and *Asiana Airlines*, the statutory language was mandatory and directed at a specific rulemaking procedure that Congress clearly wanted to occur expeditiously." *Id.* at 19. In contrast, the court found, the "HIPAA provisions are permissive ('The Secretary *may* promulgate any interim final rules as the Secretary determines are appropriate . . .'), wide-ranging (applying to any regulatory proceeding relating to group health insurance plans), and do not contain any specific deadlines for agency action." *Id.* at 18–19.

The district court here, the Ninth Circuit, and the court in Coalition for Parity all reached the correct result: the three provisions cited by Defendants do not authorize them to dispense with the procedural requirements of the APA without establishing "good cause" to do so.

b. Defendants Lacked "Good Cause" To Avoid Notice and Comment.

The district court also correctly rejected the argument that the Agencies had "good cause" to issue the Rules without following the procedural requirements of

the APA.[22] An agency may forego compliance with the APA's procedural requirements if it "for good cause" finds that the procedures are "impracticable, unnecessary, or contrary to the public interest" and it "incorporates its reasoning into the Rules." 5 U.S.C. § 553(b)(3)(B). This exception "is to be 'narrowly construed and only reluctantly countenanced.'" *Util. Solid Waste Activities Grp. v. E.P.A.*, 236 F.3d 749, 754 (D.C. Cir. 2001) (citation omitted). It is not an "'escape clause[]' that may be arbitrarily utilized at the agency's whim," but instead "should be limited to emergency situations." *Am. Fed'n of Gov't Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981).

In the IFRs, Defendants argued that they had "good cause" to dispense with the procedural requirements of the APA by the need to "bring[] to a close the uncertainty caused by years of litigation and regulatory changes made under section 2713(a)(4) of the PHS Act."[23] The district court relied on this Court's

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[22] Intervenor claims that the "an agency's assertion of good cause to bypass notice and comment in rulemaking calls for deference to agency factual findings (unless they are arbitrary and capricious) and de novo review on matters of law," citing *United States v. Reynolds*, 710 F.3d 498, 508–09 (3d Cir. 2013). Int. Br. 28. But the *Reynolds* court actually found that the standard of review was "a question for another day." *Reynolds*, 710 F.3d at 209.

[23] Intervenor takes issue with the district court's use of the term "uncertainty." Int. Br. 64 ("[D]ozens of injunctions are certainty, not uncertainty."). But "uncertainty" is the government's term: it argued throughout the IFRs and Final Rules that "legal uncertainty" justified bypassing notice and comment. *See* J.A. 826, 891; *see also* Def. Br. 72 (noting "conflicting court decisions").

decision in *United States v. Reynolds*, 710 F.3d 498, 510 (3d Cir. 2013), in rejecting this argument. *Reynolds* held that "[t]he desire to eliminate uncertainty, by itself, cannot constitute good cause [under the APA]." *Id.* It continued, "To hold otherwise would have the effect of writing the notice and comment requirements out of the statute." *Id.*

Defendants seem to recognize that *Reynolds* forecloses their argument that the need to eliminate uncertainty justifies foregoing notice and comment, as they now claim that they are not making it. *See* Def. Br. 74 ("But the agencies here are not relying on 'urgency alone,' or the need to eliminate 'any possible uncertainty' regarding existing law."). But the APA requires an agency that wishes to short-circuit the process to "incorporate[] its reasoning into the Rules." 5 U.S.C. § 553(b)(3)(B). The Agencies did so here, repeatedly referring to the "uncertainty" generated by conflicting judicial decisions. *See* J.A. 826 ("Good cause exists to provide immediate resolution to this myriad of situations rather than leaving them to continued uncertainty, inconsistency, and cost during litigation challenging the previous rules."); *id.* ("Good cause is also supported by the effect of these interim final rules in bringing to a close the uncertainty caused by years of litigation and regulatory changes made under section 2713(a)(4) of the PHS Act."). Whether the Agencies had "good cause" must be judged based on the arguments they put forward in the rules, not their after-the-fact justification.

Defendants do advance one argument in their brief that is consistent with the IFRs: skipping notice and comment is justified, they argue, by the "need to protect objecting employers that were not already protected by court injunctions from the threat of devastating civil penalties for following their religious and moral precepts." Def. Br. 72; *see also* J.A. 826 ("Good cause exists to issue the expanded exemption in these interim final rules in order to cure such violations (whether among litigants or among similarly situated parties that have not litigated)[.]"); *id.* (claiming good cause based on need to protect organizations from experiencing burden "for many more months"). By definition, entities that are not protected by injunctions either did not challenge the mandate in the years since it was created in court or challenged it and lost. It is difficult to see why either scenario would qualify as an "emergency situation."

2. Defendants Failed to Comply with the APA in Promulgating the Final Rules.

The Defendants claim that even if they issued the IFRs in violation of the APA, their subsequent review of comments cures the final Rules of any latent procedural defect. J.A. 898, 955; Def. Br. 61–65. Not so. Unless good cause or clear statutory authorization applies, the APA requires agencies to issue notices of proposed rulemaking, take public comment, then issue final rules. By issuing binding IFRs, taking public comment, then issuing final rules—all in the absence

of good cause or statutory authorization—Defendants violated the APA. The district court properly concluded, in accordance with this Court's precedent, that 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); *see also Reynolds*, 710 F.3d at 519; *Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979).

In *NRDC v. EPA*, this Court held that the EPA violated the APA when it took regulatory action that did not allow for public comment, an initial defect that fatally infected later rules issued after notice and comment. 683 F.2d at 767–69. The EPA had promulgated a number of final amendments with an effective date of March 30, 1981. *Id.* at 755. Just before March 30, the EPA summarily issued an order—which this Court held to be a "rule" promulgated in violation of the APA, *id.* at 760, 767—that indefinitely postponed the effective date of all the final amendments. *Id.* at 756. Several months later, the EPA issued an NPRM seeking public comment on further postponement of the effective date. *Id.* at 757. In early 1982, the EPA issued a final rule that made some of the amendments effective as of January 31, 1982, and further postponed four others. *Id.* The EPA argued that the final postponement rule, taken after public comment, cured the procedural defect in the initial postponement order. *Id.* at 767.

This Court disagreed, holding that *all* amendments became effective as of March 30, 1981. *Id.* at 768. The Court 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).

The crux of the Court's holding is the APA itself. Since 1966, Congress has required agencies to follow notice-and-comment procedures prior to issuing rules that carry the binding effect of law, unless narrow exceptions apply. 5 U.S.C. § 553. This basic democratic principle ensure that the public can "effective[ly] participat[e]" in developing the laws to which they will be subject *before* those laws go into effect, "while the decisionmaker is still receptive to information and argument." *NRDC*, 63 F.2d at 768 (quoting *Sharon Steel*, 597 F.2d at 381); *see also Reynolds*, 710 F.3d at 511 (stating that "the very purpose of notice and comment" is "for agencies to 'maintain a flexible and open-minded attitude towards its [*sic*] own rules'" (quoting *Prometheus Radio Project v. FCC*, 652 F.3d 431, 449 (3d Cir. 2011))). But when an agency improperly issues a rule without first allowing for comment, the public is immediately subject to a law and must instead ask the agency to reconsider, "run[ing] the risk that the decisionmaker is likely to resist change." *NRDC*, 63 F.2d at 767–68 (cleaned up).

