No. 19-15072, 19-15118, 19-15150

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

THE STATE OF CALIFORNIA, *et al.*,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al.*,
Defendants-Appellants,

AND

THE LITTLE SISTERS OF THE POOR JEANNE JUGAN RESIDENCE,
Intervenor-Defendant-Appellant,

AND

MARCH FOR LIFE EDUCATION DEFENSE FUND,
Intervenor-Defendant-Appellant.

On Appeal from the United States District Court
for the Northern District of California
No. 17-cv-05783-HSG
Hon. Haywood S. Gilliam, Jr., Judge

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INTRODUCTION

This case is about whether federal agencies have the power to transform a Congressional mandate into a mere suggestion. The Women's Health Amendment to the Patient Protection and Affordable Care Act (ACA) gave women across the country guaranteed access to preventive healthcare at no cost to them. Before passage of the Women's Health Amendment, millions of women lacked access to affordable preventive care, including contraceptives. This resulted in a fundamental inequity whereby women were routinely and systematically charged more for preventive services than men, incurring significant out-of-pocket costs. As a result, women experienced poorer health outcomes as well as economic disadvantages.

To remedy this problem, Congress statutorily guaranteed that women receive full and equal health coverage. The Women's Health Amendment—or the statutory "Mandate," as defendants and intervenors call it—provides that health plans "shall" provide women's "preventive care and screenings" without "impos[ing] any cost sharing." 42 U.S.C. § 300gg-13(a)(4). This guarantee empowered a woman, in consultation with her preferred medical provider, to select the best contraception to meet her healthcare needs. Since 2012, over 62 million women have benefited from this landmark law, with resulting societal benefits from greater female engagement in the workforce and economic self-sufficiency.

The regulations at issue in this case are the classic example of the exception that swallowed the rule. The Religious and Moral Exemption Rules permit nearly any employer with a religious or moral objection to contraceptives to just stop covering them.[1] The Exemption Rules do not independently require that employers give any particular notice to their employees. Nor do the Exemption Rules take any steps to ensure that employers' female employees or female dependents continue receiving the seamless contraceptive coverage to which they are legally entitled.

But defendants lacked the legal authority to promulgate these far reaching Rules. The only delegation of authority to defendants—through the Health Resources and Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services (HHS)—was limited to determining the additional preventative services to be covered under the Women's Health Amendment. 42 U.S.C. § 300gg-13(a)(4). HRSA was not delegated authority to determine *who* must provide those services, nor to unilaterally allow employers to exempt themselves from providing preventive care. *Id*. Nor are these rules required by the Religious Freedom and Restoration Act (RFRA). As eight courts of appeals have held, the existing accommodation process—which completely

[1] The States will collectively refer to the Religious and Moral Exemption Rules as the "Exemption Rules" through this brief.

separates objecting employers from the provision of contraceptives—does not substantially burden religious exercise.

The States seek only to "ensur[e] that women covered by [objecting employers'] health plans receive full and equal health coverage, including contraceptive coverage," while protecting the religious beliefs of employers. *Zubik v. Burwell*, 136 S.Ct. 1557, 1560 (2016) (per curiam). The new Rules fail to adhere to the directives of Congress and the Supreme Court.

JURISDICTIONAL STATEMENT

The States agree with defendants' statement of jurisdiction. AOB 3.

ISSUES PRESENTED FOR REVIEW

1. Whether the States have Article III standing.
2. Whether the district court abused its discretion by entering a limited preliminary injunction preserving the status quo because (a) the States were likely to succeed on the merits of their claim that the challenged regulations are invalid, (b) the States will suffer irreparable harm absent an injunction, and (c) the balance of the equities tips in the States' favor.

STATEMENT OF THE CASE

A. Statutory and Regulatory Framework

The ACA is a landmark piece of legislation through which Congress sought to "increase the number of Americans covered by health insurance and decrease the cost of health care." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538

(2012); 42 U.S.C § 18091(2)(C), (F) & (G). Congress aimed to increase access to affordable and quality healthcare through a series of reforms, including strengthening consumer protections in the private insurance market, expanding Medicaid, providing subsidies to lower premiums, and creating effective state health insurance exchanges. *Id.*; *see also King v. Burwell*, 135 S. Ct. 2480, 2485-2487 (2015).

Among its many reforms to the nation's healthcare system, the ACA sought to increase access to preventive care by requiring that certain employer group health insurance plans cover enumerated categories of preventive health services at no additional cost to the insured. One such category of preventive services is women's "preventive care and screenings." 42 U.S.C. § 300gg-13(a)(4). Known as the Women's Health Amendment, this provision sought to redress the discriminatory practice of charging women more for preventive services than men. 155 Cong. Rec. S12027 (Dec. 1, 2009) (statement of Sen. Gillibrand). At the time, "more than half of women delay[ed] or avoid[ed] preventive care because of its cost." *Id.* Supporters of the amendment expected that eradicating these discriminatory barriers to preventive care—including contraceptive care—would result in substantially improved health outcomes for women. *See, e.g.*, *id.* at S12052 (statement of Sen. Franken); *id.* at. S12059 (statement of Sen. Cardin); *id.* (statement of Sen. Feinstein) (same). Around the same time that the Women's

Health Amendment was adopted, Congress rejected a competing amendment that would have permitted broad moral and religious exemptions to the ACA's coverage requirements. 158 Cong. Rec. S539 (Feb. 9, 2012); 159 Cong. Rec. S2268 (Mar. 22, 2013).

Rather than set forth a comprehensive definition of women's preventive services that must be covered, Congress opted to rely on the expertise of HRSA. 42 U.S.C. § 300gg-13(a)(4). HRSA, in turn, commissioned the Institute of Medicine (IOM) to study the issue, and make evidence-based recommendations.[2] The IOM assembled a panel of independent experts who surveyed the relevant literature and peer-reviewed medical research, and ultimately issued a final Report. IOM, Clinical Prevention Services for Women: Closing the Gaps (2011) (IOM Report).[3]

The IOM Report echoed many of the concerns raised by sponsors of the Women's Health Amendment. *Id.* at 102-110. It concluded, for example, that 49% of all pregnancies in the United States are unintended, and that this phenomenon was most prevalent among low-income women and women of color,

[2] "The IOM is an arm of the National Academy of Sciences, an organization Congress established 'for the explicit purpose of furnishing advice to the Government.'" *Burwell v. Hobby Lobby*, 573 U.S. 682, 742 n.3 (2014) (Ginsburg, J., dissenting).

[3] Available at https://www.nap.edu/read/13181/chapter/1.

who are least likely to have access to contraceptive care. *Id.* at 102. The IOM Report relatedly found that the most effective forms of contraception carry substantial upfront costs, *id.* at 105, 108, and that even modest out-of-pocket fees can appreciably reduce use of these methods, *id.* at 109. The IOM Report also discussed the important public health benefits and cost-savings to society associated with increased access to contraception and fewer unintended pregnancies. *Id*. at 102-110. In light of its findings, the IOM recommended covering all FDA-approved contraceptive methods. *Id*. at 79-156.

HRSA adopted the IOM Report's recommendations in its Guidelines, and the three federal agencies responsible for implementing the ACA promulgated regulations requiring that regulated-entities cover all FDA-approved contraceptive methods. 77 Fed. Reg. 8,725, 8,725-26 (Feb. 15, 2012).[4] In 2016, HRSA reaffirmed their Guidelines based on recommendations by the American College of Obstetricians and Gynecologists, and that remains the standard today.[5]

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[4] Certain plans that existed before the ACA's enactment were statutorily exempted from the contraceptive coverage requirement. These so-called "grandfathered plans" are a "transitional measure," meant to ease regulated entities into compliance with the ACA, and "will be eliminated as employers make changes to their health care plans." *Priests For Life v. HHS*, 772 F.3d 229, 266 (D.C. Cir. 2014), *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016); 80 Fed. Reg. 72,192, 72,216 (Nov. 18, 2015) (Grandfathered plans are designed to "ease the transition required by the market reforms").

[5] *See* https://www.hrsa.gov/womens-guidelines/index.html.

The regulations included an exemption to the contraception coverage provision for houses of worship, where it would be reasonable to presume that line-level employees would share their employer's religious objection to contraception. 76 Fed. Reg. 46,621-01, 46,623 (Aug. 3, 2011) ("the Departments seek to provide for a religious accommodation that respects the unique relationship between a house of worship and its employees in ministerial positions"); 77 Fed. Reg. at 8,728.[6] This "church exemption" imported a category of employers defined in the Internal Revenue Code. *Hobby Lobby*, 573 U.S. at 698 (quoting 26 U.S.C. § 6033(a)(3)(A)(i) and (iii)). The agencies declined to implement a broader exemption out of concern that it might sweep in employers "more likely to employ individuals who have no religious objection to the use of contraceptive services," and thereby risk "subject[ing] [such] employees to the religious views of [their] employer." 77 Fed. Reg. at 8,728. In creating the church exemption, defendants did not identify any provision in the ACA authorizing them to create such an exemption. 76 Fed. Reg. at 46,623.

[6] As defined by the regulations, a "religious employer": "(1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization [under the relevant statutes, which] refer[] to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order." *Id.* at 8,726.

The agencies then implemented new regulations to promote "two important policy goals": (1) to "advanc[e] the compelling government interests in safeguarding public health and ensuring that women have equal access to health care;" and (2) to "advance these interests in a narrowly tailored fashion that protects certain religious organizations with religious objections to providing contraceptive coverage from having to contract, arrange, pay, or refer for such coverage." 78 Fed. Reg. 39,870, 39,872 (July 2, 2013). To accomplish these goals, the rule instituted an "accommodation" process for religious non-profits. 78 Fed. Reg. at 39,870. To avail itself of the accommodation, an employer submits a government-issued self-certification form to its health insurance carrier—or in the case of a self-insured plan, to its third party administrator (TPA)—certifying that: (1) it is a non-profit organization that (2) holds itself out as a religious organization, and (3) opposes providing contraceptive coverage on religious grounds. *Id.* at 39,874-39,875; *Wheaton College v. Burwell*, 134 S. Ct. 2806, 2807 (2014).[7] Upon submitting the self-certification form, the employer is freed of any obligation to "contract, arrange, pay, or refer for contraceptive coverage" to which it objects. 78 Fed. Reg. at 39,874. The insurance carrier becomes solely

[7] For simplicity and clarity, the States will refer to TPAs and health insurers collectively as "insurers" or "health insurers."

responsible for continuing to provide seamless contraceptive coverage to the insured. *Id.* at 39,876, 39,893.

