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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE STATE OF CALIFORNIA; THE STATE OF CONNECTICUT; THE STATE OF DELAWARE; THE DISTRICT OF COLUMBIA; THE STATE OF HAWAII; THE STATE OF ILLINOIS; THE STATE OF MARYLAND; THE STATE OF MINNESOTA, BY AND THROUGH ITS DEPARTMENT OF HUMAN SERVICES; THE STATE OF NEW YORK; THE STATE OF NORTH CAROLINA; THE STATE OF RHODE ISLAND; THE STATE OF VERMONT; THE COMMONWEALTH OF VIRGINIA; THE STATE OF WASHINGTON,

Plaintiffs,

THE STATE OF OREGON,

Plaintiff-Intervenor,

THE STATE OF COLORADO; THE STATE OF MICHIGAN; THE STATE OF NEVADA,

Proposed-Plaintiffs-Intervenors,

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; R. ALEXANDER ACOSTA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF LABOR; U.S.

4:17-cv-05783-HSG

STATES' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT, WITH MEMORANDUM OF POINTS AND AUTHORITIES

Date: September 5, 2019
Time: 2:00 p.m.
Dept: 2, 4th Floor
Judge: The Honorable Haywood S. Gilliam, Jr.

Action Filed: October 6, 2017

DEPARTMENT OF LABOR; STEVEN MNUCHIN, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF THE TREASURY; U.S. DEPARTMENT OF THE TREASURY; DOES 1-100,

Defendants,

and,

THE LITTLE SISTERS OF THE POOR, JEANNE JUGAN RESIDENCE; MARCH FOR LIFE EDUCATION AND DEFENSE FUND,

Defendant-Intervenors.

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on September 5, 2019, at 2:00 p.m., in Courtroom 2 of the above-entitled court, at 1301 Clay Street, Oakland, California, Plaintiffs the State of California, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Hawaii, the State of Illinois, the State of Maryland, the State of Minnesota, by and through its Department of Human Services, the State of New York, the State of North Carolina, the State of Oregon, the State of Rhode Island, the State of Vermont, the Commonwealth of Virginia, and the State of Washington (collectively, "the States") will and hereby do move this Court for summary judgment on each of the five causes of action set forth in the Second Amended Complaint. The States respectfully request that the Court enter judgment in their favor because the two interim final rules, 82 Fed. Reg. 47,792 (Oct. 13, 2017) and 82 Fed. Reg. 47,838 (Oct. 13, 2017), and the two final rules, 83 Fed. Reg. 57,536 (Nov. 15, 2018) and 83 Fed. Reg. 57,592 (Nov. 15, 2018), violate the Administrative Procedures Act, 5 U.S.C. § 553 and 5 U.S.C. § 706, and the United States Constitution's Establishment and Equal Protection Clauses. In the alternative, the States respectfully request that the Court enter judgment as to those causes of action that the Court sees as fit for resolution at this time.

This motion is based on this notice, the memorandum of points and authorities, the administrative record, this Court's file, and any matters properly before the Court.

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MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

Access to contraceptive care—and a woman's decision about whether and when to use it—is a fundamental precept of women's freedom and equality. The Patient Protection and Affordable Care Act (ACA), through the Women's Health Amendment and its implementing regulations, revolutionized women's access to preventive care by guaranteeing "no cost" coverage of all approved contraceptive methods and contraceptive counseling, empowering women to select the best contraception to meet their healthcare needs. Over 62 million women have benefited from this provision since 2012, saving up to $1.4 billion, with resulting societal benefits from greater female engagement in the workforce and economic self-sufficiency. The Women's Health Amendment ensures that women have full and equal healthcare coverage through their employer-sponsored plan. But the Exemption Rules promulgated by Defendants "transform contraceptive coverage from a legal entitlement to an essentially gratuitous benefit wholly subject to [an] employer's discretion." Dkt. No. 105 at 25-26. This Court should set aside the Exemption Rules and the interim final rules (IFRs) because they are contrary to law, are arbitrary and capricious, violate the Constitution, and were improperly promulgated.[1]

FACTUAL AND LEGAL BACKGROUND

I. PROVIDING CONTRACEPTIVE COVERAGE BENEFITS EVERYONE

The benefits of contraception to women—and ultimately society—are universal. Nearly two-thirds of the 72.2 million women aged 15-49 in the United States use contraceptives.[2] By the age of 40, American women have used an average of three or four different methods (many of which are available only by prescription), after considering their effectiveness, convenience, cost, accessibility, side effects, drug interactions and hormones, perceived risk of sexually transmitted

[1] Because this Court indicated that the effect of striking down the validity of the Final Rules would be to reinstate the prior legal regime, Dkt. No. 105 at 28, the States have included their challenges to the validity of the IFRs.

[2] *Current Contraceptive Status Among Women Aged 15-29*, Ctrs. for Disease Control and Prevention, NCHS Data Brief (Dec. 2018), https://www.cdc.gov/nchs/data/databriefs/db327-h.pdf; *see also* Ex. 57 (D10 00207386-87), Ex. 87 (D12 00804499).

infections, desire to control risk of pregnancy, and a host of other factors.[3] Ex. 57 (D10 00207390). As the American College of Obstetricians and Gynecologists explained, "the benefits of contraception . . . are widely recognized and include improved health and well-being, reduced global maternal mortality, health benefits of pregnancy spacing for maternal and child health, female engagement in the workforce, and economic self-sufficiency for women." Ex. 87 (D12 00804499); *see also* Exs. 1 (D1 0000665-80), Ex. 49 (D10 00207141-42), Ex. 28 (D10 00195106-08), Ex. 55 (D10 00207240-47).[4]

Since the ACA's contraceptive-coverage requirement took effect in 2012, more than 62 million women nationwide have benefited. Ex. 49 (D10 00207142), Ex. 49 (D10 00207145-46), Ex. 28 (D10 00195105), Ex. 64 (D10 00208988), Ex. 24 (D9 668958-59), Ex. 63 (D10 00208945). The cost reductions have been significant, with estimates ranging from $483 million to $1.4 billion in savings related to just one form of contraception (the pill) in one year alone.[5] Some studies have concluded that "[w]omen now save an average of 20% annually in out-of-pocket expenses, including $248 savings for IUDs and $255 for the contraceptive pill." Ex. 57 (D10 00207311) (citing N.V. Becker, et al., *Women Saw Large Decrease In Out-of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing*, Health Affairs (2015), http://content.healthaffairs.org/content/34/7/1204.abstract#aff-2.). The government itself acknowledges "that without coverage, many methods would cost women $50 per month, or upwards of $600 per year." Ex. 57 (D10 00207394); *see also* Ex. 16 (D9 570602) ("Between fall 2012 and spring 2014 [during which time the coverage guarantee went into wide effect], the

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[3] Because the Exemption Rules intentionally and explicitly target women's health benefits, this motion frequently uses female pronouns as well as the term "woman," in discussing the impact of the Rules. However, the States recognize that all persons who may become pregnant, including people who do not identify as women, need access to a full range of reproductive healthcare services, including access to contraception.

[4] *See also* Ex. 9 (D4 0000401) ("Pregnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)." (citing Exs. 12 (D4 000559-000573), 11 (D4 000544-000551), 10 (D4 000535-000543))).