Critically, this Court necessarily 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.* The Court recognized that the only possible remedy was 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.*

Defendants' attempts to sidestep *NRDC* fail to escape this Court's holding. First, they argue that the final Rules satisfied the APA because the agencies considered public comments, "[r]egardless of whether the *interim final rules* violated notice-and-comment requirements." Def. Br. 60. Were this so, then the Court in *NRDC* would have merely affirmed the effective dates laid out in the final postponement rule, likewise promulgated after consideration of public comment. Instead, this Court concluded that the final postponement rule was "ineffective"

and "invalid," and made all amendments effective as of March 30, 1981. *NRDC*, 683 F.2d at 767, 768.

Second, Defendants argue that the *NRDC* Court did not find procedural fault with the final postponement rule; instead, it merely invalided the final postponement rule as an incidental consequence of its obligation to "plac[e] petitioner in the position it would have occupied had the APA been obeyed." Def. Br. 63 (quoting 683 F.2d at 767). But this is a distinction without a difference: no matter the framing, "the period for comments after promulgation cannot substitute for the prior notice and comment required by the APA." *NRDC*, 683 F.2d at 767. Had Defendants here not improperly issued IFRs 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 or further sustained. *See id.* at 767–68.

Contrary to Appellants' apprehensions, reaffirming what this Court recognized 37 years ago will not throw the administrative state into chaos. Agencies remain free to "adopt the substance of the interim rules," Def. Br. 64; they must simply follow the procedural requirements of the APA when doing so. Here, that would mean revoking the religious and moral exemptions and issuing an NPRM asking the public to comment on *proposed* religious and moral exemptions to the contraceptive mandate. Nor would affirming the district court here "cast a

pall on thousands of regulations." Int. Br. 73. The principle recognized in *NRDC* applies only when agencies issue binding rules in violation of the APA; if an agency issues an IFR pursuant to statutory authorization or good cause, any subsequent final rule based on that IFR would not be *per se* invalid.[24]

That the IFRs no longer exist does not change the analysis. The States allege—and the district court properly held—that Defendants failed to comply with the APA in issuing the final Rules because the Agencies started with IFRs, not NPRMs. The IFRs themselves need not be enforceable for this Court to affirm that Defendants contravened the requirements of the APA and the final Rules must consequentially be enjoined.

3. The Final Rules Violate the Affordable Care Act.

The district court correctly concluded that the final Rules "exceed the scope of the Agencies' authority under the ACA." J.A 93. Neither the text of the Women's Health Amendment, nor the purpose of the law, nor the legislative

[24] Contrary to Intervenor's characterization, the States do not argue that "lack of prior opportunity for comment on an IFR necessarily invalidates the resulting final rule." Int. Br. 67. Instead, the States argue that the lack of prior opportunity for comment on an IFR *issued in violation of the APA* necessarily invalidates the resulting final rule. This dooms Intervenor's claim that the district court's reasoning would upend the contraceptive mandate itself. The States are aware of no decision holding that the agencies violated the APA when they issued the prior IFRs. To the contrary, the D.C. Circuit concluded that agencies had good cause to issue the IFR in August 2014 (79 Fed. Reg. 51,092). *Priests For Life*, 772 F.3d at 276.

history support Defendants' contention, Def. Br. 39–49, that the ACA gave them statutory authority to issue the final Rules.

a. The Women's Health Amendment Provides No Authority for Defendants to Create the Final Religious and Moral Exemption Rules.

The Women's Health Amendment requires that group health plans and health insurance issuers "shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for— . . . with respect to women, such additional preventive care and screenings not described in paragraph (1) as 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 every non-grandfathered "group health plan" and "health insurance issuer offering group or individual health insurance coverage." *Id.*

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. J.A. 984 (2011 Guidelines); J.A. 979 (2016 Guidelines). HRSA made this determination based on the expert opinions of sixteen medical and health professionals commissioned by the IOM. J.A. 1027–35. Even Defendants acknowledge that the Guidelines remain binding. *E.g.*, J.A. 883 ("The rules do not remove the contraceptive coverage requirement generally from

HRSA's Guidelines."); J.A. 885 ("Since 2011, HRSA has exercised [its] discretion to require coverage for, among other things, certain contraceptive services.").

The language of the Women's Health Amendment is clear: "group health plan[s]" and "health insurance issuer[s]" "shall" provide coverage for preventive services and "shall" do so without cost-sharing requirements. § 300gg-13(a)(4). "This repeated use of 'shall' creates 'an obligation impervious to discretion.'" *Prometheus Radio Project*, 824 F.3d at 50 (cleaned up) (quoting *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)). The plain language of the statute, therefore, does not provide HRSA with authority to create exemptions from the entities that "shall" provide such coverage. And "[w]here the language of the statute is clear[,] the text of the statute is the end of the matter." *United States v. Cooper*, 396 F.3d 308, 310 (3d Cir. 2005) (cleaned up).

In the absence of express statutory language, the Defendants claim their authority from the words "as" and "the." Def. Br. 40–41, 47. But as the district court aptly explained, the word "as" in § 300gg-13(a)(4) indicated "that the HRSA guidelines would be *forthcoming*," J.A. 97–99—a necessary indication, since the Guidelines did not exist when Congress passed the ACA. The rest of § 300gg-13 confirms this conclusion. In the preceding section, Congress required coverage of "preventive care and screenings provided for in *the* comprehensive guidelines,"

§ 300gg-13(a)(3) (emphasis added).[25] HRSA had already prepared guidelines concerning children, which explains the absence of "as" and the addition of a definite article. Although courts must construe statutes to avoid rendering any phrase superfluous, *Cooper*, 396 F.3d at 312, it is not superfluous for Congress to use the definite article "the" in one sentence to refer to extant guidelines for children and to use the word "as" in a separate sentence to refer to forthcoming preventive care guidelines.

Even if "as" were ambiguous, Defendants' construction would not be entitled to deference. *Cf. Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–32 (1984). HRSA's authority to prepare "comprehensive guidelines" extends only "for purposes of this paragraph," § 300gg-13(a)(4)—to define *what* must be covered ("additional preventive care and screenings not described in paragraph (1)"). The entities *who* must provide coverage are defined at § 300gg-13(a), outside the reach of HRSA's guidelines. Nor does the lack of the words "evidence-based" or "evidence-informed" indicate that HRSA could "consider factors beyond the scientific evidence." Def. Br. 41. Section 300gg-

[25] Congress's use of the word "guidelines" in § 300gg-13(a)(3) rebuts the Intervenor's contention that the word "guidelines" in § 300gg-13(a)(4) requires something other than a list of services. Int. Br. 43–44. As the district court observed, the guidelines concerning children "simply define a list of 'preventive care' services—that is, *what* must be covered." J.A. 99.

13(a)(4) explicitly incorporates "paragraph (1)," which covers "*evidence-based* items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force." § 300gg-13(a)(1) (emphasis added). By requiring HRSA to issue guidelines with "*additional* preventive care and screenings not described in paragraph (1)," § 300gg-13(a)(4) (emphasis added), Congress was telling HRSA to include evidence-based items or services that do not have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force.

MCI Telecommunications Corp. v. Am. Tel. & Tel. Co., 512 U.S. 218 (1994), bolsters these conclusions. The Supreme Court rejected the government's contention that the word "modify" allowed it to make "basic and fundamental changes" to a statutory requirement at "the heart of the common carrier subchapter of the Communications Act of 1934." *Id.* at 218. Here, mandating coverage of preventive services without cost sharing is at the heart of the Women's Health Amendment. As the Amendment's lead sponsor explained, "women often forgo those critical preventive screenings because they simply cannot afford it, or their insurance company won't pay for it unless it is mandated by State law." 155 Cong. Rec. S11987 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). If the Supreme Court could not find such significant authority in the word "modify," *MCI*, 512 at

229–32, less likely is such significant authority hidden in the word "as." And "an agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear." *Id.* at 229 (citing *Chevron*, 467 U.S. at 842–43).