Two subsequent legal developments caused the agencies to further amend the accommodation. In *Hobby Lobby*, the Court held that the Religious Freedom Restoration Act of 1993 (RFRA) applies to closely-held for-profit corporations with religious objections to contraception, and that the government must allow these companies to utilize the accommodation. 573 U.S. at 736. The Court emphasized that its holding would have no effect on women's access to contraceptive coverage. *Id.* at 693, 729 n.37; *see* 80 Fed. Reg. 41,318, 41,343 (July 14, 2015).

Next, in *Wheaton College*, a nonprofit college that qualified for the religious accommodation challenged the requirement to file the self-certification form. 134 S. Ct. at 2806-08. It reasoned that doing so made it complicit in providing contraception, and therefore violated its exercise of religion under RFRA. *Id.* at 2807-2808. The Court granted Wheaton's application for an interim injunction pending appeal, while expressing no view on the merits. *Id.* at 2807. Just as it did in *Hobby Lobby*, the Court emphasized that nothing in its order "affects the ability of [Wheaton's] employees and students to obtain, without cost, the full range of FDA approved contraceptives." *Id.* In response, the agencies provided an alternative process to the self-certification form, whereby employers need only

notify HHS in writing (without resort to any particular form) "of [their] religious objection to covering all or a subset of contraceptive services." 80 Fed. Reg. at 41,323. Upon receiving a written objection, the agencies contact the employer's insurer to inform it of its obligation to separately provide contraceptive coverage to the insured employees. *Id.*

In *Zubik*, nonprofit employers challenged the revised accommodation process, arguing that it still violated RFRA. 136 S.Ct. at 1559. The Court vacated and remanded the matters to the Courts of Appeals to afford the parties an opportunity to resolve the matter in light of their evolving legal positions. *Id.* at 1560. The Court emphasized that it was expressing no view on the merits. *Id.* And as it did in *Wheaton College* and *Hobby Lobby*, the Court again underscored that nothing in its order "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 1560-1561.

After the *Zubik* remand, the agencies solicited public comment on modifications that would allow objecting employers to obtain an accommodation, "while still ensuring that women enrolled in the organizations' health plans have access to seamless [contraceptive] coverage." 81 Fed. Reg. 47,741, 47,741 (July 22, 2016). After considering the comments received, the agencies determined that no change to the accommodation process was warranted. They concluded that the

accommodation complied with RFRA by protecting the interests of religious objectors, while also fulfilling the agencies' statutory duty to ensure that women maintained no-cost contraceptive coverage. Dep't of Labor, FAQs About Affordable Care Act Implementation Part 36 at 4-5.[8]

B. The Challenged Interim Final Rules

On October 6, 2017, without prior notice to the public, the agencies issued two interim final rules (IFRs), the Religious IFR and the Moral IFR, that immediately created new broad exemptions to the contraceptive requirement. The Religious IFR allowed any employer—regardless of corporate structure or religious affiliation—or health insurer or university to self-exempt from the contraceptive mandate on religious grounds.[9] 82 Fed. Reg. 47,792, 47,809-812 (Oct. 13, 2017). The second regulation, the Moral IFR, created an entirely new and unprecedented exemption for certain entities that object to contraception on non-religious moral grounds. *See id.* at 47,838-854. The IFRs did not require that the objecting entity submit a self-certification form, or otherwise notify its insurer or the federal government that it is availing itself of the exemption. *Id.* at 47,808.

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

[9] For brevity, throughout this brief, the States generally discuss "employers" exempting themselves under the Rules. However, as noted *infra*, the IFRs and the final Exemption Rules extend to health insurers, universities, and in some instances, individuals as well.

And the IFRs made the accommodation process entirely voluntary at the employer's sole discretion. *Id.* at 47,812-813. No substitute mechanism was installed to ensure that women could continue to receive contraceptive coverage if their employer (or health insurer) opted out. *Id.* Both rules became effective immediately. *Id.* at 47,792; *id.* at 47,838.

C. The First Preliminary Injunction

On November 1, 2017, the States of California, Delaware, Maryland, New York, and Virginia filed their initial complaint challenging the IFRs. ER 11. The complaint alleged causes of action under the Administrative Procedure Act (APA) and the United States Constitution. On December 21, 2017, the district court enjoined implementation of both IFRs on a nationwide basis, concluding that the States were likely to succeed on their claim that the IFRs were procedurally invalid. *California v. Azar*, 281 F.Supp.3d 806 (N.D. Cal. 2017). This Court affirmed in part and vacated in part. *California v. Azar*, 911 F.3d 558 (9th Cir. 2018).

This Court first held that the States have standing to sue because the IFRs would "first lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states." *Id*. at 571. The Court highlighted that defendants' "own regulatory impact analysis (RIA)—which explains the anticipated costs, benefits, and effects of the IFRs—estimates that

between 31,700 and 120,000 women nationwide will lose some coverage." *Id*. The Court noted that the RIA estimated the direct cost of filling the coverage loss as $18.5 or $63.8 million per year (depending on the method of estimating) and the IFRs identify state and local programs as filling that gap. *Id*. The RIA, therefore, "assumed that state and local governments will bear additional economic costs." *Id*. The Court concluded that the "declarations submitted by the states further show that women losing coverage from their employers will turn to state-based programs or programs reimbursed by the state." *Id*. On the merits, this Court concluded that the States were likely to succeed on their APA notice-and-comment claim and that the harm to the States was "not speculative; it is sufficiently concrete and supported by the record." *Id.* at 575-81. This Court vacated the portion of the injunction barring enforcement of the IFRs in non-plaintiff states. *Id*. at 584-85.

D. The Challenged Final Rules

Shortly before this Court issued its decision, defendants promulgated the final Religious and Moral Exemption Rules which superseded the IFRs on January 14, 2019. 83 Fed. Reg. 57,536 (Nov. 15, 2018); 83 Fed. Reg. 57,592 (Nov. 15, 2018). These Rules are very similar to the IFRs. *See* Defs.' Supplemental Br., Ninth Circuit No. 18-15144, Dkt. No. 125 at 6 ("the substance of the rules remains largely unchanged"); Sisters Supplemental Br., Ninth Circuit No. 18-15144, Dkt.

No. 128 at 2 (noting the final rule is "substantively identical" to the IFR). However, there are two noteworthy differences.

First, the final Exemption Rules estimate that even *more* women will be harmed by the expanded exemptions, up to 126,400. *See, e.g.*, 83 Fed. Reg. at 57,551 n.26, 57,578. Second, the Rules suggest that women take additional steps—outside their employer-sponsored coverage—to access contraceptive coverage through the federal Title X family planning clinics, a safety-net program designed for low-income populations. 83 Fed. Reg. at 57,548, 57551; 83 Fed. Reg. at 57,605, 57,608.[10] As the record demonstrates, the Title X program is ill-equipped to replicate or replace the seamless contraceptive-coverage requirement.[11] SER 53, 67, 72-73, 93, 155-156, 159-162, 228-229, 230, 247, 249, 254, 262-263, 273, 292.

In response to the final Rules, the original plaintiff States, joined by Connecticut, Hawaii, Illinois, Minnesota (by and through its Department of Human Services), North Carolina, Rhode Island, Vermont, Washington, and the District of

[10] Defendants have also proposed drastic changes to the Title X program that would make it even more unsuitable as a remedy for the harm imposed by the Exemption Rules. *See also* SER 136, 146-47, 185-86.

[11] The Title X program is discretionary funding that is subject to the annual appropriations process. SER 159-160. From 2010-2014, even as the number of women in need of publicly funded contraceptive care grew by 5%, (an additional 1 million women), Congress cut funding for Title X by 10%. SER 160.

Columbia filed an amended complaint on December 18, 2018.[12] The States assert that both the IFRs and the final Exemption Rules violate the APA and the Constitution. ER 129-196. On December 19, 2018, the States promptly moved for a preliminary injunction requesting that the Exemption Rules be enjoined before they were set to take effect on January 14, 2019. Defendants filed the full 805,099-page administrative record on January 7, 2019—a mere four days before the hearing. Dkt. No. 206; Dkt. No. 169.

E. The Second Preliminary Injunction

On January 13, 2019, the district court issued a preliminary injunction enjoining implementation of the Exemption Rules. ER 1-45. First, the court concluded that the case was properly venued in the Northern District and that the States had standing. ER 15-16.

On the merits, the court held that the States had shown that they were likely to succeed on their argument that the Exemption Rules are not in accordance with the ACA, or have at a minimum raised serious questions in that regard. ER 21-37.

[12] On November 30, 2018, the States moved to lift the stay in the district court so that they could move swiftly to challenge the newly-issued final Exemption Rules. Dkt No. 152. On December 13, 2018, the district court denied the States' motion. Dkt. No. 161; *see also* Dkt No. 171. Once this Court issued its decision and mandate, the district court promptly set the briefing schedule. Dkt. No. 169. The court also denied defendants' motion to stay all proceedings (Dkt No. 180), explaining that "[g]iven the impending January 14, 2019 effective date of the challenged rules, a stay of these proceedings is not feasible." Dkt No. 183.

The court rejected defendants' assertion that the Women's Health Amendment "delegated total authority to exempt anyone they wish from the contraceptive mandate." ER 22. The court then concluded that the Religious Exemption Rule is not required by RFRA, agreeing with eight courts of appeals that have concluded that the already-existing "accommodation does not impose a substantial burden on objectors' exercise of religion." ER 25-26.

The court further concluded that the States were also likely to succeed on their claim that the Exemption Rules are arbitrary and capricious because the agencies failed to provide a reasoned explanation for disregarding facts and circumstances that underlay the prior policy. ER 37-38. The court also concluded that the Moral Exemption Rule was likely not in accordance with the ACA (ER 38-39), and that absent a preliminary injunction the States would suffer irreparable harm (ER 39-40).

The court highlighted the expedited nature of its preliminary injunction, noting that "[a]s this case proceeds to a merits determination, the Court will have to determine how to develop the relevant record" and "the parties' positions on the legal issues . . . will need to be laid out in substantially greater detail for the Court to sufficiently address the merits of this claim on a full record in the next stages of the case." ER 37-38. In granting preliminary relief, the court ordered the parties to devise a "plan for expeditiously resolving this matter on the merits." ER 45.