[5] Initial estimates from HHS stated that women in 2013 saved $483.3 million due to the increase in oral contraceptive prescriptions dispensed with no co-pay. Ex. 17 (D9 571363). A later study, using a different methodology, estimated that privately insured women saved $1.4 billion in 2013 on the oral contraceptive alone. Ex. 86 (D12 00715489).

proportion of privately insured women paying zero dollars out of pocket for oral contraceptives increased substantially, from 15% to 67%. Similar changes occurred among privately insured women using injectable contraception, the vaginal ring and the intrauterine device."). The mandate has also enabled women to use contraception more consistently, thereby decreasing the likelihood of an unintended pregnancy. Ex. 57 (D10 00207389-91) (women who use contraception consistently are substantially less likely to have an unintended pregnancy), Ex. 57 (D10 00207393-97) (describing empirical evidence that eliminating costs leads to more effective and consistent use of contraception), Ex. 23 (D9 668358-64) (varying effectiveness of birth control).

Increased access to contraception has had a corresponding impact on society, including the States. Ex. 57 (D10 00207398-400). For instance, the "ACA's implementation correlates with a decrease" in enrollment in state-funded healthcare programs. Ex. 57 (D10 00207357). The Women's Health Amendment has also resulted in decreases in the number of unintended pregnancies, and costs associated with those pregnancies. Ex. 57 (D10 00207348), Ex. 3 (D1 0000695). And because unintended pregnancy is associated with poor birth outcomes and maternal health complications, the contraceptive-coverage requirement reduces the number of medically-complicated births and infants born in poor health.[6]

II. THE ACA REQUIRES COVERAGE OF WOMEN'S PREVENTIVE SERVICES, INCLUDING CONTRACEPTIVES

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

[6] Ex. 20 (D9 666689), Ex. 9 (D4 000401-02) (recommending family planning to avoid adverse pregnancy outcomes), Ex. 25 (D9 669089), Ex. 24 (D9 668955), Ex. 24 (D9 668957) (recommending that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes), Ex. 12 (D4 000559-573), Ex. 22 (D9 667730-667738), Ex. 6 (D1 0000776-777), Ex. 15 (D4 001609).

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 requires that "group health plan[s]" "shall" include women's "preventive care and screenings" and "shall not impose any cost sharing" on the consumer. 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). Before the ACA, "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) (describing "family planning services" as a "top priority," a "fundamental right of every adult American," and necessary for "women and families to make informed decisions about when and how they become parents," and stating "affordable family planning services must be accessible to all women in our reformed health care system"); *id.* at S12059 (statement of Sen. Cardin) ("General yearly well-women visits would be covered . . . [including] family planning services."); *id.* (statement of Sen. Feinstein) (same). After the Women's Health Amendment was adopted, Congress *twice* rejected legislation that would have permitted broad moral and religious exemptions to the ACA's coverage requirements. *See* 158 Cong. Rec. S538-39 (Feb. 9, 2012); 158 Cong. Rec. S1172-73 (Mar. 1, 2012); 159 Cong. Rec. S2268 (Mar. 22, 2013).

Congress delegated to the Health Resources and Services Administration (HRSA) the specific duty to prescribe the exact coverage. 42 U.S.C. § 300gg-13(a)(4). Specifically, the ACA provides that "with respect to women," health plans shall include "such additional preventive care and screening . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." *Id*.

Since the ACA's enactment, HRSA has carried out its statutory duty by convening panels of nationally recognized medical experts to make and update recommendations for the women's preventive care mandate. In its first response to this Congressional directive, HRSA

commissioned the nonpartisan Institute of Medicine (IOM) to assemble an expert committee to determine what should be included in "preventive care" coverage.[7] After rigorous, independent, and exhaustive review of the scientific evidence, including peer-reviewed medical research, the IOM issued its 2011 expert report, Clinical Prevention Services for Women: Closing the Gaps (2011), with a comprehensive set of evidence-based recommendations for implementing women's preventive healthcare services.[8] These recommendations addressed gaps in coverage for women, including an annual well-woman preventive care visit, counseling and screening for HIV and domestic violence, services for the early detection of reproductive cancers and sexually transmitted infections, and patient education and counseling for all women with reproductive capacity.[9] Significantly, the IOM recommended that private health insurance plans be required to cover all FDA-approved contraceptives without cost-sharing.[10]

Following the IOM's recommendations on coverage, HRSA issued 2011 guidelines that included a list of each type of preventive service, and the frequency with which it should be offered.[11] Defendants also promulgated regulations, consistent with HRSA's guidelines, requiring that employers offering group health insurance plans cover all FDA-approved contraceptive methods. 77 Fed. Reg. 8,725, 8,725-26 (Feb. 15, 2012).[12]

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[7] In 2015, the IOM changed its name to the National Academy of Medicine. Founded in 1970 as the Institute of Medicine, the National Academy of Medicine is one of three National Academies in the United States. *About the National Academy of Medicine*, National Academy of Medicine, https://nam.edu/about-the-nam/. According to their 1863 Congressional charter, the National Academies were created to "provide objective advice on matters of science, technology, and health." *Id.*; *see also* Ex. 9 (D4 000289).

[8] Inst. Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, 1-2 (2011), Ex. 9 (D4 0000286-534) [hereinafter "IOM Report"]; *id*. at Ex. 9 (D4 0000377-454).

[9] *See id*. at Ex. 9 (D4 0000407); *id*. at Ex. 9 (D4 0000377-454).

[10] *Id*. at Ex. 9 (D4 0000317, 400-408). Before the ACA, contraceptives accounted for between 30-44% of out-of-pocket healthcare spending for women. Ex. 57 (D10 00207398), Ex. 28 (D10 00195108).

[11] *Women's Preventive Services Guidelines*, Health Res. & Serv. Admin., https://www.hrsa.gov/womens-guidelines/index.html.

[12] 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);

In 2016, HRSA established a process for the ongoing review, development, and update of the medically-approved women's preventive care guidelines. Ex. 20 (D9 666688). Pursuant to an agreement with HRSA, the Women's Preventive Services Initiative was launched and led by the American College of Obstetricians and Gynecologists. *Id.* WPSI "convene[d] a coalition of clinician, academic, and consumer-focused health professionals," including the American Academy of Family Physicians, the American College of Physicians, the National Association of Nurse Practitioners in Women's Health, American Academy of Pediatrics, physician scientists from the Pacific Northwest Evidence-based Practice Center at Oregon Health & Science University, and federal partners such as the Centers for Disease Control and Prevention (CDC) and the Office on Women's Health. *Id.*; Ex. 25 (D9 669077-78). Following a rigorous methodology of reviewing medically-approved, high-quality evidence, WPSI issued a final report. Ex. 25 (D9 669080) (Final Report explaining, "[a] best evidence approach was applied when reviewing abstracts and selecting studies to include for the updates that involves using the most relevant studies with the strongest methodologies"). Like the IOM report, WPSI also recommended that all FDA-approved methods be included in "preventive care." Ex. 24 (D9 668955-668970) (Contraception Recommendations, Evidence Map, Evidence Summaries). Again, HRSA guidelines adopted that evidence-based recommendation. Ex. 20 (D9 666688). These guidelines remain the standard today.[13]

Both the IOM report and the WPSI report were the product of medical and public health experts reviewing and weighing scientific evidence and medical research. Based on their reviews, the reports reached a number of conclusions supporting broader access to contraception, including:

- Contraception has been found to be essential for women to avoid unwanted pregnancies and to space their pregnancies to promote optimal birth and maternal health outcomes. Exs. 9 (D4 000402-03), Ex. 24 (D9 668963). When women are able

80 Fed. Reg. 72,192, 72,216 (Nov. 18, 2015) (Grandfathered plans are designed to "ease the transition required by the market reforms").

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

to space and time their pregnancies, the risk of negative health outcomes for them and their children declines. *See* Ex. 9 (D4 000401) (recognizing that "[p]regnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy)"). Multiple studies showed that short interpregnancy intervals have been associated with low birth weight, prematurity, and small for gestational age births. Ex. 12 (D4 000559-73), Ex. 11 (D4 000544-51), Ex. 10 (D4 000535-43).