The ACA's structure also does not support the Defendants' tortured statutory construction. As the district court observed, Congress created only a single exception from the Women's Health Amendment: for grandfathered plans. 42 U.S.C. § 18011. "When Congress provides exceptions in a statute, it does not follow that courts"—or federal agencies—"have authority to create others." *United States v. Johnson*, 529 U.S. 53, 58 (2000). Instead, the "proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth." *Id. N.L.R.B. v. SW Gen., Inc.*, 137 S. Ct. 929, 940 (2017), is not to the contrary. That case involved construction of the term "notwithstanding," which the Supreme Court found to undermine application of the *expressio unius* canon. The ACA contains no such complicating word choice; instead, the district court's reasonable interpretation came from the clear language of the Women's Health Amendment.[26]

[26] The Senate rejected a later effort to add additional conscience exemptions to the ACA. 158 Cong. Rec. S1173 (Mar. 1, 2012) (S. Amdt. 1520, 112th Congress). In arguing that such an amendment was necessary, its sponsors fully acknowledged that the ACA did not, in fact, contain a conscience exemption.

Nor does the purpose of the Women's Health Amendment support Defendants' contention. The ACA sought to facilitate access to healthcare, not limit it. The purpose of the Women's Health Amendment was to give women greater access to necessary preventive care and more control over their personal healthcare decisions. *See, e.g.*, *Hobby Lobby*, 134 S. Ct. at 2788–89 (Ginsberg, J., dissenting) (explaining how the Amendment was intended to fill a gap that left out women's preventive services); *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 was intended to "enhance and improve women's health care" by "eliminat[ing] one of the major barriers to accessing care in the area of cost and preventive services."155 Cong. Rec. S11987 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). Congress specifically envisioned these preventive services to include family planning. *See supra* note 3. And ultimately, the Amendment was intended to "leave[] the decision of which preventive services a patient will use between the

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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." 158 Cong. Rec. S1079 (Feb. 28, 2012). That Congress sought to pass such amendment is consistent with the absence of delegated authority to create the exemptions in the final Rules.

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.

It is undisputed that the Women's Health Amendment gave HRSA authority to identify, "with respect to women, such additional preventive care and screenings not described in paragraph (1)." § 300gg-13(a)(4). But the authority to determine *what* preventive services the Guidelines cover does not give HRSA authority to determine *who* need not provide those services. Instead, Congress was clear: "group health plan[s]" and "health insurance issuer[s] offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for" the preventive services listed in the Guidelines. § 300gg-13(a). Because the ACA does not authorize the final Rules, they are contrary to law.

b. The Church Exemption Will Not Be Affected by This Court's Decision.

The Court should reject Appellants' attempts to distract the Court by claiming that the district court's conclusion cannot be squared with the preexisting church exemption. Def. Br. 43–44; Int. Br. 46. This argument is a red herring. Because the States have not challenged the church exemption, neither this Court

nor the district court can adjudicate its lawfulness. Nor is it the burden of the States to justify the existence of separate and unrelated regulations.

More fundamentally, and contrary the Defendants' assertion, Def. Br. 42, it is not clear what authority the Agencies used to create the church exemption. In the 2011 interim final rule that first created the church exemption, the Agencies noted that § 300gg-13(a)(4) "gives HRSA the authority to develop comprehensive guidelines for additional preventive care and screenings for women 'for purposes of this paragraph'"; therefore, it is "appropriate that HRSA, in issuing these Guidelines, takes into account the effect on the religious beliefs of certain religious employers if coverage of contraceptive services were required in the group health plans in which employees in certain religious positions participate." 76 Fed Reg. at 46,623. Yet in the very next paragraph, the Agencies "amend[] the interim final rules to *provide* HRSA additional discretion to exempt certain religious employers from the Guidelines where contraceptive services are concerned." *Id.* (emphasis added). If § 300gg-13(a)(4) already included a "broad delegation . . . to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on contraceptive coverage," Def. Br. 42, then the Agencies would have had no reason to *provide* HRSA with additional discretion. The Agencies offered no citation for their authority to *give* HRSA such additional discretion—but it certainly cannot be § 300gg-13(a)(4), which gives HRSA, not HHS, the authority

to create "comprehensive guidelines." And even if HRSA's authority does "ultimately belong to HHS," Def. Br. 43,"[27] then it is all the more unclear why HHS would need to give that authority back to HRSA in the form of "additional discretion." 76 Fed Reg. at 46,623.

Adding to the confusion, the Agencies in the same final rule referenced a desire "to provide for a religious accommodation that respects the unique relationship between a house of worship and its employees in ministerial positions." *Id.* at 46,623. Churches have long received special dispensation under federal law, which could have provided external authority for the church exemption. *E.g.*, 26 U.S.C. § 6033(a)(3)(A)(i), (iii) (exempting "churches, their integrated auxiliaries, and conventions or associations of churches" from the obligation to file annual tax returns); *Hosanna-Tabor Evangelical Lutheran Church & Sch. v. E.E.O.C.*, 565 U.S. 171, 188 (2012) (recognizing as well-established a ministerial exception that precludes application of federal

[27] In their brief, Defendants provide no authority for this assertion. Def. Br. 43. In the final Rules, Defendants point only to the notice establishing HRSA. J.A. 896 (citing 47 Fed. Reg. 38,409 (Aug. 31, 1982)). But if HRSA's authority truly belonged to HHS, then HHS could, for example, order the Centers for Disease Control to prepare the Guidelines—in direct contravention of Congress. This cannot be the case. *See Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 520–21 (2010) (Breyer, J., dissenting) (noting that federal statutes "create a host of different organizational structures": "sometimes they place authority in a long-established Cabinet department" and "sometimes they place it in a subcabinet bureau, office, division, or other agency").

nondiscrimination laws to religious institutions); *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 330 (1987) (applying the religious exemption of Title VII to the secular nonprofit activities of religious organizations).

This uncertainty underscores the point: because the States are not aware of any case challenging the legality of the church exemption, the Defendants have never had the opportunity to assert the basis of their authority and a court has never determined whether that authority indeed exists. In promulgating the final Rules, however, Defendants claim only two sources of authority: § 300gg-13(a)(4) (for both Rules) and RFRA (for the Religious Exemption Rule). Regardless of what this Court determines with respect to the final Rules and § 300gg-13(a)(4), the church exemption will remain.

4. The District Court Correctly Concluded that Defendants Lack Authority Under the Religious Freedom Restoration Act (RFRA) to Promulgate the Final Religious Exemption Rule.

Appellants claim that RFRA provides the Executive Branch with unfettered discretion to categorically contravene duly enacted federal law. Def. Br. 49–60; Int. Br. 46–56. They are wrong. The district court correctly concluded, J.A. 101–

10, that Defendants lacked authority under RFRA to promulgate the final Religious Exemption Rule.[28]

RFRA is a statutory rule created by Congress to protect individual religious exercise. In *Employment Div., Dept. of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990), the Supreme Court held that "the Free Exercise Clause of the First Amendment does not prohibit governments from burdening religious practices through generally applicable laws." *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2006). In response, Congress passed RFRA, which creates a "statutory rule" that prevents the federal government from substantially burdening a person's exercise of religion with even a generally applicable law—unless that law is the least restrictive means of furthering a compelling government interest. *Id.* (citing 42 U.S.C. § 2000bb-1).