Neither defendants nor intervenors sought to stay the preliminary injunction, either in this Court or in the district court.

The parties submitted a proposed schedule (Dkt No. 273), and the court scheduled cross-dispositive motions beginning on April 30, 2019, to be completed by August 15, 2019, with oral argument on September 5, 2019. Dkt No. 275.

SUMMARY OF ARGUMENT

1. As this Court held in an earlier appeal in this case, the States have established Article III standing. Defendants' Exemption Rules threaten to harm the States' concrete interests, including harming the States' fiscs. *California*, 911 F.3d at 570-74. Some women who lose contraceptive coverage as a result of the regulations will seek care through State-run programs, or programs that the States are legally responsible for reimbursing. Other women who lose coverage will not qualify for these programs and will be at heightened risk for unintended pregnancies, which often impose direct financial costs on the States. Finally, reduced access to contraceptives will have a negative impact on a woman's educational attainment, ability to participate in the labor force, and earnings potential. These social, economic, and public health outcomes also inflict great harm on the States. As this Court concluded, these harms each constitute a cognizable injury directly caused by the challenged regulations, which can be remedied only by a favorable judicial decision.

2. The district court did not abuse its discretion in concluding that "[g]iven the 'serious reliance interests' of women who would lose coverage to which they are statutorily entitled if the Final Rules go into effect," the States are "likely to prevail on their claim that the agencies failed to provide a 'reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy.'" ER 37. At this preliminary stage of the proceedings, it cannot be concluded that the district court abused its discretion.

The district court also correctly concluded that the Exemption Rules violate the Women's Health Amendment. The Women's Health Amendment mandates that women "shall" be provided with "preventive services." And while the Amendment delegates to HRSA the responsibility of setting forth "comprehensive guidelines," Congress did not grant defendants authority to carve out broad exemptions to this statutory requirement. The Amendment delegates to HRSA the responsibility to define the types of preventive services that shall be included—not *who* must abide by the statute. Moreover, HRSA may not exercise its limited discretion in a manner that contradicts the provision's core purpose. The Exemption Rules effectively eliminate the provision's primary goal—the mandate—and are therefore invalid under the APA.

Nor is the Religious Exemption Rule compelled by RFRA. As eight courts of appeals have concluded, the act of opting out of providing contraceptive coverage

does not substantially burden the exercise of religion. And the existing religious accommodation is the least restrictive means of furthering the compelling governmental interest in ensuring that women have full and equal access to preventive care, including contraceptives. That is especially true where, as here, the Religious Exemption Rule requires tens of thousands of women to bear the cost of their employers' religious views about contraceptives. Nor do defendants' authorities support the notion that RFRA bestows federal agencies with broad authority to create sweeping exemptions to generally applicable statutory law.

3. The district court did not abuse its discretion in holding that the States would suffer irreparable harm absent a preliminary injunction. The financial harms that would be sustained by the States, *infra* at 20-21, are irreparable because they cannot be recovered once dispensed. *See California*, 911 F.3d at 581. The increase in unintended pregnancies would also inflict irreparable harm to the States' economic and public health interests.

Nor did the district court abuse its discretion in finding that the balance of the equities and public interest tips in the States' favor. While the harm inflicted upon the States is irreparable, the government has pointed to no countervailing irreparable harm, especially given the numerous stipulated permanent injunctions in place for employers with objections to the contraceptive mandate. Indeed, intervenors concede that numerous employers will be unaffected in light of these

stipulated injunctions. Sisters Br. 15; March Br. 12. To date, defendants have not identified a single employer that is being harmed as a result of the current preliminary injunction.

STANDARDS OF REVIEW

A district court's order entering a preliminary injunction is reviewed for abuse of discretion. *Disney Enterprises, Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017). Given this "highly deferential" standard, this Court will not reverse the district court, "even if [this Court] would have arrived at a different result, so long as the district court did not clearly err in its factual determinations" and "identified the correct legal rule." *Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872, 881 (9th Cir. 2012); *Disney Enterprises*, 869 F.3d at 856; *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 422 F.3d 782, 793 (9th Cir. 2005) ("[a] district court's order with respect to preliminary injunctive relief is subject to limited appellate review").

Standing is reviewed de novo. *California*, 911 F.3d at 568.

ARGUMENT

I. THE STATES HAVE ARTICLE III STANDING

As this Court previously concluded, the Exemption Rules "will first lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states." *California*, 911 F.3d at 571; *see also e.g.*, SER 163, 165, 167, 168-169, 170, 172, 299-300, 53, 282-283, 284, 228, 254-256.

Defendants concede that this Court's earlier decision is "controlling" on this point. AOB 49. Intervenors evade any substantive discussion of this Court's prior decision, while essentially urging that its holding be overruled. March Br. 21-28; *see Rocky Mountain Farmers Union v. Corey*, 913 F.3d 940, 951 (9th Cir. 2019) ("law of the case doctrine generally precludes reconsideration of 'an issue that has already been decided by the same court, or a higher court in the identical case.'"). As explained above, this Court already considered the effects of the Rules on the States. Intervenors do not argue that the underlying basis of the Court's prior ruling has changed. If anything, the States now have even more evidentiary support demonstrating their harms and defendants themselves expect even more women to be harmed by the Exemption Rules. *See* SER 55-65, 66-73, 77-104, 135-203, 212-218, 236-252, 261-273 288-293; 83 Fed. Reg. at 57,551 n.26, 57,578. Thus, as this Court has already concluded, the States have standing. *California*, 911 F.3d at 570-74.

II. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION BY ENTERING A PRELIMINARY INJUNCTION PRESERVING THE STATUS QUO

A. The District Court Properly Concluded that the States Were Likely to Succeed on the Merits

The district court did not abuse its discretion in holding that the States were likely to succeed on the merits of their APA claim. ER 21-37. The APA requires that agency action must be held "unlawful and set aside" where it is "arbitrary,

capricious," "not in accordance with the law," or is "in excess of statutory jurisdiction." 5 U.S.C. §§ 706(2)(A), 706(2)(C). Here, the district court did not abuse its discretion in issuing a preliminary injunction to maintain the status quo based on a showing that the Exemption Rules are arbitrary and capricious, are not in accordance with the Women's Health Amendment, and are not compelled by RFRA.

1. The District Court Did Not Abuse Its Discretion in Concluding that the Exemption Rules Are Invalid Because They Are Arbitrary and Capricious

Defendants have not established that the district court abused its discretion in concluding that the Exemption Rules are arbitrary and capricious for failure to explain defendants' stark departure from prior policy. ER 37-38; 5 U.S.C. § 706(2)(A); *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-2127 (2016). HHS itself estimated that 30 million women gained access to contraceptive coverage due to the Women's Health Amendment. SER 305 (AR 571,363). The number of women who filled prescriptions for oral contraceptives with no out-of-pocket costs more than quadrupled from 1.2 million in 2012 to 5.1 million in 2013. SER 311 (AR 571,369). As HHS's own statements demonstrate, millions of women nationwide rely on the Women's Health Amendment for full and equal healthcare coverage. And, the Rules themselves state that up to 126,400 women stand to lose their contraceptive coverage. 83 Fed. Reg. at 57,551.

Because defendants' policy reversal implicates these "serious reliance interests," it must be justified by a "reasoned explanation." *Encino Motorcars*, 136 S. Ct. at 2125-26; *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 535-36 (2009) (Kennedy, J., concurring).

Yet, as the district court recognized, defendants failed to offer a reasoned explanation for the Exemption Rules, given the lack of any material change in the underlying factual and legal circumstances that supported their prior position. ER 37. Defendants broadly expanded the ability of employers to exempt themselves from the Women's Health Amendment less than a year after concluding that plan participants and beneficiaries "should not be required to enroll in new programs or to surmount other hurdles to receive access" to coverage. Dep't of Labor, FAQs About Affordable Care Act Implementation Part 36 at 11; *see also Hobby Lobby*, 573 U.S. at 737 (Kennedy, J., concurring) (noting HHS's position that the contraceptive-coverage requirement "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."). The district court did not abuse its discretion in concluding that plaintiffs were likely to succeed on their claim that defendants' "dramatically changed position" is arbitrary and capricious. *Organized Village of Kake v. U.S. Dep't of Agric.*, 795

F.3d 956, 959 (9th Cir. 2017) (en banc) (concluding that agency's "dramatically changed position" only two years later was arbitrary and capricious).

Defendants argue that the Exemption Rules properly rely on defendants' conclusion that there is "more uncertainty" regarding the "efficacy and health benefits of contraceptives" than they had previously acknowledged. AOB 46 (citing 83 Fed. Reg. at 57,552-55). But those pages of the rulemaking record do not conclude that the "health benefits of contraceptives" are *scientifically* less certain. 83 Fed. Reg. at 57,552-55. Defendants simply cite commentators on both sides of the issue and then conclude that "we do not take a position on the variety of empirical questions discussed above." 83 Fed. Reg. at 57,555.[13] And if the health benefits of contraceptives really had been called into question over the past two years, defendants would have addressed whether HRSA should include contraceptives in the Guidelines at all. To that end, defendants fail to provide a rationale connecting the purported "uncertainty" about contraceptives with their purported solution, namely broad Exemption Rules. *See generally* 83 Fed. Reg. at

[13] The Religious Exemption Rule does state that "significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged," but it is entirely unclear what "these issues" refers to. 83 Fed. Reg. at 57,555. The Rule does not squarely challenge the well-established health benefits of contraceptives, let alone the scientific or medical consensus about contraceptives that has developed over the past decades.

57,545; SER 311, 320-323, 328-331[14]; *see also Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 48-51 (1983) (regulation rescinding prior regulation after change in presidential administration was arbitrary and capricious where agency failed to address prior fact findings).

To the extent that defendants simply disagree with the district court on this point (AOB 46), "[m]ere disagreement with the district court's conclusion is not sufficient reason for [the Court] to reverse the district court's decision regarding a preliminary injunction." *Nat'l Wildlife Fed'n*, 422 F.3d at 793. As noted above, this issue will be resolved on the merits by the district court in approximately five months, after a full and fair hearing. And through the upcoming cross-dispositive motions process, the parties will grapple with the 805,099-page administrative record for the first time. But for now, defendants have not carried their burden of demonstrating that the district court abused its discretion in granting a preliminary injunction to maintain the status quo while this issue is fully litigated.