- Women who face unintended childbearing encounter a variety of health risks, including higher levels of depression and anxiety, and a decline in psychological well-being. Ex. 9 (D4 000401), Ex. 14 (D4 001279-001299), Ex. 24 (D9 668959-60).
- Pregnancy poses grave health risks for women with certain serious medical conditions, including but not limited to pulmonary hypertension, certain forms of heart disease, and Marfan Syndrome. Ex. 9 (D4 000401-402) (IOM citing various studies).
- Women with unintended pregnancies are more likely than those with planned pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, and to experience domestic violence during pregnancy. Ex. 9 (D4 000401), Ex. 24 (D9 668959-60).
- Prenatal and preconception visits optimize the chance of a healthy pregnancy through various health screenings and promoting practices that help prevent birth defects, but women with unintended pregnancies are less likely to pursue this care. Ex. 24 (D9 668959-60).
- There are significantly increased odds of preterm birth and low birth weight among unintended pregnancies ending in live births compared with pregnancies that were intended. Ex. 9 (D4 000401); Ex. 24 (D9 668959), Ex. 14 (D4 001279-001299).
- U.S. children born as the result of unintended pregnancies are less likely to be breastfed or are breastfed for a shorter duration than children born as the result of intended pregnancies. Ex. 9 (D4 000401), Ex. 14 (D4 001279-001299).

- Our nation's leading healthcare professional associations and other organizations recommend the use of family planning services, including contraception, as part of preventative care for women. These organizations include the American College of Obstetrics and Gynecology, the American Academy of Family Physicians, the American Academy of Pediatrics, the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, the Association of Women's Health, and Obstetric and Neonatal Nurses. Ex. 9 (D4 000402), Ex. 24 (D9 668963).
- The CDC has recommended family planning services as part of preventive visits for preconception health. Ex. 9 (D4 000430); Ex. 24 (D9 668960).
- Removing cost barriers for the "most effective contraceptive methods," particularly for "long-acting, reversible contraceptive methods" with "high up-front costs" is critical for women's preventive care. Ex. 9 (D4 000405-06), Ex. 2 (D1 0000685-94); *see also* Ex. 9 (D4 000316-318).
- WPSI recognized that the ACA had had a significant impact on reducing out-of-pocket expenses for FDA-approved contraceptive methods and vastly increased the number of women currently accessing birth control without copayments. Ex. 24 (D9 668958-59).

All together, in formulating the guidelines to implement the Women's Health Amendment, the expert panels found abundant evidence of the effectiveness of contraception, the importance of contraception for women's and children's health and wellbeing, and increased usage of contraceptives when cost barriers are eliminated. Therefore, both IOM and WPSI recommended that all FDA-approved contraceptive methods be included as "preventive services," a recommendation adopted by HRSA which still applies today.

III. THE FEDERAL GOVERNMENT SEEKS TO PROTECT WOMEN'S ACCESS TO EQUAL HEALTHCARE COVERAGE AND RELIGIOUS LIBERTY

From the outset, Defendants recognized that some employers would have religious objections to contraceptive coverage. To address those concerns, in 2011, Defendants exempted

houses of worship from the contraceptive mandate, with the understanding 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.[14] This "church exemption" imported a long-standing category of employers defined in the Internal Revenue Code. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 698 (2014) (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.

Two years later, the agencies implemented additional 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 affiliated non-profits. 78 Fed. Reg. at 39,876-77.

Under the accommodation—a process unnecessary for and inapplicable to houses of worship—a nonprofit employer certified its religious objection to the federal government or to the

[14] 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 8726.

insurer, and the insurer became responsible for providing separate contraceptive coverage for female employees. 45 C.F.R. § 147.131(c)(2). Upon notification, the government worked with the insurer to guarantee that women received coverage.[15] This process ensured a seamless, automatic mechanism for female employees and dependents to receive contraceptives to which they are statutorily entitled outside of their employer-sponsored health plan. 45 C.F.R. § 147.131(b).[16] In short, Defendants concluded that the accommodation process protected the rights of female employees to equal healthcare coverage while safeguarding religiously affiliated nonprofit employers' ability to opt out of providing or paying for this coverage. *See* 80 Fed. Reg. at 41,318; 45 C.F.R. § 147.131(c)-(d).

The religious accommodation was later expanded to include certain closely held for-profit organizations with religious objections to contraceptives, consistent with *Hobby Lobby*, 573 U.S. 682; 80 Fed. Reg. at 41,318; 45 C.F.R. § 147.131(c)(4). The Court stated that its opinion in that case "should not be understood to hold that an insurance-coverage mandate must necessarily fall if it conflicts with employer's religious beliefs." *Hobby Lobby*, 573 U.S. at 733.

In *Zubik v. Burwell*, nonprofit employers challenged the accommodation process itself, arguing that the act of opting out of providing contraceptive coverage violated the Religious Freedom Restoration Act of 1993 (RFRA) because it caused the provision of contraceptive coverage by the insurer or third party administrator (TPA). 136 S. Ct. 1557, 1559-60 (2016). 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.* ("The Court expresses no view on the merits of the cases."). Significantly, however, the Court declined to hold that the accommodation process violated the RFRA, and instead instructed that: "the parties on remand should be afforded an opportunity to arrive at an approach going forward that accommodates

[15] The health insurer covered the contraceptive benefits and services, and, in turn, could be reimbursed with a fee for providing such benefits and services from the federal government. 80 Fed. Reg. 41,318, 41,346 (July 14, 2015).

[16] *Ctr. for Consumer Info. & Ins. Oversight, Women's Preventive Services Coverage and Non-Profit Religious Organizations*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/womens-preven-02012013.html.

[religious organizations'] religious exercise while *at the same time ensuring that women covered by* [religious organizations'] *health plans receive full and equal health coverage, including contraceptive coverage.*" *Id.* at 1559-60 (emphasis added) (internal quotation marks and citation omitted). As this Court recognized, in *Zubik* Defendants represented to the Supreme Court that the government "has a compelling interest in ensuring access to" contraceptive coverage for women. Dkt. No. 105 at 1-2 (citation omitted).

In response to *Zubik*, Defendants published a Request for Information in the Federal Register on July 22, 2016, seeking input on whether and how the regulations could be changed to resolve the objections asserted by Plaintiffs in *Zubik*, while still ensuring that affected women receive full and equal health coverage. 81 Fed. Reg. 47,741 (July 22, 2016). Notably, the Request did not propose a "moral" exemption and did not propose expanding the religious exemption to all employers, insurers, and individuals. Upon review, the agencies concluded on January 9, 2017 that the accommodation complied with RFRA by protecting the interests of religious objectors, while also fulfilling the agencies' statutory duty to ensure women retained access to no-cost contraceptive coverage. Ex. 19 (D9 666661-62);[17] *see also* 82 Fed. Reg. at 47,798 n.17; 83 Fed. Reg. at 57,539. Specifically, the agencies found that "the accommodation is the least restrictive means of furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage." Ex. 19 (D9 666662).

IV. DEFENDANTS PROMULGATED IFRS THAT BROADLY EXPANDED EMPLOYERS' ABILITY TO DEPRIVE FEMALE EMPLOYEES OF EQUAL ACCESS TO HEALTHCARE

On October 6, 2017, Defendants promulgated sweeping new rules upending women's entitled contraceptive coverage in two interim final rules (IFRs), effective immediately, denying the public an opportunity to comment before these drastic changes went into effect. Dkt. Nos. 24-1 & 24-2. The "Religious Exemption IFR" vastly expanded the scope of the exemption to the

[17] *Also available at* U.S. Dep't Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4-5 (Jan. 09, 2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf.

contraceptive-coverage requirement, permitting any employer (regardless of corporate structure or religious affiliation), individual, or even a health insurer with religious objections to coverage of all or a subset of FDA-approved contraceptives, to exempt themselves. The "Moral Exemption IFR" provided that nearly any employer could stop covering contraceptive services for their employees if they have a "moral" objection. Like the Religious Exemption IFR, the Moral Exemption IFR extended to employers, insurers, and individuals, allowing those objectors to exempt themselves as well.