Contrary to Appellants' claims, RFRA does not permit the Executive Branch to decline to enforce duly enacted federal law simply upon the assertion of a religious objection. A burden is not substantial nor is a religious belief sincere just because the claimant says it is. *See Hobby Lobby*, 573 U.S. at 717 n.28; *Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 356 (3d Cir. 2017) ("[W]hether a burden is 'substantial' under RFRA is a question of law,

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

not a question of fact." (cleaned up)). Courts must objectively evaluate both the "*nature* of the claimed burden and the *substantiality* of that burden on the claimant's religious exercise." *Real Alternatives*, 867 F.3d at 356 (cleaned up). RFRA also does not allow the Executive Branch to grant an exception whenever a law imposes a substantial burden on religious exercise. Instead, an exception may be created only if the government lacks a compelling interest in applying the challenged law to the person or if a lesser restrictive means is available. *Holt v. Hobbs*, 135 S. Ct. 853, 863–67 (2015),[29] *Hobby Lobby*, 573 U.S. at 730–31; *Gonzales*, 546 U.S. at 430–31.

At bottom, Appellants' RFRA theory rests on a host of assumptions, none of which is supported by any authority. Appellants cite no case for their theory that RFRA grants agencies affirmative rulemaking authority. They cite no case holding RFRA allows agencies to create categorical, rather than individualized, accommodations from generally applicable law. They cite no case in which agencies have received deference in their interpretation or application of RFRA.

[29] *Holt* involved a claim under the Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA), 42 U.S.C. § 2000cc–2000cc-5. The Supreme Court has consistently recognized that RLUIPA "mirrors RFRA," *Holt*, 135 S. Ct. at 860, and has applied RLRIPA and RFRA cases interchangeably. *E.g., Gonzales*, 546 U.S. at 436.

And they cite no case in which the Executive Branch has unilaterally disclaimed a compelling government interest in duly enacted federal law.

This absence of authority is no coincidence. Under RFRA, individual claimants assert burdens on their exercise of religion, while courts must determine whether those burdens are substantial, whether enforcing the law is the least restrictive means of furthering a compelling government interest, and whether the requested accommodation unduly burdens third parties. Appellants' theory—in which the Executive Branch steps into the shoes of both individual claimants and the Judiciary—flouts Congress's intent and should be rejected.

a. The Final Religious Exemption Rule is Neither Required Not Permitted by the RFRA.

The district court found final Religious Exemption Rule "cannot be justified under RFRA." J.A. 110. The court's conclusion rested on two key holdings, both of which are correct.

i. Courts—Not Agencies—Adjudicate RFRA Violations.

First, the district court held that courts—not agencies—provide the final word on RFRA violations. "[A]dministrative agencies may not simply formulate a view of a law outside their particular area of expertise, issue regulations pursuant to that view, claim that the law requires those regulations, then seek to insulate their legal determination from judicial scrutiny." J.A. 103. This conclusion garners

no real challenge on appeal—and for good reason. "RFRA [] plainly contemplates that *courts* would recognize exceptions—that is how the law works." *Gonzales*, 546 U.S. at 434 (citing § 2000bb–1(c)). Indeed, "RFRA makes clear that is the obligation of the courts to consider whether exceptions are required under the test set forth by Congress." *Id.* at 434; *accord Hobby Lobby*, 573 U.S. at 719 n.30 (noting that RFRA calls for subjecting "religious-based objections to [] judicial scrutiny," in which "a court must consider not only the burden of a requirement on religious adherents, but also the government's interest and how narrowly tailored the requirement").[30]

Appellants present no real rebuttal. Defendants claim that the "agencies reasonably exercised their discretion in adopting the exemption as a valid means of complying with their obligation under RFRA," Def. Br. 53, but provide no source for this discretion.[31] The final Religious Exemption Rule, for its part, attempts to

[30] *See also Holt*, 135 S. Ct. at 864; *Hobby Lobby*, 573 U.S. at 718; *Gonzales*, 546 U.S. at 439.

[31] The only case mentioned by Defendants—*Ricci v. DeStefano*, 557 U.S. 586, 585 (2009)—has never been held to apply to RFRA. 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, *infra* note 33, and the Supreme Court, *Hobby Lobby*, 573 U.S. at 730–31. 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

cloak its permissive authority in *Hobby Lobby*, J.A. 890–92. But *Hobby Lobby* held that the contraceptive mandate violated RFRA under the facts of that case only because the accommodation was a less restrictive means of accomplishing a compelling government interest. 573 U.S. at 730–31. To justify the final Religious Exemption Rule, Defendants had to further conclude that the accommodation constitutes a separate RFRA violation, *and* that they lack a compelling government interest in enforcing the contraceptive mandate, *and* that a categorical exemption is the only possible remedy. J.A. 891–94. The Supreme Court has not reached these questions and Defendants cite no authority for their independent authority to resolve them unilaterally.

Defendants' inability to locate a source of permissive authority to recognize categorical RFRA exemptions is no accident. Nothing in RFRA explicitly or implicitly suggests that Congress expected *every* "agency to be able to speak with the force of law" on RFRA. *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001). Instead, as the district court correctly recognized, "RFRA is fundamentally a remedial measure," J.A. 109 n.23. Contrary to Appellants' arguments, Def. Br. 56–57, Int. Br. 47–48, RFRA can apply to all agencies and all federal law and yet

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Title VII's disparate-treatment provision). *Ricci*, 557 U.S. at 578–79. No such binary circumstance exists here.

be fundamentally remedial. It simply means that any person has a private right of action against any agency for a purported violation of RFRA.

RFRA's individualized application reinforces its remedial purpose. The text of RFRA is plain: "*A person* whose religious practices are burdened in violation of RFRA 'may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief.'" *Gonzales*, 546 U.S. at 434 (quoting § 2000bb–1(c)) (emphasis added). Only the individual has the necessarily personal knowledge about whether a rule of general applicability compels her "to perform acts *undeniably* at odds with fundamental tenets of [her] religious beliefs." *Real Alternatives*, 867 F.3d at 355 (quoting *Wisconsin v. Yoder*, 406 U.S. 205, 218 (1972)). This is why RFRA places the onus on the individual—not the agency—to assert a burden on religious exercise.[32] *Holt*, 135 S. Ct. at 862 (holding that plaintiff bore "initial burden" of proving that law both implicated and substantially burdened religious exercise); *accord Gonzales*, 546 U.S. at 428.

[32] Allowing the Executive Branch to determine in the first instance whether a rule of general applicability substantially burdens religious exercise could also raise Establishment Clause problems: the government would be establishing both what constituted private religious exercise and what substantially burdened that exercise. *See Amos*, 483 U.S. at 348 (O'Connor, J., concurring in judgment) (stating that to avoid the perception of government endorsement of religion, there "must in fact be an identifiable burden *on the exercise of religion* that can be said to be lifted by the government action").

Hobby Lobby bolsters this framework. There, the Supreme Court concluded that the contraceptive mandate fell afoul of RFRA only because the government had a less restrictive means—the accommodation—that "d[id] not impinge on the *plaintiffs' religious belief* that providing insurance coverage for the contraceptives at issue here violates their religion" and "serve[d] HHS's stated interests equally well." 573 U.S. at 730–31 (emphasis added). That the Court "d[id] not decide" whether "an approach of this type complies with RFRA for purposes of all religious claims," *id.*, is exactly the point: the accommodation complied with RFRA under the facts of that case. The Court did not go any further, because there was no need to do so.

ii. The Final Religious Exemption Rule Rests on Three Assumptions That Fail as a Matter of Law.