2. The Religious and Moral Exemption Rules Are Invalid Because They Are Contrary to the Women's Health Amendment

Congress did not delegate to HRSA, or any other agency, the ability to promulgate rules undermining the Affordable Care Act's requirement that women receive no-cost preventive care. The limited authority delegated to HRSA was to

[14] *See also* https://www.hrsa.gov/womens-guidelines-2016/index.html.

issue "guidelines" that would outline what "additional preventive care" "shall" be covered by regulated group health plans. The Exemption Rules simply cannot be reconciled with the text or purpose of the Women's Health Amendment or the ACA—which seek to expand access to women's healthcare, not limit it.

1. The Rules cannot be reconciled with the plain text of the Women's Health Amendment. Statutory interpretation "start[s], of course, with the statutory text," and "statutory terms are generally interpreted in accordance with their ordinary meaning." *See BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 91 (2006). Here, the Rules are contrary to the implementing statute itself, which states that "a group health plan and a health insurance issuer offering group or individual health insurance coverage *shall*, at a minimum provide coverage for and shall not impose any cost sharing requirements for . . . (4) with respect to *women*, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4) (emphasis added). The statute makes clear that "preventive care" for "women" "shall" be provided by the specified regulated entities. Nothing in this provision either expressly or implicitly allows HRSA to "contradict[] what Congress has said" by crafting exemptions that permit broad categories of employers, plan sponsors, issuers, or individuals to exempt themselves from the statutory

requirement. *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 n.4 (2009); *Nw. Envtl. Def. Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 681-86 (9th Cir. 2007) (setting aside agency action that is contrary to governing law).

To be clear, Congress did not provide a fixed list of covered preventive services. Instead, it directed experts at HRSA to delineate the required preventive services. This makes sense given that HRSA is the "primary federal agency for improving health care to people" and its mission is to "improve health and achieve health equity through access to quality services."[15] But Congress made the services defined by HRSA mandatory, by stating that they "shall" be provided.[16] *See Kingdomware Technologies, Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) ("Shall" is a mandatory term that "normally creates an obligation impervious to judicial [or agency] discretion"); *see also Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 578 (E.D. Pa. 2017) (use of the word "shall" indicates that

[15] *About HRSA*, https://web.archive.org/web/20190302054343/www.hrsa.gov/about/index.html. Notably, HRSA's expertise is in *providing* access to medical care; it has no expertise in crafting religious or moral exceptions to such care.

[16] It would be untenable practically to expect Congress—a body of individuals without medical training—to expressly enumerate the specific services contained within the broad category of "preventive services." In an evolving discipline such as medicine, new treatments and therapies are developed and added (and sometimes deleted from or rendered obsolete) to the physician's toolkit every year. HRSA itself notes that since the Guidelines were originally established in 2011 "there have been advancements in science and gaps identified in the existing guidelines." *See* https://www.hrsa.gov/womens-guidelines-2016/index.html.

"no exemptions created by HHS are permissible (unless they are required by RFRA)").

Furthermore, Congress did not just instruct HRSA to develop "comprehensive guidelines," but to do so "for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4). Thus, HRSA's express, limited role is to craft Guidelines carrying out the purpose of the Women's Health Amendment by determining the scope of preventive care services. *See* 83 Fed. Reg. at 57,537 ("The rules do not remove the contraceptive coverage requirement generally from HRSA's Guidelines."). HRSA does not have the authority to decide which employers are exempt from providing such statutorily mandated preventive care.

Here, having included all FDA-approved contraceptives within women's "preventive care"—first, based on the Institute of Medicine's recommendations in 2011 and then, based on American College of Obstetricians and Gynecologists' recommendations in 2016—HRSA cannot now declare that some employers need not provide the care that it determined is statutorily required. *See La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("an agency literally has no power to act . . . unless and until Congress confers power upon it").

2. Additional statutory text within the ACA demonstrates that defendants' interpretation is erroneous. For instance, Congress expressly considered which employers to exempt (grandfathered plans), and it did not choose to exempt

employers with religious or moral objections. Further, in enacting the ACA, Congress did create moral and religious exemptions—just not for the Women's Health Amendment. *See, e.g.*, 42 U.S.C. § 18113 (providing a statutory exemption for those who have a religious objection to participating in aid-in-dying procedures). And "[w]hen Congress provides exceptions in a statute," "[t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited that statute to the ones set forth." *United States v. Johnson*, 529 U.S. 53, 58 (2000); *see Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993) ("*Expressio unius est exclusio alterius*"). Lastly, in enacting the ACA, Congress expressly prohibited HHS from promulgating regulations that would "create[] any unreasonable barriers" to medical care *or* "impede[] timely access to health care services." 42 U.S.C. § 18114(1), (2); *see infra* at 61-63. These statutory indicators undermine defendants' position that Congress delegated to them broad authority to promulgate rules permitting employers to exempt themselves from statutory requirements.

In fact, Congress rejected an amendment that would have permitted broad moral and religious exemptions to the ACA's coverage requirements—the same moral and religious exemptions that are reflected in the IFRs and the Rules. 158 Cong. Rec. S539 (suggesting that a "conscience amendment" was necessary

because the ACA does not allow employers or plan sponsors "with religious or moral objections to specific items or services to decline providing or obtaining coverage of such items or services").[17] This Court should reject defendants' attempt to accomplish by regulation what Congress itself expressly declined to do. *See Landgraf v. USI Film Products*, 511 U.S. 244, 285 n.38 (1994) (Courts are "not free to fashion remedies that Congress has specifically chosen not to extend").

3. The Exemption Rules cannot be squared with Congress's purpose. Specifically, the ACA's requirement that certain group health plans cover women's "preventive care and screenings" (42 U.S.C. § 300gg-13(a)(4)) was added by the Women's Health Amendment—the purpose of which was ensuring that women have equal access to healthcare and are not required to pay more than men for preventive care. The Women's Health Amendment sought to end the widespread practice of systematically charging women more than men for preventive services. 155 Cong. Rec. S12027.[18] These Exemption Rules disregard what the Women's

[17] *See also Hobby Lobby*, 573 U.S. at 719 n.30; *id.* at 744 (Ginsburg, J., dissenting); 159 Cong. Rec. S2268.

[18] *See id.* at S12051; *id.* at S12027 ("women of child-bearing age spend 68 percent more in out-of-pocket heath care costs than men"); *id.* at S12051. This Amendment also fit into the ACA's overall goals, including Congressional goals of eliminating gender rating, providing maternity coverage, ensuring preventive care for domestic violence survivors, and providing public health programs for women. Jennifer B. Wheller & Austin Rueschhoff, *Improving Women's Health Opportunities and Challenges in Health Reform*, Nat'l Conference of State

Health Amendment sought to accomplish. *Securities Indu. Ass'n v. Bd. of Governors of Fed. Reserve Sys.*, 468 U.S. 137, 143 (1984) (Court must reject construction of a statute that is "inconsistent with the statutory mandate or that frustrate[s] the policy that Congress sought to implement").

More broadly, the ACA, including the Women's Health Amendment, sought to *provide* affordable, high quality healthcare to millions of Americans. 42 U.S.C § 18091. Defendants' Rules—which allow employers to eliminate contraceptives from health plans—thus contravene not only the intent of the Women's Health Amendment, but also of the ACA itself. *See Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 91-92, 95-96 (2002) (concluding that the challenged regulation is invalid as inconsistent with Congress' intent).

Attempting to justify their insistence that HRSA can determine which employers must abide by the ACA preventive services requirement, defendants assert that nothing in the statute requires that HRSA's Guidelines be applicable to "all types of employers." AOB 19. Not so. The statute directly states which entities are subject to its requirements: "a group health plan and a health insurance issuer offering group or individual health insurance coverage." 42 U.S.C. § 300gg-13. Ignoring the statute's command that its requirements apply to these designated

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Legislatures (2012), http://www.ncsl.org/documents/health/ImproWomenshealth112.pdf.

entities, defendants assert that HRSA only had to "consider the statutory mandate . . . ." AOB 20. However, in general, agencies are bound and limited by Congress's delegation of authority—agencies must abide by a "statutory mandate" rather than merely "consider" it. Nor do defendants point to any legal authority for their novel view that Congressional directives may be treated as mere suggestions. And here, HRSA was bound by Congress' narrow delegation of authority, which requires HRSA to provide Guidelines "for purposes of this paragraph," which was to ensure that "women" receive "*additional* preventive care and screening." 42 U.S.C. § 300gg-13(a)(4) (emphasis added). Moreover, when Congress wants to grant broad rulemaking authority to an agency, it knows how to do so.[19] It did not here. *See City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) ("Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge agency discretion").

[19] *See, e.g.*, 47 U.S.C. § 201(b) (delegating federal agency authority to "prescribe such rules and regulations as may be necessary in the public interest to carry out the provisions of the Act"); 15 U.S.C. § 1604(a) (delegating agency authority to "prescribe regulations to carry out" the statute); 15 U.S.C. § 77s(a) ("The Commission shall have authority from time to time to make, amend, and rescind such rules and regulations as may be necessary to carry out the provisions of this subchapter ...."); *see also* Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 Harv. L.Rev. 467, 471 n.8 (2002) ("According to one report, by January 1, 1935, more than 190 federal statutes included rulemaking grants that gave agencies power to 'make any and all regulations 'to carry out the purposes of the Act.'' Report of the Special Committee on Administrative Law, 61 Ann. Rep. A.B.A. 720, 778 (1936).").

Defendants place undue reliance on the phrase "as provided for" to confer authority on HRSA to create Rules permitting categories of employers to exempt themselves from the Women's Health Amendment. AOB 20. As one court properly explained, "'as' is used in anticipation of HRSA issuing guidelines"; it does not signal "that the ACA implicitly provides the Agencies with the authority to create non-statutory exemptions." *Pennsylvania*, 281 F. Supp. 3d at 579. Further, that Congress did not include the phrase "evidence-based" in the Women's Health Amendment does not transform HRSA's authority from creating guidelines addressing which preventive services must be included to determining who must include them. *Cf.* AOB 20.