Under the IFRs, employers did not need to use the regulatory accommodation, which ensured that women received their statutorily guaranteed contraceptive coverage. The IFRs did not require that employers notify the federal government or even tell their affected employees. Rather, employers "objected" by simply exempting themselves from the statutory requirement, resulting in female employees losing their contraceptive coverage. The only way a woman would discover that her employer has exempted itself from providing contraceptives is by examining her annual notice of benefits and coverage or by receiving a surprise medical bill.

In determining the impact of the IFRs, Defendants expressly relied on state and local programs to fill in the gaps of coverage. 82 Fed. Reg. at 47,803 (noting that state and local programs "provide free or subsidized contraceptives for low-income women" and concluding that this "existing inter-governmental structure for obtaining contraceptives significantly diminishes" the impact of the expanded exemptions).

Since issuing the IFRs, Defendants have entered numerous stipulated judgments with objecting employers in pending litigation. *See* Dkt. Nos. 197 at 10 n. 4 (listing the stipulated injunctions); 197-1; Dkt. No. 234 at 30 (recognizing that "the Federal Defendants [have] simply reversed their position and stopped defending the accommodation, and [do] not seemingly disavow any obligation to ensure coverage under the ACA. As a result, the post-*Zubik* orders were entered without objection by the government, based on the agencies' new position that the accommodation violates RFRA.").

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V. THIS COURT ENJOINED THE IFRS AND THE NINTH CIRCUIT LARGELY AFFIRMED

On December 21, 2017, this Court enjoined implementation of the IFRs. This Court held that the States were likely to succeed on their claim that Defendants violated the Administrative Procedure Act (APA) by issuing the IFRs without advance notice and comment; that absent a preliminary injunction, the States would suffer irreparable substantive and procedural injuries; and that the equities and public interest tipped in the States' favor. Dkt. No. 105 at 17-28. This Court rejected Defendants' standing challenge because the States had demonstrated that they would incur economic harm, either to cover contraceptive services necessary to fill in the gaps left by the IFRs or for costs associated with unintended pregnancies. *Id*. at 12-16.

On December 13, 2018, the Ninth Circuit largely upheld this Court's decision. *California v. Azar*, 911 F.3d 558 (9th Cir. 2018). The Ninth Circuit held that the States have standing to sue because the declarations showed that the IFRs would "first lead to women losing employer-sponsored contraceptive coverage, which [would] then result in economic harm to the states." *Id*. at 571. The Court explained that "it is reasonably probable that women in the plaintiff states will lose some or all employer-sponsored contraceptive coverage due to the IFRs." *Id*. at 572. The Court noted that even the 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 highlighted Defendants' estimate of direct cost of filling the coverage loss as $18.5 or $63.8 million per year and Defendants' identification of state and local programs to fill that gap; thus, the Defendants' analysis "assumed that state and local governments will bear additional economic costs." *Id*. The Ninth Circuit also concluded that the States were likely to succeed on their APA notice-and-comment claim. *Id*. at 575-581.

VI. DEFENDANTS PROMULGATED THE FINAL EXEMPTION RULES

On November 15, 2018, Defendants promulgated the final Exemption Rules (Exemption Rules). 83 Fed. Reg. at 57,536; 83 Fed. Reg. at 57,592. These Rules are very similar to the IFRs, with two noteworthy differences. First, the regulatory impact analysis in the final Exemption Rules estimates 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 of their employer-sponsored coverage—and seek out 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, 57,551; 83 Fed. Reg. at 57,605, 57,608.[18] As the record demonstrates, the Title X program is ill-equipped to replicate or replace the seamless contraceptive-coverage requirement.[19] Ex. 57 (D10 00207405-08), Ex. 44 (D10 00207048-49), Ex. 44 (D10 00207048) ("[A] recent study published in the American Journal of Public Health confirms that reductions in funding for Title X limit the number of patients Title X-funded providers are able to serve, concluding that Congress would have to increase federal funding for Title X by over $450 million to adequately address the existing need for publicly funded family planning services."), Ex. 28 (D10 00195115-18), Ex. 30 (D10 00195141-42), Ex. 64 (D10 00208990-94), Ex. 60 (D10 00207662-66), Ex. 55 (D10 00207247-52), Ex. 57 (D10 00207405-06) ("With its current resources, Title X is only able to serve one-fifth of the nationwide need for publicly funded contraceptive care."), Ex. 82 (D12 00651932-33) (Congressional leaders noting current efforts to undermine and dismantle Title X), Ex. 57 (D10 00207347), Ex. 74 (D11 00373535-39).

VII. THIS COURT ENJOINED THE FINAL EXEMPTION RULES

On January 13, 2019, this Court issued a preliminary injunction enjoining implementation of the Exemption Rules. Dkt. No. 234. The Court held that the States had shown that they were likely to succeed in showing that the Exemption Rules violated the APA. *Id*. at 21-24. The Court rejected Defendants' assertion that the Women's Health Amendment "delegated total authority [to Defendants] to exempt anyone they wish from the contraceptive mandate." *Id*. at 22. The Court then concluded that the religious Exemption Rule is not required by RFRA, noting its agreement with the eight Courts of Appeals that have concluded that the "accommodation does

[18] Defendants have proposed drastic changes to the Title X program, making it even more unsuitable as a stop-gap for the Rules. *See* Second Am. Compl. ¶¶ 7, 54-55, 218-222; Ex. 44 (D10 00207044).

[19] The Title X program is subject to discretionary funding. Ex. 57 (D10 00207405). 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%. *Id*.

not impose a substantial burden on objectors' exercise of religion." *Id*. at 24-25. The Court further concluded that the States were 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. *Id*. at 37-38. The Court also concluded that the Moral Exemption Rule was likely contrary to the ACA (*id*. at 38-39), and that absent a preliminary injunction the States would suffer irreparable harm (*id*. at 39-40).

LEGAL STANDARD

A moving party is entitled to summary judgment if that party demonstrates the absence of a genuine issue as to any material fact and that he or she is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Section 706 of the APA governs judicial review of administrative decisions. Agency actions must be set aside where they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or are promulgated "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D). In contrast to the deferential standard applied to substantive agency decision-making, "review of an agency's procedural compliance with statutory norms is an exacting one." *NRDC v. SEC*, 606 F.2d 1031, 1048 (D.C. Cir. 1979). Moreover, in reviewing an agency's adherence to procedural requirements, courts have found it appropriate to "scrutinize the procedures employed by the agency all the more closely where the agency has acted, within a compressed time frame, to reverse itself by the procedure under challenge." *NRDC v. EPA*, 683 F.2d 752, 760 (3d Cir. 1982).

ISSUE PRESENTED

Do the Exemption Rules and the IFRs violate the APA and the Constitution?

ARGUMENT

I. THE EXEMPTION RULES ARE CONTRARY TO LAW

The Exemption Rules must be held "unlawful and set aside" because they are "not in accordance with the law" and are "in excess of statutory jurisdiction." 5 U.S.C. §§ 706(2)(A), 706(2)(C).[20] Here, Defendants' Rules are not in accordance with the implementing statute—the Women's Health Amendment. Nor is the Religious Exemption Rule compelled or authorized by

[20] Although this section refers to the Exemption Rules, the argument applies to the IFRs as well.