Second, the district court rejected as a matter of law three core assumptions on which the final Religious Exemption Rule rests: (a) that RFRA requires a blanket exemption from the contraceptive mandate, J.A. 106–07; (b) that the accommodation imposes a substantial burden on religious exercise, J.A. 107–08; and (c) that the contraceptive mandate imposes a substantial burden on the religious exercise of publicly traded for-profit corporations, J.A. 108–10. The court was correct on all counts.

"[B]lanket exemption[s]"—such as the final Religious Exemption Rule—are fundamentally inconsistent with RFRA's individualized requirement because they do not subject "religious-based objections to the judicial scrutiny called for by RFRA, in which a court must consider not only the burden of a requirement on religious adherents, but also the government's interest and how narrowly tailored the requirement is." *Hobby Lobby*, 573 U.S. at 719 n.30. Contrary to Defendants, Def. Br. 58–59, this has been the Court's longstanding position. *See id.* (stating that blanket exemptions "extend[] more broadly than the pre-existing protections of RFRA"; *Gonzales*, 546 U.S. at 430–31 ("RFRA requires the Government to demonstrate that the compelling interest test is satisfied through application of the challenged law *'to the person'—the particular claimant whose sincere exercise of religion is being substantially burdened*." (emphasis added) (quoting § 2000bb–1(b)). The rest of Defendants' rebuttal is nonsensical: *Hobby Lobby* explicitly rejected the use of blanket exemptions even as it found that the contraceptive mandate imposed a substantial burden. 573 U.S. at 719 n.30. Nothing in its holding compels the use of them now.

In addition, the accommodation does not impose a substantial burden on religious exercise. As in the final Religious Exemption Rule, J.A. 892, Defendants provide no actual explanation for their newfound conclusion to the contrary, other than that some employers have a sincere religious objection to the accommodation.

Def. Br. 57; *accord* Int. Br. 48–49. But "whether a burden is 'substantial' under RFRA is a question of law, not a question of fact." *Real Alternatives*, 867 F.3d at 356. As aptly explained by this and seven other federal appellate courts,[33] the accommodation causes the eligible organization to play "no role whatsoever" in the provision of federally mandated contraception services. *Geneva Coll.*, 778 F.3d at 435–42. Self-certification "does not trigger or facilitate the provision of contraceptive coverage because coverage is mandated to be otherwise provided by federal law." *Id.* at 437. And the "Supreme Court has consistently rejected the

[33] *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. J.A. 812. The final Religious Exemption Rule does not.

argument that an independent obligation on a third party can impose a substantial burden on the exercise of religion in violation of RFRA." *Id.* at 440. Appellants present no legal argument to the contrary.

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 a fatal concession. J.A. 891 &n.15 (quoting 2017 FAQs at 4)); *see* Def. Br. 53–54. To the contrary, the existence of a religious objection does not *per se* mean that RFRA is violated. *E.g.*, *Real Alternatives*, 867 F.3d at 356; *see* 2017 FAQs at 4–5 (identifying no substantial burden). Nor does the existence of litigation over the accommodation, Def. Br. 51–52, Int. Br. 51, 55–56, justify adopting an exemption instead.[34] A RFRA claim is always as-applied; no generally applicable law can facially violate RFRA. Therefore, any determination that the accommodation violated RFRA would extend no further than the plaintiff in that case.

[34] Intervenor is wrong that post-*Zubik*, the government has "lost every case." Int. Br. 50–51. In all of the post-*Zubik* cases cited by Intervenor, Int. Br. 10–11, 51, Defendants have conceded that the accommodation violates RFRA and therefore have failed to present an actual case or controversy. And all of the cited pre-*Zubik* cases, Int. Br. 7–10, involved either joint motions pursuant to *Hobby Lobby* or cases in which the government appealed an adverse decision, then voluntarily dismissed that appeal after the change in administration.

Lastly, Defendants provide no support for the inclusion of publicly traded companies in the final Religious Exemption Rule, proving that it "sweeps further than RFRA would require." J.A. 109. Defendants concede they "are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief" and agree with "the Supreme Court's statement in *Hobby Lobby* that it is unlikely that many publicly traded companies will adopt religious objections to offering women contraceptive coverage." J.A. 908. Yet they categorically conclude that requiring these corporations "to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA." J.A. 888.[35] This flies in the face of RFRA's individualized application. *Holt*, 135 S. Ct. at 862.

In sum, Appellants' novel theory would upend decades of jurisprudence under which the Executive Branch must enforce facially neutral laws unless an individual demonstrates that a law imposes a substantial burden on religious exercise, and then only if that law is not narrowly tailored to a compelling

[35] They also reach this conclusion on behalf of health insurance issuers—despite conceding that they "are not currently aware of existing issuers that would use it," J.A. 912—and on behalf of individuals—despite the holding of this Court that the contraceptive mandate itself does not impose a substantial burden on employees' religious beliefs, *Real Alternatives*, 867 F.3d at 366.

government interest, and then only to the extent that any accommodation does not impose burdens on third parties, *Hobby Lobby*, 573 U.S. at 730 n.37 ("[C]ourts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries." (cleaned up)). The district court was right to reject it.

Finally, the Court should reject Defendants' red herring claims that the district court's RFRA analysis cannot be squared with the accommodation. Def. Br. 55–56. The States have not challenged the accommodation; as with the church exemption, neither this Court nor the district court can adjudicate its lawfulness and the States do not bear the burden of justifying its legality. Moreover, unlike the final Rules, the Agencies created the accommodation without invoking RFRA; indeed, the final rule adopting the accommodation expressly disclaimed reliance on RFRA. 78 Fed. Reg. at 39,886 ("[T]he accommodations for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), or student health insurance coverage arranged by eligible organizations that are institutions of higher education, are not required under RFRA."). Regardless of the originating source of agency authority, however, the accommodation is now mandated by RFRA for (at least) closely held companies. *Hobby Lobby*, 573 U.S. at 730–31 (holding that the accommodation "does not impinge on the plaintiffs' religious belief that providing

insurance coverage for the contraceptives at issue here violates their religion, and it serves HHS's stated interests equally well").

b. Defendants Fail to Explain Their Change in Position on the Applicability of RFRA.

Defendants also violated the law by failing to explain their change in position on the applicability of RFRA. Agencies are "free to change their existing policies," *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016), 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).

i. Defendants Fail to Explain Why the Accommodation Violates RFRA.

First, Defendants provide no rationale for their new position that the accommodation imposes a substantial burden on all exercise of religion. J.A. 892. Their abrupt 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). In the final Religious Exemption Rule, Defendants baldly assert 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." J.A. 892. But as in *Navarro*, 136 S. Ct. at 2126–27, this paragraph fails to explain *why* Defendants believe the accommodation poses a substantial burden—a necessary showing given that *Hobby Lobby* endorsed the accommodation for (at least) closely held corporations, 573 U.S. at 731, and the majority of appellate courts upheld it against RFRA challenges, *see supra* note 33. "[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." *Navarro*, 136 S. Ct. at 2125.

ii. Defendants Fail to Explain Why They Lack a Compelling Interest in Enforcing the Mandate.

Second, Defendants fail to "show that there are good reasons" for departing from their established position that the contraceptive mandate furthers a compelling government interest. *See Navarro*, 136 S. Ct. 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).

Defendants rightly do not disclaim a compelling interest in enforcing the contraceptive mandate generally. The congressional record underlying the Women's Health Amendment, *supra* Statement Part I, coupled with the conclusions reached in the IOM report, *supra* Statement Part II, clearly show that the government has a compelling interest in ensuring that women have access to contraceptive services without cost-sharing. *See also 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").