Defendants' interpretation also runs afoul of separation-of-powers principles and, practically speaking, would render defendants' authority limitless. *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 485 (2001) (agency "may not construe the statute in a way that completely nullifies textually applicable provisions meant to limit its discretion"); *Schein v. Archer & White Sales*, 139 S. Ct. 524, 530 (2019) (the parties and the Court "may not engraft [their] own exceptions onto the statutory text."). Under their interpretation, HRSA—and by extension HHS, Labor, and/or Treasury—could exempt all employers from the Women's Health Amendment because, in their view, HRSA has the authority to determine the "scope" of who must abide by the statutory requirements. Strikingly, defendants

do not dispute this. They embrace this capacious authority and declare that so long as such exemptions are not arbitrary and capricious, then they are lawful. AOB 25.

But Congress clearly did not intend for HRSA to have unlimited authority to exempt broad categories of employers from the Women's Health Amendment; such a notion would defeat the statute itself. *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (in its statutory interpretation, the court "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency"). As a branch of a federal agency, HRSA may not issue a regulation unless it has "textual commitment of authority" to do so. *Whitman*, 531 U.S. at 468. This is a fundamental principle of separation of powers.[20]

[20] Defendants are not owed any *Chevron* deference, as they suggest (AOB 21), because where Congress has spoken on the issue—here, HRSA's delegated authority—"the inquiry is at an end; the court must give effect to the unambiguously expressed intent of Congress." *Food & Drug Admin.*, 529 U.S. at 132 (concluding that the FDA lacked authority to regulate certain tobacco problems). "Regardless of how serious the [purported] problem an administrative agency seeks to address, [], it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" *Id.* at 125. As the Court has stated, *Chevron* deference "does not license interpretive gerrymanders under which an agency keeps parts of statutory context it likes while throwing away parts it does not." *See Michigan v. EPA*, 135 S. Ct. 2699, 2708 (2015). Furthermore, "[a]n agency interpretation . . . which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a

Recognizing the limits of their argument, defendants rely heavily on the prior, narrow exemption for churches as precedent for the much broader Exemption Rules at issue in this litigation. AOB 21-25. This argument fails for several reasons.

First, as the district court properly concluded, the States challenge only the IFRs and the final Rules, and request that the 2016 Regulations remain in effect. ER 24. Thus, "the legality of th[e church] exemption is not before the Court." ER 24. To the contrary, it is part of the regulations currently in effect that the States seek to have the Court preserve. *See Alameda Conservation Ass'n v. State of Cal.*, 437 F.2d 1087, 1093 (9th Cir. 1971) ("a federal court will not render an advisory opinion" on the lawfulness of a statute); *Clark v. City of Seattle*, 899 F.3d 802, 808 (9th Cir. 2018) (Article III prohibits the court from issuing "advisory opinions").

Second, the church exemption is different from the current Exemption Rules. The former is narrowly crafted and tethered to the Internal Revenue Code. *See Hobby Lobby*, 573 U.S. at 698 (quoting 26 U.S.C. § 6033(a)(3)(A)(i) and (iii)). The church exemption was adopted based on defendants' recognition that "churches are more likely to hire co-religionists" and "against the backdrop of the longstanding governmental recognition of a particular sphere of autonomy for

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consistently held agency view." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987).

houses of worship." 80 Fed. Reg. at 41,325 (July 14, 2015) (explaining that churches have "special status under longstanding tradition in our society and under federal law"); *see also* 76 Fed. Reg. at 46,623.[21]

3. The Religious Exemption Rule Is Not Compelled (or Authorized) by RFRA

RFRA provides that the government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" unless the burden: (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest. 42 U.S.C. § 2000bb-1(a)-(b). A "'substantial burden' is imposed [] when individuals are . . . coerced to act contrary to their religious beliefs by the threat of civil or criminal sanctions . . . ." *Navajo Nation v. U.S. Forest Serv.*, 535 F.3d 1058, 1070 (9th Cir. 2008). Only after "the plaintiff first proves the government action substantially burdens his exercise of religion" must the government demonstrate that it has employed the least restrictive means of furthering a compelling interest. *Id*. at 1069.

Defendants assert that the Religious Exemption Rule is necessary because the accommodation—which was crafted with the sole purpose of relieving any

[21] That "no one filed a lawsuit challenging" (AOB 21) the church exemption does not mean that the agencies have the authority to enact the Exemption Rules at issue in this case.

burden on the exercise of religion—itself substantially burdens the exercise of religion. *See, e.g.*, AOB 36-37. But that assertion fails at the first step of the analysis. As eight courts of appeals have concluded, the act of opting out of providing contraceptive coverage does not substantially burden the exercise of religion. And the existing accommodation is the least restrictive means of furthering the compelling governmental interest in ensuring that women have full and equal access to preventive care, including contraceptives.[22] The Religious Exemption Rule, moreover, requires tens of thousands of women to bear the cost of their employers' religious views about contraceptives. That extensive third party harm distinguishes this case from *Hobby Lobby*, *Wheaton College*, and *Zubik*, where the Supreme Court insisted—time and again—that no woman would lose access to coverage for the full range of FDA-approved contraceptives. RFRA does not require female employees and their female dependents to forgo their statutorily guaranteed benefits for the sake of their employers' religious beliefs.

a. The Accommodation Does Not Substantially Burden the Exercise of Religion

Defendants assert that the Religious Exemption Rule was legally required because the accommodation violates RFRA. AOB 36-45; *see also* Sisters Br. 35-

[22] Defendants do not have—nor do they assert—interpretive authority over RFRA. Thus, their reading of RFRA is entitled to no deference. *See Gonzales v. Oregon*, 546 U.S. 243, 258-259 (2006).

39. Defendants claim that the act of informing the government of its religious objections is inherently problematic because it "triggers" the employers' insurers to separately provide contraceptive coverage to their employees, which the employers sincerely believe "renders them 'complicit' in the provision of contraceptive coverage." AOB 36-37. In other words, defendants' complicity-based RFRA argument posits that: opting out of a generally-applicable requirement will cause the government to respond by reaching out to others to fill the resulting gap, which will cause third parties to engage in lawful conduct that the objector regards as morally wrong, which would thus make the objector complicit in that moral wrong by way of their relationship to that third party (such as an employer-employee relationship).

1. Whether a law substantially burdens religious exercise is a legal question for the courts to decide. Defendants assert that as long as religious employers sincerely believe that participating in the accommodation makes them complicit in the provision of contraceptive coverage, that belief establishes—as a matter of law—that the accommodation substantially burdens the exercise of religion. *See* AOB 36; *see also Sharpe Holdings, Inc. v. U.S. Dep't of Health and Human Servs.*, 801 F.3d 927 (8th Cir. 2015). Like the district court below, the States do not question the sincerity of religious employers' beliefs. But sincerely held religious beliefs cannot—in and of themselves—answer the legal question of whether a law

imposes a substantial burden under RFRA. 42 U.S.C. § 2000bb-1(a); *see also Guam v. Guerrero*, 290 F.3d 1210, 1222 n.20 (9th Cir. 2002) ("Whether a prosecution for importation of marijuana substantially burdens one's religion is a legal question for courts to decide.").

First, the text and structure of RFRA do not support defendants' position. RFRA expressly requires that there be a "substantial[] burden" on a person's "exercise of religion." 42 U.S.C. § 2000bb-1(a)-(b). Yet defendants' argument would "read out of RFRA the condition that only *substantial* burdens on the exercise of religion trigger the compelling interest requirement." *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 217 (2d Cir. 2015) (emphasis added). In other words, RFRA "requires a substantial burden, and assessing substantiality is a matter for the court." *Id*. at 218. "RFRA's reference to 'substantial' burdens expressly calls for a qualitative assessment of the burden that the accommodation imposes on the [ ] exercise of religion." *Geneva Coll. v. Sec'y U.S. Dep't Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015). Therefore, "[w]hether a law substantially burdens religious exercise under RFRA is a question of law for courts to decide, not a question of fact." *Priests for Life v. HHS*, 772 F.3d 229, 247 (D.C. Cir. 2014).

Second, defendants' contention that a substantial burden is present anytime a litigant sincerely believes it to be so would "collapse the distinction between

beliefs and substantial burden, such that the latter could be established simply through the sincerity of the former." *Catholic Health Care Sys.*, 796 F.3d at 218. No case sanctions that result. Defendants rely on dicta from *Hobby Lobby* stating that courts should not address "whether the religious belief asserted in a RFRA case is reasonable." AOB 38 (citing *Hobby Lobby*, 573 U.S. at 724); *see also* March Br. 63. But the context is missing. In that case, HHS took the position that complying with the contraceptive mandate (without the accommodation option) did not burden religion because the connection between providing comprehensive health insurance coverage and the morally objectionable end result "is simply too attenuated." 573 U.S. at 723. The Court rejected that argument, explaining that:

> This argument dodges the question that RFRA presents (whether the HHS mandate imposes a substantial burden on the ability of the objecting parties to conduct business in accordance *with their religious beliefs*) and instead addresses *a very different question* that the federal courts have no business addressing (whether the religious belief asserted in a RFRA case is reasonable).

Id. at 724 (second emphasis added); *see also Catholic Health Care Sys.*, 796 F.3d at 218.

In *Hobby Lobby*, moreover, the Court explained 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." 573 U.S. at 731. The Supreme Court, therefore, accepted the sincerity of petitioners' religious belief while *also*

concluding that the accommodation would not burden it. *Id*. Sincerely held beliefs and substantial burden may not be collapsed into a single inquiry under RFRA.[23]

Third, there would be no limiting principle if courts were required to treat sincerely held beliefs and substantial burden as one and the same. If "RFRA plaintiffs need only to assert that their religious beliefs were substantially burdened, federal courts would be reduced to rubber stamps, and the government would have to defend innumerable actions demanding strict scrutiny analysis." *Catholic Health Care Sys.*, 796 F.3d at 218. Every plaintiff with a sincere belief that governmental action burdened his or her exercise of religion would be granted an exemption unless the government could meet the "exceptionally demanding," least-restrictive-means standard. *Hobby Lobby*, 573 U.S. at 728.

In fact, under this view of RFRA, *any* religious accommodation requiring objectors to notify the government of their objections could be considered a substantial burden on religious exercise solely because of the governmental action taken in response. For example, as several courts have pointed out, a religious conscientious objector to the military draft could object to even notifying the

[23] The Supreme Court has since reaffirmed that evaluating belief and substantial burden is a two-part inquiry. *Holt v. Hobbs*, 135 S.Ct. 853, 862 (2015) ("In addition to showing that the relevant exercise of religion is grounded in a sincerely held religious belief, petitioner bore the burden of proving that the Department's grooming policy substantially burdened that exercise of religion.").

government of his religious opposition because "his act of opting out triggers the drafting of another person in his place." *Eternal Word Television Network v. Sec'y of U.S. Dep't Health & Human Servs.*, 818 F.3d 1122, 1150 (11th Cir. 2016). Yet the courts "would reject the assertion that the government's subsequent act of drafting another person in his place . . . transforms the act of lodging a conscientious objection into a substantial burden." *Id*; *see also Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 623 (7th Cir. 2015) (same).