RFRA. The Rules are also contrary to Section 1554 and Section 1557 of the ACA because they create barriers for women to obtain healthcare coverage, impede timely access to healthcare, and permit employers to exclude women from full and equal participation in their employer-sponsored health plan.

A. The Exemption Rules 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 issue "guidelines" that would outline what "additional preventive care" "shall" be covered by regulated 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.

The Rules cannot be harmonized 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." *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 nearly any employer, university, plan sponsor, issuer, or individual 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 law).

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While Congress did not provide a fixed list of covered "preventive services," it directed HRSA to delineate the required preventive services. This was reasonable 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."[21] But Congress made the services defined by HRSA mandatory, by stating that they "shall" be provided.[22] *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 "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 which additional preventive care services must be provided. HRSA does not have the authority to decide that some employers are exempt from providing statutorily mandated preventive care. *See* 42 U.S.C. § 300gg-13(a)(4) (mandating that "a group health plan and a health insurance issuer offering group or individual health insurance coverage *shall*," provide defined preventive services).

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 WPSI's 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*,

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[21] *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.

[22] 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 provider'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.

476 U.S. 355, 374 (1986) ("an agency literally has no power to act . . . unless and until Congress confers power upon it"). Even if HRSA would have authority to remove contraceptives from the guidelines, it is very clear that it did not do that. *See* 83 Fed. Reg. at 57,537 ("The rules do not remove the contraceptive coverage requirement generally from HRSA's guidelines."). And HRSA clearly does *not* have authority to create exemptions for certain types of employers.

Additional statutory text within the ACA demonstrates that Defendants' interpretation is erroneous. For instance, Congress expressly considered which employers to exempt from the Women's Health Amendment (grandfathered plans), and it did not exempt employers with religious or moral objections. Further, in enacting the ACA, Congress created 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 35-36. 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 Exemption 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").[23] 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."); *Pacific Gas & Elec. Co. v. Energy Res. Conserveration & Dev. Comm'n*, 461 U.S. 190, 220 (1983) (it is "improper [] to give a reading to [an] Act that Congress considered and rejected"); *Doe v. Chao*, 540 U.S. 614, 622 (2004) (reversing grant of general damages because the "drafting history show[ed] that Congress cut out the very language in the bill that would have authorized" them).

Lastly, the Exemption Rules cannot be squared with Congress's purpose. Specifically, the ACA's requirement that certain 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 Amendment was designed to ensure 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.[24] The Exemption Rules disregard what the Women's Health Amendment sought to accomplish. *See Securities Indus. 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—contravene not only the intent of the Women's Health Amendment, but the ACA itself. *See Ragsdale v.*

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

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

Wolverine World Wide, Inc., 535 U.S. 81, 91-92, 95-96 (2002) (concluding that the challenged regulation is invalid as inconsistent with Congress's intent).

Defendants' interpretation of the Women's Health Amendment is not only contrary to the plain statutory text and Congressional purpose, but it 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, 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. But Congress clearly did not intend for HRSA to have unlimited authority to exempt any and all 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. *See Util. Air. Reg. Grp. v. EPA*, 573 U.S. 302, 327 (2014) (allowing an agency to act inconsistently with an "unambiguous statute" violates separation of powers).[25]

[25] Defendants are not owed any *Chevron* deference 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 products). "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 consistently held agency view." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987).

B. 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, 1069-70 (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 burden on the exercise of religion—itself substantially burdens the exercise of religion. *See, e.g.*, 83 Fed. Reg. at 57,546, 57538.[26] 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.[27] The Religious Exemption Rule, moreover, requires tens of thousands of women to bear the cost of their employers' religious views about contraceptives. That extensive harm to third parties 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 because employers with objections could use the accommodation, which ensures women receive crucial healthcare benefits. RFRA does not require female employees and their female dependents to

[26] Defendants do not claim that the Moral Exemption Rule is authorized by RFRA. Indeed, Ninth Circuit precedent forecloses any such argument. *See, e.g.*, *United States v. Christie*, 825 F.3d 1048, 1056 (9th Cir. 2016).

[27] 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).

forgo their statutorily guaranteed benefits for the sake of their employers' religious beliefs.

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

Defendants assert that the Religious Exemption Rule was legally mandated because requiring entities to comply with "the accommodation violate[s] RFRA." 83 Fed. Reg. at 57,546. Defendants claim that an employer's 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. *Id.*; *see also* 82 Fed. Reg. at 47,800. In other words, Defendants' complicity-based RFRA argument posits that: opting out of a generally-applicable requirement will cause the government to reach 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).

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* 83 Fed. Reg. at 57,546; *see also Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015). 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 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 misconstrue *Hobby Lobby* in arguing that the accommodation violates RFRA as a matter of law, 83 Fed. Reg. at 57,545, 57,546. 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 ("[T]he fact that a RFRA plaintiff *considers* a regulatory burden substantial does not make it a substantial burden. Were it otherwise, no burden would be insubstantial.")

The Court went on to explain 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 (emphasis

added). 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.[28]

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 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

[28] 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 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.[29] As discussed below, 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 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 demonstrate, whether the accommodation substantially burdens religious exercise is a question of law for this Court to decide.

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 it allows religious objectors to opt out of providing, paying for, referring, contracting, or arranging for 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.

[29] 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 Servs.*, 808 F.3d 1, 26 (D.C. Cir. 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)).

§ 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.[30] The Supreme Court itself has described the accommodation as "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 minimis burden that the plaintiffs face in notifying the government that they have a religious objection." *Eternal Word*, 818 F.3d at 1150.

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

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 healthcare—including contraceptive services—as a compelling governmental interest.

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

[30] *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.

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. The Supreme Court, too, has held that preventing gender discrimination qualified as a compelling government interest. *Roberts v. United States Jaycees*, 468 U.S. 609, 625 (1984) ("Assuring women equal access to such goods, privileges, and advantages clearly furthers compelling state interests.").[31]

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. 83 Fed. Reg. at 57,546-57,548. Essentially Defendants argue 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

[31] *See also Bd. of Dirs. of Rotary Int'l v. Rotary Club of Duarte*, 481 U.S. 537 (1987) (holding that the State was justified in enacting protections for persons, regardless of sex, to full and equal privileges in all business establishments because it had a compelling interest in preventing discrimination against women); *Presbytery of N.J. of the Orthodox Presbyterian Church v. Whitman*, 99 F.3d 101 (3d Cir. 1996) (holding that New Jersey had a compelling interest of preventing discrimination when it added sexual orientation to its list of protected classes); *Doe v. Boyertown Area Sch. Dist*., 897 F.3d 518 (3d Cir. 2018) (upholding a policy allowing students to use bathrooms consistent with their gender identity on the grounds that the state had a compelling interest in protecting transgender students from discrimination).

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 (Kennedy, J., concurring) (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").[32]

Defendants also claim that the contraceptive coverage requirement cannot be a compelling governmental interest primarily because: (1) the ACA exempted small businesses, grandfathered health plans, and churches; and (2) various state programs provide contraceptives. 83 Fed. Reg. 57,547, 57,548. 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;[33] small employers need not provide health insurance at all but are required to provide contraceptive coverage if they choose to do so;[34] 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 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).

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[32] *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 . . . .").

[33] *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); Ex. 13 (D4 000663).

[34] 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).

Second, the fact that *some* (a minority of) 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 compared 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* Ex. 58 (D10 00207600-05), Ex. 57 (D10 00207355-58), Ex. 57 (D10 00207374), Ex. 57 (D10 00207381-82), Ex. 57 (D10 00207410-18). And such programs exist only in certain states and are typically means-tested; they are not broadly available to all women. *See, e.g.*, Ex. 57 (D10 00207405-08). 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.