Instead, Defendants claim to lack a compelling interest in applying the contraceptive mandate *to objecting entities*. But Defendants do not provide any reason—much less a good reason—for why the government is less interested in providing contraception to women working for objecting employers. That HRSA has discretion to prepare the Guidelines, J.A. 893–94, does not explain why Defendants lack a compelling interest in extending the mandate to female employees of objecting entities. Nor does Defendants' inability to enforce the mandate against some employers, J.A. 894, 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 some women most at risk for unintended pregnancy, J.A. 894–95, does not explain why women who work for employers with religious 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. That some women may be able to get contraceptive services and counseling from other sources, J.A. 895, does not explain a lack of compelling interest because Defendants cannot claim that all women who work for objecting entities are able to do so. State laws mandating contraceptive coverage are neither as uniform nor as comprehensive as the mandate, J.A. 260–61 (¶ 53), and ERISA bars states from regulating a significant portion of employers, 29 U.S.C. § 1144(a); J.A. 191 (¶ 140). Defendants also mischaracterize the impact the ACA has had on

women's use of contraceptive methods. J.A. 249–52 (¶¶ 31–36) (showing how study cited by Defendants actually showed positive trends). Finally, that Defendants no longer think seamlessness is important, J.A. 894, fails to explain why women working for objecting entities are uniquely unaffected by the absence of seamless contraceptive coverage.

More fundamentally, Defendants offer no authority or explanation for their newfound ability to unilaterally determine that certain duly enacted federal laws are less compelling than others. The Constitution vests "All Legislative Powers here granted" in Congress, U.S. Const. Art. I § 1, and charges the Executive Branch with "tak[ing] Care that the Laws be faithfully executed," U.S. Const. Art. II § 3. The Executive Branch lacks authority to cease "tak[ing] care" that a law be faithfully executed simply because it has unilaterally decided that the law is less compelling—and Defendants cite no case where it has done so. The Women's Health Amendment, as part of the ACA, was enacted by the 111th United States Congress and signed into law by President Barack Obama on March 23, 2010. The Women's Health Amendment mandates that covered plans provide coverage without cost sharing for preventive services listed in HRSA Guidelines. § 300gg-13(a)(4). Since 2011, these Guidelines have listed "[c]ontraceptive methods and counseling" among the forms of preventive care that must be provided to women without cost sharing. J.A. 984 (2011 Guidelines); J.A. 979 (2016 Guidelines).

RFRA enables "[a] person whose religious practices are burdened in violation of RFRA [to] assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief" and "plainly contemplates that *courts* would recognize exceptions"—because "that is how the law works." *Gonzales*, 546 U.S. at 434 (cleaned up). Unless Congress repeals the Women's Health Amendment, HRSA modifies the Guidelines, or the Judiciary concludes that the government lacks a compelling government interest in enforcing the contraceptive mandate, Defendants cannot unilaterally decline to "take care" here.

B. The District Court Did Not Commit Clear Error in Finding that the States Would be Irreparably Harmed by the Rules.

The district court found that the States likely would suffer two forms of irreparable harm from the final rules: harm to the States' quasi-sovereign interest in the health, safety, and well-being of their citizens and harm to the States' fiscal integrity. J.A. 110–13. Those findings, which are well-supported in the record, are not clearly erroneous.

There can be little doubt that the health and well-being of the States' residents is likely to suffer as a result of the Rules. By the Defendants' own estimates, at least 70,515 women will lose contraceptive coverage under the Final Rules. J.A. 924, 972. As the district court noted, given the Defendants' admission concerning the minimum number of women who will be affected by the Final

rules, "the only serious disagreement is not whether the States will be harmed, *but how much*." J.A. 45.

The district court credited affidavits submitted by the States demonstrating that when employers take advantage of the Final Rules, women will lose access to no-cost contraceptive coverage, and that as a result, "women will likely forgo contraceptive services or seek out less expensive and less effective types of contraceptive services." J.A. 47; *see, e.g.*, J.A. 244 (detailing how long-acting reversible contraceptives are both most effective and most costly); J.A. 303. These disruptions in contraceptive coverage, the court found, "will lead to women suffering unintended pregnancies and other medical consequences." J.A. 113 (citing J.A. 296, 1032). Access to safe and effective contraceptive services is time-sensitive, and unintended pregnancies have life-altering consequences that are "irreversible." *Id.* Indeed, among the negative health outcomes for mothers and children associated with unintended pregnancy are increased risk of material depression, increased risk of physical violence during pregnancy, reduced likehood of breastfeeding, poorer mental and physical health during childhood, and lower rates of teenage educational attainment. J.A. 330 (¶¶ 31-32). The Court did not clearly err in finding irreparable harm to the States' quasi-sovereign interest in the health, safety, and well-being of its residents.

The district court also credited the States' evidence that the Final Rules will result in increased expenditures by the States, and that those fiscal harms constitute irreparable injury because the States will not be able later to recover those costs from the Defendants. *See* 5 U.S.C. § 702 (APA does not permit money damages); *Feinerman v. Bernardi*, 558 F.Supp.2d 36, 51 (D.D.C. 2008) (where plaintiff cannot recover money due to defendant's sovereign immunity, loss of income is irreparable). Again, the Defendants themselves conceded when issuing the IFRs that women who lose access to no-cost contraceptive coverage may turn to State and local programs for free or subsidized contraceptives. *See* J.A. 894, 815.

The States provided declarations demonstrating the financial costs to them from providing contraceptive coverage to low and moderate income women. *See, e.g.*, J.A. 312 (¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births); J.A. 305–06 (¶23); J.A. 317 (¶19); J.A. 328 (¶25). Crediting the declarations submitted, the Court found that "it is likely that the States will bear the added financial burden occasioned by the increase in women who need contraceptive care coverage." J.A. 111 (citing J.A. 299–300, 305–06, 322). The Court did not clearly err in finding irreparable pecuniary harm to the States when, as a result of the Final Rules, employers free themselves of the obligation to provide the no-cost contraceptive care coverage required under the ACA.

Intervenor argues that the States have not identified particular employers who will drop contraceptive coverage or particular women who will qualify for state assistance for contraceptive services if the future under the Final Rules. But the district court was entitled to accept the Defendants' own concession that, at a minimum, more than 70,000 women would lose contraceptive coverage under the Final Rules. Where the harm is that widespread, there is no need to identify particular individuals, thousands of whom doubtless reside in states that are as populous as Pennsylvania and New Jersey. And the IFRs likewise identified employers in Pennsylvania and New Jersey who were expected to take advantage of the exemptions provided by the IFRs simply by virtue of their having already filed lawsuits seeking expanded exemptions. J.A. 350–56, 384–90.

In sum, the district court did not commit clear error in crediting the declarations submitted by the States and finding as a fact that the States would be irreparably harmed by the Final Rules.

C. The District Court Did Not Commit Clear Error In Finding that the Balance of Equities and the Public Interest Weigh Strongly In Favor of a Preliminary Injunction.

Finally, the district court did not commit clear error in finding that the public interest and the balance of equities favored issuance of a preliminary injunction. "If a plaintiff proves 'both' a likelihood of success on the merits and irreparable injury, it 'almost always will be the case' that the public interest favors preliminary

relief." *Issa*, 847 F.3d at 143 (quoting *Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc*., 42 F.3d 1421, 1427 n.8 (3d Cir. 1994)). Analyzing whether an injunction favors the public interest is thus "often fairly routine." *Id.* (citing *Kos Pharm., Inc. v. Andrx Corp*., 369 F.3d 700, 730 (3d Cir. 2004)).

So it is here. As the district court put it, the public interest "unquestionably" favors a preliminary injunction in this case. J.A. 114. 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. And the public interest further favors an injunction because direct financial and other harm will befall the States, and that harm, too, is irreparable.