Fourth, adopting defendants' RFRA interpretation would cause significant harm to third parties. *See* Douglas Nejaime & Reva B. Siegel, *Conscience Wars: Complicity-Based Conscience Claims in Religion and Politics*, 124 Yale L.J. 2516, 2526-28 (2015). As the government acknowledges, the Religious Exemption Rule will cause up to 126,400 women to lose their contraceptive coverage. 83 Fed. Reg. at 57,551. That is a heavy burden that falls on innocent third parties.[24] And as discussed in the next section, defendants' complicity-based religious claims are far removed from the traditional Free Exercise claims that led to the passage of RFRA. In traditional Free Exercise cases, the effects of the religious accommodation were

[24] The need to avoid third party harm has been widely recognized. *See, e.g.*, *Priests for Life v. U.S. Dep't of Health and Human Services*, 808 F.3d 1, 26 (2015) (Kavanaugh, J., dissenting from the denial of rehearing en banc) ("The Government may *of course* continue to require religious organizations' *insurers* to provide contraceptive coverage to the religious organizations' employees, even if the religious organizations object." (first emphasis added)).

limited and borne by the government or society as a whole. Discrete groups of citizens were not singled out to bear the costs of another's religious exercise. Yet that is the result expressly contemplated by the Exemption Rules. RFRA was never intended to inflict such harm on third parties. *See Woodford v. Garceau*, 538 U.S. 202, 209 (2003) (relying on the "legal backdrop" against which "Congress legislated" to clarify what Congress enacted).

As the statutory text, purpose, and case law demonstrates, whether the accommodation substantially burdens religious exercise is a question of law for this Court to decide.

2. In assessing this legal question, the Court should conclude that the accommodation—carefully designed by HHS to "accommodate" religious beliefs—does not substantially burden religious exercise because the accommodation allows religious objectors to opt out of providing, paying for, referring, contracting, or arranging contraceptive coverage. *See* 45 C.F.R. § 147.131(d)-(e). Once the insurer is notified by the employer or the Secretary, it "must *expressly exclude* contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide *separate* payments for any contraceptive services required to be covered . . . ." 45 C.F.R. § 147.131(d)(2)(i) (emphases added). And those separate payments "occur entirely

outside the employers' plans." *Zubik*, Resp. Supplemental Reply Br., 2016 WL 1593410, at *2.

Furthermore, the insurer "must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services." 45 C.F.R. § 147.131(d)(2)(ii). And the insurer must provide separate, written notice to plan participants and beneficiaries that their employer "will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [the insurer] will provide separate payments for contraceptive services that you use" and the employer "will not administer or fund these payments." *Id*. at (e).

Therefore, the accommodation process meticulously separates the employer's health plan from any involvement in the provision of contraceptive coverage. It is telling that eight out of the nine courts of appeals to have considered this issue concluded that the accommodation does not substantially burden the exercise of religion.[25] The Supreme Court itself has described the accommodation as

[25] *See Catholic Health Care Sys.*, 796 F.3d at 217-226; *Geneva Coll.*, 778 F.3d at 435-442; *E. Tex. Baptist Univ. v. Burwell*, 793 F.3d 449 (5th Cir. 2015); *Mich. Catholic Conference & Catholic Family Servs. v. Burwell*, 807 F.3d 738 (6th Cir. 2015); *Univ. of Notre Dame*, 786 F.3d at 612-619; *Grace Schs. v. Burwell*, 801 F.3d 788 (7th Cir. 2015); *Sharpe Holdings*, 801 F.3d at 941; *Little Sisters of the Poor Home for the Aged, Denver, Colo. v. Burwell*, 794 F.3d 1151 (10th Cir. 2015); *Eternal Word*, 818 F.3d at 1143-51; *Priests for Life*, 772 F.3d at 247-56.

"effectively exempt[ing] certain religious nonprofit organizations . . . from the contraceptive mandate." *Hobby Lobby*, 573 U.S. at 698.

As the Eleventh Circuit concluded, "we simply cannot say that RFRA affords the plaintiffs the right to prevent women from obtaining contraceptive coverage to which federal law entitles them based on the de minimus burden that the plaintiffs face in notifying the government that they have a religious objection." *Eternal Word*, 818 F.3d at 1150.

3. Contrary to defendants' claims, the accommodation does not "us[e] plans that [the employers] themselves sponsor" to provide contraceptive coverage. AOB 30-31; *see also* Sisters Br. 35. As recounted above, the accommodation excludes contraceptive coverage from the group coverage, segregates all premium revenue, and provides separate notice regarding the separate contraceptive coverage. *See* 45 C.F.R. § 147.131(d)-(e). As the federal government told the Supreme Court in *Zubik*, "[i]n all cases, the regulations mandate strict separation between the contraceptive coverage provided by an insurer or [third party administrator] TPA and other coverage provided on behalf of the employer." *Zubik* Resp. Br., 2016 WL 537623, at *18.

Defendants now contradict their prior representations. AOB 30-31 (citing 82 Fed. Reg. at 47,798, 47,800). But the pages of the rulemaking record cited by defendants merely state that "[m]any religious nonprofit organizations *argued* that

the accommodation impermissibly burdened their religious beliefs because it utilized the plans the organizations themselves sponsored to provide services to which they objected on religious grounds." 82 Fed. Reg. at 47,798. Defendants point to no evidence demonstrating that employers' own health plans "sponsor" the entirely separate contraceptive coverage, because none exists. And that result is plainly impermissible under the regulations in place. *See* 45 C.F.R. § 147.131(d)-(e).

Sisters assert that, under the accommodation, contraceptive coverage depends on objectors "contracting" with their insurer to provide that separate coverage through their "own plan infrastructure." Sisters Br. 34. But Sisters never explain what they mean by "plan infrastructure." And although they cite the federal government's brief in *Zubik* as allegedly conceding this point, that brief directly refutes it: "Nor does the government, in fact, provide contraceptive coverage using any 'plan infrastructure' belonging to petitioners." *Zubik*, Resp. Br., 2016 WL 537623, at *38.

It is true that in *Zubik*, the government explained that if an objecting employer has a self-insured plan subject to ERISA, "the Departments' authority to require the TPA to provide contraceptive coverage derives from ERISA." *Zubik*, Resp. Br., 2016 WL 537623, at *38. That means that the separate contraceptive coverage between the TPA and the employee—for purposes of ERISA only—is part of the

same ERISA plan as the coverage provided by the employer. *Id*. But that does not change the fact that even for those self-insured plans, the "rules governing contraceptive coverage are established by the government, not the employer, and the employer does not fund, control, or have any other involvement in that separate coverage—instead, the TPA alone does so." *Id*.

In other words, the ERISA status of the separate contraceptive coverage between the TPA and the employee does not affect the terms of the group health coverage that the employer and the insurer have contractually agreed upon—coverage that excludes contraceptives. *See, e.g., Priests for Life*, 772 F.3d at 255 (the fact that the government names the TPA as the plan administrator of the separate contraceptive coverage, for purposes of ERISA only, "does not . . . amend or alter Plaintiffs' own plan instruments . . ."). It is inaccurate to say that objecting employers "contract[]," Sisters Br. 34, with their insurer or TPA to provide contraceptive coverage.

In sum, the accommodation does not substantially burden the exercise of religion. There is no need to proceed any further under RFRA.

b. The Accommodation Is the Least Restrictive Means of Furthering the Compelling Government Interest in Providing Women with Equal Access to Preventive Care

1. If the Court reaches the second RFRA prong, it should conclude that women's seamless access to contraceptives is a compelling government interest.

As discussed above, the text, structure, purpose, and legislative history of the Women's Health Amendment demonstrate that Congress viewed women's full and equal access to preventive health care—including contraceptive services—as a compelling governmental interest. *See supra* at 25-36.

Until recently, the federal government expressly recognized the many important benefits of cost-free contraceptive coverage, including: (1) enabling women to avoid the health problems that may occur from unintended pregnancies; (2) avoiding the increased risk of adverse pregnancy outcomes when pregnancies are too closely spaced together; (3) preventing pregnancy when women have medical conditions which would make pregnancy dangerous or life threatening; and (4) securing health benefits from contraceptives that are unrelated to pregnancy, including preventing certain cancers, menstrual disorders, and pelvic pain. *Zubik*, Resp. Br., 2016 WL 537623, at *55-57. And contraceptive coverage without cost sharing is especially important because cost barriers discourage the use of contraceptives, particularly IUDs, which have high up-front costs but are especially reliable and effective. *Id*. at *57.

Defendants do not seriously dispute the extensive legislative history underlying the Women's Health Amendment, or the bevy of medical, scientific, and public health evidence regarding the importance of contraceptives. Instead, defendants point to immaterial and irrelevant factors to undermine the compelling

interest at stake. Defendants assert that contraceptive coverage is no longer a compelling interest because "before the contraceptive-coverage mandate, women had no entitlement to have their health plans provide contraceptive coverage without cost sharing." AOB 43. Therefore, the "women affected [by the new rules] are not 'burdened' in any meaningful sense, because they are no worse off than before the agencies chose to act in the first place." *Id*.

Under the logic of this argument, however, no law could serve a compelling governmental interest because a law's intended beneficiaries will always be "no worse off" than they were before the law was passed. Laws designed to end discrimination in housing, employment, and public accommodation, for example, could never serve a compelling governmental interest because a time existed when their intended beneficiaries did not enjoy the law's protections. There is no support for such a dubious legal proposition.[26]

[26] Defendants cite just one case in support of this argument, but it is plainly inapposite. *See* AOB 44-45 (citing *Corp. of the Presiding Bishop of Church of Latter-day Saints v. Amos*, 483 U.S. 327 (1987)). *Amos* was not a RFRA case, nor did it include any discussion of what constitutes a compelling governmental interest. In *Amos*, the Court considered whether the religious exemption in Title VII—which prohibits discrimination in employment based on religion—violated the Establishment Clause when applied to religious organizations engaged in secular activities. *Id*. at 330. The Court declined to find an Establishment Clause violation, but that result has no bearing on whether a compelling interest exists here.