The accommodation is the least restrictive means 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.").

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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 because of the accommodation—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 v. Burwell*, 573 U.S. 958 (2014) ("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.[35]

[35] *See* Nejaime & Siegel, 124 Yale L.J. at 2526-28 (in the free exercise decisions that led to the

In particular, Congress enacted RFRA "in direct response" to the Supreme Court's decision in *Employment Division 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*, 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, 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 female dependents of contraceptive coverage.

To the extent that Defendants assert that the federal government could directly provide contraceptives for affected women, such as through the Title X program, such an argument must fail. Such a solution would not serve the government's interests equally well because eligible women: (1) would be required to take additional steps outside of their normal coverage to access care, thereby undermining the "fundamental inequity" that the Women's Health Amendment

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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*).

sought to remedy (155 Cong. Rec. S12027); (2) are not guaranteed to receive contraceptives through Title X because Title X provides that "the project director *may* consider" a woman as eligible;[36] and (3) would not receive contraceptives within their normal healthcare framework and from their current doctors. The Title X program is also ill-equipped to replace the seamless contraceptive-coverage requirement. Ex. 57 (D10 00207405-08), Ex. 58 (D10 00207607-10), Ex. 44 (D10 00207048-49), Ex. 75 (D11 00373565-69), Ex. 57 (D10 00207351), Ex. 27 (D10 00195098), Ex. 80 (D11 00454733-36), Ex. 55 (D10 00207247-51), Ex. 73 (D11 00373509), Ex. 74 (D11 00373535-36). 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.

For all of these reasons, the Religious Exemption Rule is not required by RFRA. Nor does RFRA independently authorize the Religious Exemption Rule. Defendants have cited no case for the proposition that RFRA gives federal agencies sweeping authority to create broad exemptions to generally applicable statutory law. That failure is remarkable given that RFRA—and its companion statute, the Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA)—have been the basis for hundreds of federal lawsuits over the past decades. Defendants' only case supporting this argument is *Ricci v. DeStefano*, 557 U.S. 557 (2009), but that is not even a RFRA case. There, 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 the language and structure of RFRA envisions *individualized* exceptions to generally applicable laws. And such exceptions are recognized by the courts on a case-by-case basis. *See* 42 U.S.C. § 2000bb-1(c) ("[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." (emphasis added). The legislative history underscores that one of the express "purposes" of RFRA was "to

[36] *See* 84 Fed. Reg. 7,714 (Mar. 4, 2019).

provide a claim or defense to persons whose religious exercise is substantially burdened by government." *See* Religious Freedom Restoration Act of 1993, PL 103–141, November 16, 1993, 107 Stat. 1488 (emphasis added).

Supreme Court precedent affirms this statutory framework. In *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 423 (2006), the Supreme Court upheld an injunction against prosecuting members of a religious sect that received communion by drinking a sacramental tea that included banned hallucinogens. The Court explained that "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." *Id*. at 430-31 (emphasis added). The Court further noted that "RFRA, however, plainly contemplates that *courts* would recognize exceptions—that is how the law works." *Id*. at 434. And the Court emphasized that "[w]e reaffirmed just last Term the feasibility of case-by-case consideration of religious exemptions to generally applicable rules." *Id*. at 436 (citing *Cutter v. Wilkinson*, 544 U.S. 709 (2005)); *see also Hobbs*, 135 S. Ct. at 859 ("We hold that the Department's policy, as applied *in this case*, violates [RLUIPA]." (emphasis added)). RFRA contemplates courts granting individual exemptions to federal statutes on a case-by-case basis. There is no statutory basis for the notion that RFRA permits agencies to impose broad, categorical exemptions to federal statutes that are not premised on a case-specific evaluation of the need for an exemption.[37]

Even setting aside the issue of whether federal agencies maintain the broad authority claimed by Defendants in this case, the question remains whether RFRA leaves space for governmental action that is "permissible under RFRA, even if it is not mandated by RFRA." Dkt No. 234 at 34. In raising this question, the Court noted that "there is room for play in the joints" between the Free Exercise and Establishment Clauses, such that there is "some space for

[37] The Little Sisters have also pointed to 42 U.S.C. § 2000bb-4, but that provision—titled "Establishment clause unaffected"—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 federal statutes based on their view of RFRA. Defendants have pointed to no authority so stating, and the Plaintiffs are aware of none.

legislative action neither compelled by the Free Exercise Clause nor prohibited by the Establishment Clause." *Id.* (citing *Cutter*, 544 U.S. at 719). As a preliminary matter, as discussed *infra*, the Religious Exemption Rule *does* violate the Establishment Clause. Moreover, whatever "play in the joints" might exist in other circumstances, such flexibility cannot exist where, as here, it deprives tens of thousands of women of their rights under a different federal statute (the Women's Health Amendment). In *Cutter*, a unanimous Court emphasized that "courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and that a religious accommodation "must be measured so that it does not override other significant interests." *Cutter*, 544 U.S. at 720, 722. That principle is especially true where, as here, third parties would be deprived of their statutorily-guaranteed rights. RFRA neither requires nor permits the exceptionally broad Religious Exemption Rule.

To the extent that Defendants are arguing that RFRA and the Women's Health Amendment are fundamentally incompatible, such that the former displaces the latter, that contention lacks merit. The Ninth Circuit recently emphasized that "[w]e will not easily conclude that one federal statute preempts another. A party seeking to suggest that two statutes cannot be harmonized, and that one displaces the other, bears the heavy burden of showing a clearly expressed congressional intention that such a result should follow." *BNSF Railway Co. v. Cal. Dep't of Tax and Fee Admin.*, 904 F.3d 755, 761 (9th Cir. 2018) (internal citations omitted). To the extent that an apparent conflict exists between two federal statutes, "the courts must strive to harmonize the two laws, giving effect to both laws if possible." *Id.* (citing *Ass'n of Am. R.R. v. S. Coast Air Quality Mgmt. Dist.*, 622 F.3d 1094, 1097 (9th Cir. 2010)). 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, categorically fails to harmonize these two congressional directives. It simply prioritizes one federal statute at the expense of another, which it cannot lawfully do. *Id.*

For all of these reasons, the Religious Exemption Rule is neither compelled nor authorized by RFRA.

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C. The Moral Exemption Rule is Not Mandated by Any Legislation

Defendants do not point to a specific congressional enactment authorizing the agencies to promulgate the Moral Exemption Rule. Instead, Defendants broadly assert that the Moral Rule is generally supported by "founding principles," various congressional enactments, federal regulations, court precedents, and other state laws and regulations. *See generally* 83 Fed. Reg. 57,599-57,601. Defendants argue that these laws highlight "Congress's history of providing" conscience protections. 83 Fed. Reg. 57,596. But, as this 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." Dkt No. 234 at 38-39.

In fact, Defendants highlight that the ACA itself contains conscience protections pertaining to euthanasia. 83 Fed. Reg. 57,618 (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. On the contrary, as discussed above, Congress considered—and rejected—adding a conscience amendment to the Women's Health Amendment. *See supra* at 18-19.