The irreparable harm that the States and their residents will suffer as a result of the Final Rules substantially outweighs any harm to the Defendants from a preliminary injunction. Although Defendants assert that they will "suffer an irreparable institutional injury" from a delay of Rules, Def. Br. 76, as the district court correctly found, Federal Defendants can suffer no harm from the injunction of an invalid regulation, and even delay of a valid regulation does not substantially prejudice the government. J.A. 114. *Maryland v. King*, which Defendants cite, is entirely inapposite, both because it concerned the implementation of a critical criminal law statute concerning collection of DNA evidence for law enforcement

purposes and because the Supreme Court had found that the statute was likely constitutional. *See* 133 S. Ct. 1, 2–3 (2012).

Although Defendants assert an interest in protecting religious liberty, the district court correctly found that Congress, in enacting the Women's Health Amendment and RFRA, has already struck its desired balance between ensuring women's access to contraceptive healthcare services and protecting employers' free exercise of religion. *See* J.A. 113–14; *see also Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609–10 (1952) (Frankfurter, J., concurring) (noting that when Congress "has defined the weight to be given to competing interests, a court of equity is not justified in ignoring that pronouncement"). Defendants—as agencies charged with implementing the ACA—have no legitimate interest in overriding Congress' judgment as to this balance. Contrary to Defendants' assertion, the district court's consideration of how competing interests are weighed in the statutory context of the Final Rules was entirely appropriate and did not treat the merits of the case as "*definitively* resolved," Def. Br. 78, any more than the Court's proper consideration of the States' likelihood of success on the merits did.

Intervenor also argues that the preliminary injunction will "impinge the religious freedom of religious objectors like the Little Sisters." Int. Br. 79. This is baseless. Intervenor's religious beliefs are *already* protected by an injunction obtained in other litigation and the preliminary injunction explicitly does not

disturb that injunction or the injunctions obtained by other entities with similar objections,[36] J.A. 114 & n.27, and does not prevent other entities "alleging RFRA violations" from "pursuing 'Judicial Relief'" under that statute, J.A. 113; *see also* 42 U.S.C. § 2000bb-1(c) (allowing person to obtain relief through judicial process from generally applicable law that burdens their religious exercise). For this reason, Defendants are also incorrect that reversing the preliminary injunction is necessary to protect some employers' religious and conscience interests. *See* Def. Br. 78. Rather, the preliminary injunction that district court carefully crafted protects the States and their residents from irreparable harm without altering the status quo for the Defendants or Intervenor or impairing others' ability to pursue RFRA claims.

In sum, the district court reasonably found that the Final Rules were likely cause irreparable harm to the States and their residents, and that the interest of the States in protecting the health and wellbeing of their residents, and the interest of women in uninterrupted contraceptive coverage, outweighed the countervailing interests asserted by Defendants.

* * *

[36] *See supra* note 34.

Because Appellants have failed to show that the district court abused its discretion, this Court should uphold the preliminary injunction of the Final Rules.

D. A Nationwide Injunction is Proper.

Defendants assert that the district court erred in issuing an injunction that extends beyond the physical boundaries of Pennsylvania and New Jersey. But it is well-settled that a district court has the legal authority to issue a preliminary injunction that provides plaintiffs and those similarly situated with complete relief, *see, e.g.*, *Trump v. Int'l Refugee Assistance Project,* 137 S. Ct. 2080, 2087–88 (2017), *National Mining Ass'n v. U.S. Army Corps of Engineers,* 145 F.3d 1399, 1409 (D.C. Cir. 1998), and that a decision to do so is reviewed only for abuse of discretion, *Ass'n of N.J. Rifle and Pistol Clubs v. Attorney General*, 910 F.3d 106, 114 (3d Cir. 2018). Here, the district court carefully considered the factors that weighed both for and against the issuance of broad injunctive relief, and it reasonably concluded that geographically-limited relief was neither feasible nor appropriate. Although Defendants disagree with the district court's weighing of the relevant factors, the Court did not abuse its considerable equitable discretion in tailoring its remedy.

There can be no serious contention that the district court misunderstood the relevant legal principles to be applied in determining the scope of equitable relief. Indeed, States and Defendants agreed that the Court had the legal authority to order

injunctive relief that would afford "complete relief to the plaintiffs." *See Commonwealth, et al. v. Trump et al.*, No. 17-4540, ECF No. 107, at 43 (Jan. 3, 2019) (Defendants' Brief). The Court recognized that it should grant temporary relief that is "no more burdensome than necessary," J.A. 116, and it endeavored to balance the defendants' right to be free from overly burdensome injunctions against the plaintiffs' right to complete preliminary relief. J.A. 116-17. Thus, there was no legal error committed here.

The district court's weighing of the relevant factors is a textbook example of the careful exercise of remedial discretion. The Court recognized the legal arguments that could mitigate against providing nationwide injunctive relief, J.A. 116, and noted that "striking the appropriate balance between providing complete relief to meritorious plaintiffs, on the one hand, and protecting defendants from overly burdensome injunctions, on the other, is necessarily a difficult line-drawing exercise." JA 118. Defendants are essentially urging this Court to itself reweigh the factors the district court carefully considered in crafting its remedy. This Court should decline that invitation.

Defendants' principal argument is that the district court should have crafted a preliminary injunction that applies only to the States. But, as the district court pointed out, affording complete relief to the States required the Court to enjoin enforcement of the Final Rules as to all entities that offer and arrange health

insurance to insureds residing in Pennsylvania or New Jersey. J.A. 119. "But drafting—much less enforcing—a preliminary injunction that runs only to those entities is nigh impossible." *Id.* While before the district court, Defendants never attempted to grapple with the complexities involved in drafting a preliminary injunction order that would provide complete relief to the Plaintiff States.

The court found as a fact that "[h]undreds of thousands of the States' citizens travel across state lines—to New York, Ohio, Delaware, Maryland, West Virginia and even further afield—to work for out-of-state entities." J.A. 120. Because an "injunction limited to Pennsylvania and New Jersey would, by its terms, not reach Pennsylvania and New Jersey citizens who work for out-of-state employers," those employees and their dependents could lose contraceptive coverage under an injunction that is geographically limited. *Id.*[37]

[37] Defendants quibble with this factual finding by raising some arguments not presented in the district court. For example, Defendants contend that many of the "cross-border employees" work in bordering states that have state-level contraceptive mandates. Def. Br. 82–83. But state mandates, unlike the ACA, frequently do not cover all FDA approved contraceptive methods (including the most effective, but also most expensive, long-acting reversible contraceptive methods). And the state mandates do not even apply to the majority of workers in these states because most employees are in self-insured health plans, which ERISA preempts from state regulation. The District Court's fact-finding was not clearly erroneous. *See Lanin*, 515 F. App'x at 117 ("Ultimately, this Court's review is "narrow because 'the grant or denial of a preliminary injunction is almost always based on an abbreviated set of facts, requiring a delicate balancing that is the responsibility of the district judge.'" (quoting *Frank's GMC Truck Center*, 847 F.2d at 101–02)).