Further, that argument suggests that guaranteeing contraceptive coverage was an act of administrative grace, rather than a Congressional directive that federal agencies are duty-bound to implement. The Supreme Court, however, has recognized that the contraceptive coverage requirement is an important—and likely compelling—interest. *See Hobby Lobby*, 573 U.S. at 737-39, 761; *see also Priests for Life*, 808 F.3d at 15 (Kavanaugh, J., dissenting from the denial of rehearing en banc) ("*Hobby Lobby* strongly suggests that the Government has a compelling interest in facilitating access to contraception for the employees of these religious organizations."). Justice Kennedy was the fifth vote in *Hobby Lobby*, and he noted that religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems *compelling*." *Hobby Lobby*, 573 U.S. at 738 (emphasis added); *see also Priests for Life*, 808 F.3d at 22-23 (Kavanaugh, J., dissenting from the denial of rehearing en banc) ("It is not difficult to comprehend" why facilitating access to contraceptive coverage is a "compelling interest").[27]

Sisters claim that the contraceptive coverage requirement cannot be a compelling governmental interest primarily because: (1) the ACA exempted small

[27] *See also id.* (further noting that "50% of all pregnancies in the United States are unintended" which "causes significant social and economic costs" and thus "numerous benefits would follow from reducing the number of unintended pregnancies . . . .").

businesses, grandfathered health plans, and churches; and (2) various state programs provide contraceptives. Sisters Br. 39-40. Neither of these rationales is persuasive.

First, that the ACA exempted some employers from providing contraceptive coverage does not undermine the compelling nature of the underlying interest. Grandfathered plans are a short-lived and transitional measure;[28] small employers need not provide health insurance at all but are required to provide contraceptive coverage if they choose to do so;[29] and exempting houses of worship acknowledges "our nation's longstanding history of deferring to a house of worship's decisions about its internal affairs." *Eternal Word*, 818 F.3d at 1155-1157. Every compelling governmental interest—including raising revenue through taxation, conscripting an army through a draft, and protecting citizens from discrimination in a wide range of areas—might be subject to exceptions under appropriate

[28] *See Hobby Lobby*, 573 U.S. at 764 (Ginsburg, J., dissenting) (Grandfathering these plans was a "temporary," transitional measure, "intended to be a means for gradually transitioning employers into mandatory coverage."); *see also 2018 Employer Health Benefits Survey*, Kaiser Family Found. (Oct. 3. 2018), https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-13-grandfathered-health-plans/ (showing decline in percentage of workers enrolled in a grandfathered plan from 36% in 2013 to 26% in 2014 and to 17% in 2017).

[29] Moreover, "[f]ederal statutes often include exemptions for small employers, and such provisions have never been held to undermine the interests served by these statutes." *Hobby Lobby*, 573 U.S. at 763 (Ginsburg, J., dissenting).

circumstances. *See, e.g.*, *United States v. Lee*, 455 U.S. 252, 261 (1982) (recognizing exemption to participating on the social security system for self-employed Amish, but not for employees of an Amish employer). Sisters point to no case law holding that the existence of an exception to a statutory requirement renders the underlying governmental interest uncompelling.

Second, the fact that *some* states provide contraceptives to low-income women does not diminish the federal government's interest in ensuring that female employees across the country receive preventive care at no cost, just like their male colleagues. *See* 77 Fed. Reg. at 8,728 (explaining that pre-ACA coverage created a "disparity" that "place[d] women in the workplace at a disadvantage compare to their male co-workers"). Indeed, the federal government previously estimated that the contraceptive mandate protects over 100 million employees and dependents. *Zubik*, Resp. Br., 2016 WL 537623, at *62. The final Rule itself estimates "that 55.6 million women aged 15 to 64 were covered by private insurance [that] had preventive services coverage under the Affordable Care Act." 83 Fed. Reg. at 57,578. State programs come nowhere close to replicating that, nor do they have the capacity to do so. *See generally* SER 159-162, 164, 166, 168, 170, 171-72, 173, 52, 75. And such programs exist only in certain states and are typically means-tested; they are not broadly available to all women. *See, e.g.*, SER 51, 85, 98, 103, 132. Nor is there any legal support for the notion that because states have

also taken steps to address a problem, the federal government's interest in solving the same problem is less compelling.

In light of the text, structure, purpose, and legislative history of the Women's Health Amendment, the contraceptive mandate furthers a compelling governmental interest. No appellate court has ruled to the contrary.

2. The accommodation is the least restrictive method of ensuring that women continue to receive their statutorily entitled benefits, while accommodating religion. Providing contraceptive services seamlessly with other health services—and without cost-sharing or additional logistical or administrative hurdles to receiving that coverage—is the most effective means of ensuring that women have full and complete access to contraceptives. *See, e.g.*, *Eternal Word*, 818 F.3d at 1158 ("Because there are no less restrictive means available that serve the government's interest equally well, we hold that the mandate and accommodation survive strict scrutiny under RFRA.").

In determining whether the accommodation is the least restrictive means of furthering a compelling interest, a primary consideration is whether other alternatives would impose harm on third parties. In *Hobby Lobby*, the Court instructed that "courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" which "will often inform the analysis of the Government's compelling interest and the availability of a less

restrictive means of advancing that interest." 573 U.S. at 729 n.37; *see also id.* at 739 (Kennedy, J., concurring) (religious exercise should not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling.").

Here, the Religious Exemption Rule requires tens of thousands of women (at a minimum) to bear the cost of their employers' religious views about contraceptives. That result sets this case apart from every other contraceptive mandate case that has come before the Supreme Court. The common thread in *Hobby Lobby*, *Wheaton College*, and *Zubik* was the Supreme Court's insistence that no woman would lose access to the full range of FDA-approved contraceptives—a result that is no longer the case under the Religious and Moral Exemption Rules. *See Hobby Lobby*, 573 U.S. at 693 ("under that accommodation, these women would still be entitled to all FDA-approved contraceptives without cost sharing"); *Wheaton College*, 134 S. Ct. at 2807 ("Nothing in this interim order affects the ability of the applicant's employees and students to obtain, without cost, the full range of FDA approved contraceptives"); *Zubik*, 136 S. Ct. at 1560-61 ("Nothing in this opinion . . . 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.'") (internal citation omitted).

The Court's emphatic and repeated insistence in these cases that women would not lose their statutory right to contraceptive coverage is no accident. The Court's concern about third party harm reflects the fact that in traditional Free Exercise cases, the effects of the religious accommodation were limited and borne by the government or society as a whole. That is, discrete groups of citizens were not singled out to bear the costs of another's religious exercise.[30] In particular, Congress enacted RFRA "in direct response" to the Supreme Court's decision in *Emp't Div. v. Smith*, 494 U.S. 872 (1990). *City of Boerne v. Flores*, 521 U.S. 507, 512-13 (1997). In *Smith*, the Supreme Court rejected a Free Exercise claim brought by members of the Native American Church who were denied unemployment benefits when they lost their jobs for using peyote (a banned substance) for sacramental purposes. *Id.* Critically, the religious accommodation sought in *Smith*—and in other seminal cases—would not have harmed third parties in order to accommodate religion.

This principle has held true in both Free Exercise and Establishment Clause cases. For example, in another Free Exercise case, the Court rejected religious claims that would "impose the employer's religious faith on the employees." *Lee*,

[30] *See* Nejaime & Siegel, *supra*, 124 Yale L.J. at 2526-28 (in the free exercise decisions that led to the passage of RFRA, "accommodating the religious liberty claims would not have harmed specifically identified third parties," citing *Sherbert v. Verner*, *Wisconsin v. Yoder*, and *Employment Division v. Smith*).

455 U.S. at 261 (refusing to exempt Amish employer and his employees from social security taxes). Conversely, courts have invoked the Establishment Clause to invalidate accommodations which "would require the imposition of significant burdens on other employees . . ." *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985) (invalidating Connecticut statute which gave Sabbath observers an absolute and unqualified right not to work on the Sabbath).

Thus, harm to third party employees is an important part of the RFRA analysis. *Hobby Lobby*, 573 U.S. at 729 n.37. The existing accommodation is the least restrictive means of ensuring that women continue to receive the benefits to which they are statutorily entitled benefits, especially when the alternative proposed—any employer with a religious or moral objection can self-exempt without informing anyone—would deprive those employers' female employees and their female dependents of contraceptive coverage.

The Sisters assert that the federal government could directly provide contraceptives for affected women, such as through the Title X program. Sisters Br. 40.[31] But that would not serve the government's interests equally well because eligible women: (1) would be required to take additional steps outside of their

[31] Neither defendants nor March for Life offer any suggestions for how the government could further the compelling interest in access to contraceptives in a less restrictive manner without denying women their statutory benefits.

normal coverage to access care, thereby undermining the "fundamental inequity" that the Women's Health Amendment sought to remedy (155 Cong. Rec. S12027 (Dec. 1, 2009) (statement of Sen. Gillibrand)); (2) are not guaranteed to receive contraceptives through Title X because Title X provides that "the project director *may* consider" a woman as eligible;[32] and (3) would not receive contraceptives within their normal health care framework and from their current doctors. The Title X program is also ill-equipped to replace the seamless contraceptive-coverage requirement.[33] SER 155-162, 67, 72, 254, 263. This purported remedy does not erase the threat inflicted by the Rules; it compounds the injury and expects the States to pick up the costs.[34]

3. For all of these reasons, the Religious Exemption Rule is not required by RFRA. Nor does RFRA independently authorize the Religious Exemption Rule. *See, e.g.*, AOB 32-33. Defendants cite no authority for the proposition that RFRA gives federal agencies sweeping authority to create broad exemptions to generally

[32] *See* 84 Fed. Reg. 7714 (Mar. 4, 2019).

[33] *See supra* at 14 & n.11.

[34] Funneling women to Title X will also cost the states more money because in some states Title X clinics screen every patient for state family-planning eligibility under state-based programs. *See, e.g.*, SER 53, 249, 273. These States' safety-net programs would see an increase in the number of consumers, resulting in economic harm to the States.

applicable statutory law.[35] Defendants rely on *Ricci v. DeStefano*, 557 U.S. 586 (2009), but that is not a RFRA case. In that case, the Court addressed how to resolve a conflict between Title VII's disparate treatment and disparate impact provisions. *Id*. at 584. That analysis was limited to those statutory provisions, and sheds no light on whether RFRA grants federal agencies license to create broad exemptions from otherwise applicable federal law.