D. The Exemption Rules Create Barriers for Women to Obtain Healthcare Coverage and Impede Timely Access to Healthcare, Thereby Violating the ACA

Congress was clear in its directive to HHS: The Secretary "shall not promulgate *any* regulation that—(1) creates *any* unreasonable barrier to the ability of an individual to obtain appropriate medical care [or] (2) impedes *timely access* to health care services." 42 U.S.C. § 18114(1), (2) (emphasis added). These Exemption Rules, at a minimum, will result in women *losing* full and equal healthcare coverage, which necessarily will create additional barriers for women seeking healthcare. Without complete coverage, women will need to pay out-of-pocket for their basic healthcare services, unless they secure funding from other sources. Ex. 57 (D10 00207394) (without coverage, contraceptives cost $50 per month or upwards of $600 per year);

id. (cost of IUD exceeds $1000, which equates to a month's salary for a woman working full time at the federal minimum wage of $7.25 an hour); *see also* Ex. 57 (D10 00207310-11) (describing cost barriers to various highly effective methods of contraception). Women who lose contraceptive coverage may also need to locate and secure a separate qualified medical provider, which may require transferring medical records or re-providing a complete medical history to a new provider to ensure proper care. Ex. 57 (D10 00207368-69), Ex. 57 (D10 207401-02) (explaining the importance of seamless holistic coverage to ensure that women's "chosen provider" can "manage all health conditions and needs at the same time"). Women may also need to switch to a less expensive, but less effective, contraceptive method given the requirement to pay out-of-pocket. Ex. 57 (D10 00207393-94) ("[e]xtensive empirical evidence demonstrates what common sense would predict: eliminating costs leads to more effective and continuous use of contraception"); Ex. 57 (D10 00207395), Ex. 57 (D10 00207311-12). By impeding access to contraceptives, these obstacles, "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." Ex. 57 (D10 00207401), Ex. 57 (D10 00207402-04) (describing health, economic and social harms to women facing unintended pregnancies). These consequences demonstrate that the Rules undeniably create barriers obstructing women's access to care; this disruption in continuity of care results in delayed or no access to contraception. *See California v. Azar*, 2019 WL 1877392, at *24 (N.D. Cal. Apr. 26, 2019) (concluding that HHS likely violated Section 1554 where Title X regulations "obfuscate and obstruct patients from receiving information and treatment for their pressing medical needs").

E. The Exemption Rules Violate the ACA's Nondiscrimination Provision

The Exemption Rules must be held unlawful and set aside because they permit employers to exclude women from full and equal participation in their employer-sponsored health plan, deny women full and equal healthcare benefits, and license employers to discriminate on the basis of sex. 42 U.S.C. § 18116. 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* Commission Decision on Coverage of Contraception, U.S. Equal Employment Opportunity Commission, 2000 WL 33407187 (Dec. 14, 2000) (concluding that offering coverage for preventive prescription drugs and services but not contraception constitutes discrimination on the basis of sex).

The Exemption Rules permit employers to exempt themselves from providing only one type of preventive service—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. That unfair choice directly violates Section 1557 by subjecting female employees (and employees' female dependents) to discrimination on the basis of sex with respect to access to federally-entitled coverage. 45 C.F.R. § 92.1.

II. THE EXEMPTION RULES ARE INVALID BECAUSE THEY ARE ARBITRARY AND CAPRICIOUS

A rule is arbitrary and capricious if the agency has (1) "entirely failed to consider an important aspect of the problem," (2) "offered an explanation for its decision that runs counter to the evidence before the agency," (3) "relied on factors which Congress has not intended it to consider," or (4) "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("*State Farm*"). In reviewing Defendants' actions, this Court must engage in "a thorough, probing, in-depth review." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977). And where an agency departs from a prior policy, it must "display awareness that it is changing position," show that "there are good reasons" for the reversal, and demonstrate that its new policy is "permissible under the statute." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also State Farm*, 463 U.S. at 42 (an agency rescinding a rule must supply a

reasoned analysis for the change). Here, Defendants' Exemption Rules fail for the aforementioned reasons.[38]

A. Defendants Failed to Provide a Reasoned Explanation for their Policy Reversal

Since 2012 Defendants have required coverage of women's preventive services provided for in the HRSA guidelines, including all FDA-approved contraceptives. 77 Fed. Reg. at 8,725. The prior regulatory scheme, including the 2016 exemption and accommodation process, involved several years of reasoned process, including consideration of the IOM's 2011 expert committee report, WPSI's 2016 Final Report, public comment, and two Supreme Court decisions. Indeed, the IOM's committee and WPSI included expert researchers, practitioners, and other leaders in preventive and women's medicine, used a rigorous methodology, examining high-quality systematic evidence, peer-reviewed studies, federal priorities, and existing professional guidelines, and state, federal, and international practices to "systematically query support for each potential preventive measure."[39] Most recently, after considering over 54,000 responses to a request for information, Defendants concluded on January 9, 2017, that the accommodation complied with RFRA by protecting the interests of religious objectors, while also fulfilling the agencies' statutory duty to ensure women retained access to no-cost contraceptive coverage.[40] Defendants' Exemption Rules constitute a complete change in position and Defendants have failed to adequately explain this reversal.

1. Because of the Serious Reliance Interests at Stake, Defendants Must Meet a Higher Standard

Where, as here, "serious reliance interests [are] at stake," Defendants' "conclusory

[38] Although this section generally refers to the Exemption Rules, the arguments apply to the IFRs as well.

[39] Ex. 9 (D4 000289-293) (IOM committee members and reviewers), Ex. 9 (D4 000312) (structure for updating preventive services), Ex. 9 (D4 000374) (four categories of evidence "to systematically query support for each potential preventive measure"), Ex. 25 (D9 669077-78) (WPSI structure and participating organizations), Ex. 25 (D9 669080) (best evidence approach), Ex. 24 (D9 668955-668970) (recommendations, evidence map, and study summaries).

[40] Ex. 19 (D9 666661-62) (also available at www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf), Ex. 19 (D9 666650-51).

statements do not suffice to explain its decision." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016). As this Court previously concluded, given the "serious reliance interests" of women who would lose coverage to which they are statutorily entitled if the Final Rules go into effect, a reasoned explanation for disregarding facts and circumstances that underlay or were engendered by the prior policy is required. Dkt. No. 234 at 37. Indeed, since 2012, millions of women across the country have relied on the ACA's contraceptive-coverage requirement. Ex. 57 (D10 00207404), Ex. 49 (D10 00207145-46), Ex. 30 (D10 00195139-41) (noting that women of color made up the majority of those who gained contraceptive coverage and thus will be the population most affected by efforts to curtail those gains), Ex. 76 (D11 00396709-711), Ex. 47 (D10 00207116-17), Ex. 68 (D10 00209104-06), Ex. 29 (D10 00195127), Ex. 37 (D10 00206955-56), Ex. 55 (D10 00207238), Ex. 54 (D10 00207234). HHS itself estimated that 30 million women gained access to contraceptive coverage due to the Women's Health Amendment. Ex. 17 (D9 571363); *see also* 83 Fed. Reg. at 57,551 (estimating that up to 126,400 women stand to lose contraceptive coverage due to the Religious Exemption Rule). As HHS's own statements demonstrate, women nationwide rely on the Women's Health Amendment for full and equal healthcare coverage. Because Defendants' policy reversal implicates these "serious reliance interests," it must be justified by a more "reasoned explanation." *Encino Motorcars*, 136 S. Ct. at 2125-26; *see also Fox*, 556 U.S. at 535-36 (Kennedy, J., concurring). And when agencies seek to disregard facts underlying the original rule, they must provide "a more detailed justification than what would suffice for new policy created on a blank slate." *Fox*, 556 U.S. at 515; *Encino Motorcars*, 136 S. Ct. at 2126. For the reasons explained below, Defendants have failed to meet that test.