Similarly, the Court found as a fact that universities and educational institutes in Pennsylvania and New Jersey take in tens of thousands of out-of-state students each year, and that students covered by their parents' out-of-state employer-based health plans could, when they lose contraceptive coverage, turn to in-state publicly-funded clinics for that coverage, which would add to the Plaintiff States' economic burdens. J.A. 120–21. These factual findings are not clearly erroneous. College-age students are in an age-group with high demand for contraceptive services, and the loss of no-cost contraceptive coverage can be expected to result in more unintended pregnancies, with all of the associated health risks and costs. Based on facts like these, the Court found that a narrowly-crafted injunction that applies only to the Plaintiff States "would not provide complete relief to them because it would not prevent the economic harm extensively detailed in the record." *Id.*

The district court recognized that "a nation-wide injunction may prove 'broader than necessary to provide full relief' to the States." J.A. 121. But that type of difficult line-drawing question is precisely where the exercise of discretion comes into play. The Court concluded that "in this case, potential over-inclusiveness is the more prudent route." *Id.* First, the Court found that "anything short of a nation-wide injunction would likely fail to provide the States 'complete relief.'" *Id.* The Court also found that the relief ordered would not be overly

burdensome, particularly in light of the general rule that when an agency action is unlawful, the ordinary result is simply to vacate the rule, not particular applications of it. *Id.* Third, the Court found that the concern that a nationwide injunction would foreclose adjudication in other courts was not particularly pronounced here, since there was parallel litigation already proceeding in the Ninth Circuit. J.A. 123. Also, the preliminary injunction would not prevent other entities alleging RFRA violations from pursuing judicial relief under that statute. J.A. 114. .

Indeed, the injunctive relief ordered here is the best and most effective way to preserve the status quo while this case proceeds to a final merits determination. *See Acierno v. New Castle Cty*., 40 F.3d 645, 647 (3d Cir. 1994) ("A primary purpose of a preliminary injunction is maintenance of the status quo until a decision on the merits of a case is rendered."). The potential harm to Pennsylvania and New Jersey residents, workers, and students who lose their access to free contraceptive coverage are potentially life-altering. Pregnancy and contraceptive care by their nature are very time-sensitive needs, and a potentially over-inclusive remedy that maintains the status quo under the Affordable Care Act presents less of a danger than an under-inclusive remedy that results in unintended pregnancies, which impose significant financial costs on the States and even more difficult to measure costs on women and families. The district court did not abuse its

discretion in opting to fully maintain women's current health choices under the Affordable Care Act while this case proceeds to a final judgment on the merits.

In challenging the injunction entered here, Defendants also rely upon *California*, 911 F.3d at 582–84, in which the Ninth Circuit overturned the nationwide scope of an injunction ordered by a California district court. The Court's decision turned on the district court's failure to cite any evidence that the injunction ordered was necessary to provide complete relief to the plaintiff states. *Id.* at 584. ("*On the present record*, an injunction that applies only to the plaintiff states would provide complete relief to them.") (emphasis added). Here, the district court was able to point to record evidence demonstrating: (1) that an injunction limited to the Plaintiff States would not, in fact, provide complete relief to the Plaintiff States, and (2) that crafting a narrower injunction that would afford complete relief to the Plaintiff States would be "nigh impossible." J.A. 119. Because of the more limited record before the California court, the Ninth Circuit did not consider the impact on the State from cross-border workers and out-of-state students.

Finally, one of the factors in *California* that led the Ninth Circuit to overturn the injunction there was the district court's decision to stay the case while awaiting a decision from the appellate court. 911 F.3d at 583–84. The Court was concerned that, despite the purported urgency of the case, it languished in the district court

throughout the appeal. But that factor cuts strongly against Defendants here. Soon after this appeal was docketed, Defendants moved for a stay of proceedings in the district court, which the Plaintiff States opposed and the district court denied. Defendants' complaint about a preliminary injunction that maintains the status quo is undercut by its own desire to postpone a final resolution here.

In sum, the district court plainly understood the law governing the scope of preliminary injunctive relief, and it made factual findings that are supported by the record and not clearly erroneous. The decision to award preliminary injunctive that extends beyond the geographic boundaries of the Plaintiff States was carefully arrived at, after considering and weighing the various arguments for and against that relief. That Defendants weigh those arguments differently does not amount to an abuse of discretion by the district court. This Court should uphold the district court's thoughtful exercise of its remedial discretion, which preserves the status quo until the Court renders a final judgment on a full record.

III. Intervenor Little Sisters Lacks Appellate Standing.

Intervenor Little Sisters does not have appellate standing. These cases involve an interlocutory appeal of a preliminary injunction that, by its express terms, does not apply to Intervenor. Intervenor is not harmed by the order being appealed, and there is no relief that this Court can grant Intervenor at this time. As a result, its lacks standing and its appeal of the injunction of the Final Rules should be dismissed.

This Court has recognized that "an intervenor defendant—whether permissive or as of right—will not necessarily have standing to appeal." *McLaughlin v. Pernsley*, 876 F.2d 308, 313–14 (3d Cir. 1989). Rather, "[i]n order to have standing to appeal a party must be aggrieved by the order of the district court from which it seeks to appeal." *Id.* at 313. An intervenor "may appeal from all interlocutory and final orders *that affect him*." *Stringfellow v. Concerned Neighbors in Action*, 480 U.S. 370, 376 (1987) (emphasis added) (cleaned up); *see also Util. Contractors Ass'n of N.J., Inc. v. Toops*, 507 F.2d 83, 86 (3d. Cir. 1974) ("Where an injunction is granted, one generally cannot appeal from the order unless he is directly or indirectly restrained from the performance of some act.").

By its express terms, the district court's preliminary injunction does not apply to Intervenor. In ordering preliminary injunctive relief, the district court stated:

> A preliminary injunction will maintain the status quo: those eligible for exemptions or accommodations prior to October 6, 2017 will maintain their status; *those with injunctions preventing enforcement of the Contraceptive Mandate will maintain their injunctions*; those alleging RFRA violations may pursue "Judicial Relief;" and those with coverage will maintain their coverage as well.

J.A. 56 (emphasis added). The Court then made clear that Intervenor was protected:

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

J.A. 114 n.27.[38] Since the preliminary injunction does not apply to Intervenor, there is no relief that this Court can grant it in this appeal.

[38] Five days after the District Court entered an order granting Little Sisters' motion to intervene in Pennsylvania's challenge to the IFRs, *see* Order, *Pennsylvania v. Trump*, No. 17-4540, ECF No. 77 (E.D. Pa. May 10, 2018), the plaintiffs in *Little Sisters of the Poor Home for the Aged v. Azar*, No. 13-2611 (D. Colo.), filed a motion seeking a permanent injunction prohibiting the federal government from enforcing the mandate. *See* Proposed Order Granting Perm. Inj. & Decl. Relief, *id.*, ECF No. 80-1 (May 15, 2018). The federal government did not oppose the motion, and the Colorado District Court entered a permanent injunction as requested by the plaintiffs. *See* Defs.' Response to Pls.' Mot. for Entry of a Perm. Inj. & Decl. Relief, *id.*, ECF No. 81 (May 18, 2018); Order Reopening Case & Granting Perm. Inj., *id.*, ECF No. 82 (May 29, 2018).

CONCLUSION

For these reasons, this Court should affirm the preliminary injunction entered by the district court.

Respectfully submitted,

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COMBINED CERTIFICATIONS

I hereby certify that the following statements are true:

1. I am a member of the bar of this Court.
2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) and the Court's October 18, 2018 Order because it contains 23,910 words. This brief also complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5)–(6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font.
3. On March 18, 2019, this brief was electronically filed with the Clerk of Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. Participants in the case are registered as CM/ECF users and service will be accomplished by the appellate CM/ECF system.
4. The text of the electronic version of this brief is identical to the text of the paper copies submitted to the Court.
5. That this file was scanned using McAfee Agent Version 5.0.6.220 and no virus was detected.

/s/ Michael J. Fischer
MICHAEL J. FISCHER