Defendants' argument also overlooks that RFRA permits *individualized* exceptions to generally applicable laws—unlike the categorical Religious Exemption Rule. *See, e.g., Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430–31 (2006) ("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). This is also evident

[35] Sisters point to 42 U.S.C. § 2000bb-4, but that provision merely provides that exemptions that otherwise comply with the Establishment Clause "shall not constitute a violation of this chapter." That provision does not authorize federal agencies to affirmatively create categorical exemptions to other federal statutes based on their view of RFRA. Further, there are serious questions about whether the Religious and Moral Exemption Rules comply with the Establishment Clause. *See* ER 191-192 (States' Amended Complaint asserting an Establishment Clause claim); *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005) ("adequate account must be taken" of "the burdens a requested accommodation may impose on nonbeneficiaries"); *id*. at 722 ("an accommodation must be measured so that it does not override other significant interests").

from the remedy that RFRA provides: "A *person* whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." 42 U.S.C. § 2000bb-1(c) (emphasis added). There is no statutory basis for the notion that RFRA permits agencies to impose broad, categorical exemptions to federal statutes.

And even assuming, *arguendo*, that the Women's Health Amendment and RFRA are in conflict here (and they are not), defendants would be required to harmonize those two statutes so as not to run afoul of congressional intent. *Ass'n of Am. R.R. v. S. Coast Air Quality Mgmt. Dist.*, 622 F.3d 1094, 1097 (9th Cir. 2010) (when two federal laws purportedly conflict, courts must strive to harmonize and give effect to both laws). The Religious Exemption Rule, which disavows any obligation to ensure contraceptive coverage under the ACA while permitting nearly any employer to unilaterally disregard the contraceptive mandate, fails to do so.[36]

//

[36] Defendants also suggest that if agencies are not authorized by RFRA to create exemptions to laws of general applicability, then they lacked the authority to create the accommodation in the first place. AOB 35. But the legality of the accommodation is not being challenged in this lawsuit. And in any event, the accommodation is now required, at least for some employers, under the Supreme Court's rulings in *Hobby Lobby* and *Wheaton College*.

4. The Moral Exemption Rule Is Not Mandated by Any Legislation

On appeal, defendants do not provide any justification for the Moral Exemption Rule—an entirely new and unprecedented departure from the contraceptive mandate—beyond their novel interpretation of the Women's Health Amendment. Nor does March for Life point to a specific congressional enactment authorizing the agencies to promulgate the Moral Exemption Rule. Instead, March for Life broadly asserts that the moral rule is generally "*supported by* founding principles, congressional enactments, federal regulations, court precedents, and state laws and regulations." March Br. 44-61 (emphasis added). March for Life argues that these laws "highlight Congress's commitment to" conscience protections. March Br. 53. But, as the district court noted, these laws "highlight[ ] the problem; here, it was the agencies, not Congress, that implemented the Moral Exemption, and it is inconsistent with the language and purpose of the statute that it purports to interpret." ER 38.

In fact, March for Life highlights that "the ACA itself contains conscience protections" pertaining to euthanasia. March Br. 52 (citing 42 U.S.C. § 18113). But "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). Here, Congress did not include such an

exemption for the Women's Health Amendment.[37] On the contrary, as discussed above, Congress considered—and rejected—adding a conscience amendment to the Women's Health Amendment. *See supra* at 29-30.

5. The Religious and Moral Exemption Rules Are Invalid Because They Are Contrary to Other Provisions of the ACA

In addition to violating the Women's Health Amendment, the Exemption Rules are contrary to law because they violate other substantive provisions of the ACA. While the district court found it unnecessary to reach these other claims, this Court may uphold the preliminary injunction should it determine that there is a likelihood of success on any of these causes of action. *See Syed v. M-I, LLC*, 853 F.3d 492, 506 (9th Cir. 2017).

First, Section 1554 of the ACA forbids the HHS Secretary from promulgating "any regulation" that "creates any unreasonable barriers" to medical care *or* "impedes timely access to health care services." 42 U.S.C. § 18114(1), (2). By

[37] March for Life also asserts that the Moral Exemption Rule is required by the Fifth Amendment's Equal Protection principle. March Br. 61. That is not a basis upon which the rule was promulgated. *See generally* ER 252-291. As such, it cannot be a basis for sustaining the rule here. *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) (a court reviewing agency action will consider only the basis for that action proffered by the agency in the rule or order at issue at the time; agencies may not offer additional post hoc justifications during litigation). Furthermore, there is no support for this equal protection claim. It is clear that the government can treat religious objections differently from moral objections. *See,.e.g*, 42 U.S.C. § 2000bb-1(a)-(b) (RFRA).

forcing women to go outside their employer-sponsored healthcare provider to obtain contraceptives, the Rules create barriers and impede timely access to care. Women may need to pay out-of-pocket for such care, which will have a direct impact on healthcare. SER 148 ("[e]xtensive empirical evidence demonstrates what common sense would predict: eliminating costs leads to more effective and continuous use of contraception"). The Rules impede access to contraceptives, and that obstacle, "in turn, will increase those women's risk of unintended pregnancy and interfere with their ability to plan and space wanted pregnancies. These barriers could therefore have considerable negative health, social and economic impacts for those women and their families." SER 155, 71-72.

Second, Section 1557 of the ACA states that an "individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity" on the basis of sex. 42 U.S.C. § 18116(a); 20 U.S.C. § 1681(a); *see also Ferrer v. CareFirst, Inc.*, 265 F.Supp.3d 50, 52-54 (D.D.C. 2017) (denial of full coverage resulted in women having to pay hundreds of dollars out-of-pocket for lactation services). The Rules permit employers to exempt themselves from providing only one type of preventive services—contraceptives, which women (and only women) use. Women are forced into a Hobson's choice: accept incomplete health coverage unequal to that received by male colleagues or forgo employer-provided coverage

and purchase a comprehensive healthcare package out-of-pocket. *Cf.* SER 137. That unfair choice directly violates Section 1557 by discriminating against female employees (and employees' female dependents) in their ability to access federally-entitled coverage on the basis of sex. 45 C.F.R. § 92.1.

B. The District Court Properly Concluded that the States Satisfied the Remaining *Winter* Factors

1. The States Will Suffer Immediate and Irreparable Harm Absent a Preliminary Injunction

In addition to demonstrating a likelihood of success, the States satisfied the remaining *Winter* factors: they are "likely to suffer irreparable harm in the absence of preliminary relief," "the balance of equities tips in [their] favor," and "an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The district court did not clearly err in its factual findings regarding irreparable harm. ER 39-40; *McCormack v. Hiedeman*, 694 F.3d 1004, 1018 (9th Cir. 2012) ("district court's factual findings that underlie a preliminary injunction are reviewed for clear error, and may be reversed only if 'illogical, implausible, or without support in inferences that may be drawn from facts in the record'"); *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 573 (1985) ("appellate courts must constantly have in mind that their function is not to decide factual issues *de novo*"). To the contrary, the court correctly held that the States

would suffer irreparable harm in the absence of preliminary relief. *Winter*, 555 U.S. at 20.

Citing this Court, the court noted that if the Exemption Rules took effect, the States would face economic harm that "is not recoverable." ER 39 (citing *California*, 911 F.3d at 581). The court noted that the Exemption Rules themselves "estimate that tens of thousands of women nationwide will lose contraceptive coverage." ER 39. And the court found, in light of the "substantial evidence," that "fiscal harm" will flow to the States as a result of the Exemption Rules. ER 39-40. Every day that the Rules remain in effect employers can unilaterally eliminate contraceptive coverage for employees and their dependents, resulting in devastating consequences for the States—consequences that cannot be undone. *See, e.g.*, SER 296-297. Neither defendants nor the intervenors point to any specific factual error by the trial court. AOB 50-51.

2. By Preserving the Status Quo, the Preliminary Injunction Appropriately Balances the Equities and Serves the Public Interest

The balance of the equities and the public interest support issuing a preliminary injunction as well. *See Winter*, 555 U.S. at 2-264. The district court balanced two interests when weighing the equities: "the interest in ensuring that health plans cover contraceptive services with no cost-sharing, as provided for

under the ACA, and the interest in protecting 'the sincerely held religious [and moral] objections of certain entities and individuals.'" ER 40.

While the Rules inflict grave and lasting harm upon the States and their residents, enjoining the Rules has little impact on defendants. To date, defendants have not identified a single employer that would be harmed by enjoining the Rules. Indeed, they list numerous cases in which defendants have stipulated to permanent injunctions allowing objecting employers not to provide contraceptive coverage, including "open-ended" injunctions that allow additional employers to join. Sisters Br. 15. Furthermore, the accommodation is still available for religious employers and other eligible entities.

When weighing these interests, particular attention should be given to preserving the status quo. *Chalk v. U.S. Dist. Court Cent. Dist. Cal.*, 840 F.2d 701, 704 (9th Cir. 1988). Here, the status quo is the ACA's contraceptive-coverage requirement, as well as the carefully and deliberately crafted church exemption and broadly available accommodation. *Dep't of Parks & Recreation for State of Cal. v. Bazaar Del Mundo Inc.*, 448 F.3d 1118, 1124 (9th Cir. 2006) (status quo is "the last uncontested status that preceded the parties' controversy"). Preserving the status quo prevents irreparable harm to the States and their residents while accommodating employers with sincerely held religious opposition to contraceptives. The balance of the equities and the public interest accordingly tips

in the States' favor. *California*, 911 F.3d at 581 ("[t]he public interest is served by compliance with the APA").

Defendants' contrary arguments are unpersuasive. Defendants assert that the "institutional" harm suffered by defendants militates in favor of reversing the injunction. AOB 50-51. Such an argument is unsupported by authority, and would preclude nearly all injunctions against the federal government. Their assertion that the district court failed to account for the government's "interest in protecting religious freedom" is also inaccurate, as the district court in fact carefully considered this harm in its analysis. ER 40.

CONCLUSION

The Court should affirm the district court's preliminary injunction.

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The States are not aware of any related cases, as defined by Ninth Circuit Rule 28-2, that are currently pending in this Court and are not already consolidated here.

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