2. The Evidence Before the Agency Is Clear that Contraception is Safe and Effective

Defendants' Exemption Rules fail to provide the requisite reasoned explanation, particularly given the lack of any material change in the underlying factual and legal circumstances that supported their prior position. *Encino Motorcars*, 136 S. Ct. at 2126 ("a reasoned explanation is needed for disregarding facts and circumstances that underlay or were

engendered by the prior policy," or the "unexplained inconsistency" will be held arbitrary and capricious); *State v. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (concluding that agency violated the APA when it failed to provide a reasoned explanation for its decision to suspend a rule based on the rule's costs, while ignoring its benefits).

Defendants primarily explain that their changed policy is due in part to "more uncertainty" regarding the efficacy and health benefits of contraceptives. 83 Fed. Reg. at 57,552-55. But the rulemaking record does not conclude that the health benefits of contraceptives are scientifically less certain. *Id*. Rather, 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. Nevertheless, they used the purported "uncertainty surrounding these weighty and important issues" to justify the new, expanded exemptions. *Id.*

But this explanation runs counter to Defendants' own statements and evidence. As a threshold matter, HRSA guidelines continue to require coverage of the full range of FDA-approved contraceptive methods. And HHS continues to inform women that birth control is generally safe, depending on the type of birth control used and a woman's individual health, and directs women to talk to their doctor about the right method.[41] And absent "[n]ew facts or evidence coming to light, considerations that [the agency] left out in its previous analysis, or some other concrete basis supported in the record," Defendants cannot just "'casually ignor[e]' all of [the] previous findings and arbitrarily chang[e] course." *State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1068 (N.D. Cal. 2018); *see also U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d. at 1123 (new administrations are entitled to change policy positions, but they must give reasoned explanations for those changes and address the prior factual findings).

Moreover, Defendants' explanation runs counter to the evidence before the agencies in this rulemaking. Our country's leading medical organizations filed comment letters explaining that the assertions in the IFRs regarding purported "uncertainty" were inaccurate. *See infra* at 46-48 (listing the comment letters); *see also, e.g.*, Ex. 71 (D11 00328171-72) (letter from ACOG

[41] Ex. 23 (D9 668365-66); *see also Birth Control Methods*, Office of Women's Health, HHS, available at https://www.womenshealth.gov/a-z-topics/birth-control-methods.

describing statements within the IFRs as "false and misleading"). The overwhelming evidence before the agency, consistent with the conclusions rendered by the IOM and the WPSI—and adopted by HRSA and HHS—demonstrate that there is no "uncertainty" about contraceptives. *See California*, 2019 WL 1877392, at *36 (finding arbitrary and capricious Title X regulations based on "confusion" manufactured by HHS that was contrary to an industry-accepted understanding). Given this, Defendants' Exemption Rules fail to provide the requisite reasoned explanation, particularly given the lack of any material change in the underlying factual and legal circumstances that supported their prior position. *Encino Motorcars*, 136 S. Ct. at 2126.

And Defendants do not explain why any purported "uncertainty" regarding health risks cannot be adequately addressed through a woman's consultation with her personal physician, a fact that several commenters noted. Ex. 40 (D10 00206988-91) (American Academy of Nursing objecting to the IFRs interference with the patient-provider relationship). An agency must consider significant alternatives to the course it ultimately chooses. *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000); *Yakima Valley Cabelvision, Inc. v. F.C.C.*, 794 F.2d 737, 746 n.36 (D.C. Cir. 1986) ("The failure of an agency to consider obvious alternatives has led uniformly to reversal") (citing cases); *Farmers Union Cent. Exch., Inc. v. F.E.R.C.*, 734 F.2d 1486, 1511 (D.C. Cir. 1984) ("It is well established that an agency has a duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives."). Defendants' refusal to consider this alternative is inconsistent with HHS's position elsewhere that women seeking access to contraception can manage health risks by consulting and following the guidance of their personal physician. Ex. 23 (D9 668365-66); *see also Birth Control Methods*, Office of Women's Health, HHS, available at https://www.womenshealth.gov/a-z-topics/birth-control-methods.

3. Defendants Disregarded Extensive Record Evidence to Wrongly Claim that the Contraceptive Mandate Has Not Yielded Benefits

Defendants attempt to justify the Exemption Rules by asserting that the contraceptive coverage requirement is not increasing contraceptive use or reducing unintended pregnancy. 83 Fed. Reg. at 57,555. But the evidence overwhelmingly contradicts this justification. As a

preliminary matter, expert panels involved in the IOM and WPSI reviews that underlie the HRSA guidelines recognized the importance of cost reductions in improving access to contraception, and increasing consistent, correct usage of contraception. Ex. 9 (D4 000405-07); Ex. 24 (D9 668960-65). Indeed, in prior litigation, Defendants also took the position that the coverage mandates will decrease costs for women, which will improve access and use of contraceptives. *See Hobby Lobby*, 573 U.S. at 727 ("HHS tells us that 'studies have demonstrated that even moderate copayments for preventive services can deter patients from receiving those services.'").

A multitude of established medical groups vigorously disputed Defendants' new claim that the contraceptive mandate is ineffective, but yet again Defendants declined to respond. *See infra* at 46-48. Defendants instead relied on a handful of limited studies. But, as commenters pointed out, these studies are incomplete and inaccurate because they analyze population-wide data to discern a statistically significant uptick in contraceptive usage, though the contraceptive requirement only impacted a subset of the population overall. Ex. 57 (D10 00207399-400), Ex. 56 (D10 00207259). Furthermore, as one expert explained, multiple variables affect women's contraceptive use in various ways, and this complicates the development of empirical evidence to prove the mandate's precise impact. *Id.*

Indeed, the record evidence includes multiple studies, including some cited by Defendants, that show the positive impact of the Women's Health Amendment. Ex. 57 (D10 00207398-400). For example, the Guttmacher Institute informed HHS that "[e]xtensive evidence demonstrates what comment sense would predict: eliminating costs leads to more effective and continuous use of contraception. This is because cost can be a substantial barrier." Ex. 57 (D10 00207393). The Institute further explained that the ACA's "contraceptive coverage guarantee has had a positive impact." Ex. 57 (D10 00207398). Prior to the ACA, contraceptives accounted for between 30-44% of out-of-pocket healthcare spending for women. *Id.* In a nationally representative survey of women aged 18-39, two-thirds of those who had health insurance and were using a hormonal contraceptive method reported having no copays; among those women, 80% agreed that paying nothing out of pocket increased their use of birth control, 71% agreed this helped them use their birth control consistently, and 60% agreed that having no copayment helped them choose a better

method. *Id.* Other studies showed increased usage of the most effective and expensive forms of contraception (long acting reversible contraception) among women aged 20-24 (the age group at highest risk for unintended pregnancy). Ex. 57 (D10 00207399). Defendants did not address this evidence submitted in the public record and did not establish that the factual underpinnings for the contraceptive requirement had changed.

4. Defendants Failed to Reasonably Account for the Costs of the Rules

Despite numerous commenters highlighting the impact and associated costs of the Exemption Rules (*infra* at 46-48), Defendants boldly proclaim that they have not calculated the "related costs [women] may incur for contraceptive coverage or the results associated with any unintended pregnancies." 83 Fed. Reg. at 57,574, 57,626. Failure to account for the actual costs of the Exemption Rules renders them arbitrary and capricious. *California*, 2019 WL 1877392, at *32-34; *Michigan*, 135 S. Ct. at 2707 ("[R]easonable regulation ordinary requires paying attention to the advantages and the disadvantages of agency decisions"); *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (agency cannot "brush[] aside critical facts"). This is particularly problematic here, where the Exemption Rules allow employers to exempt themselves from the mandate without any type of notification, thereby guaranteeing that neither the agencies nor the public will ever know the extent of the Rules' impact.

Defendants also fail to account for the costs to the States. While Defendants provide that the Exemption Rules will result in "transfer costs," amounting to $68.9 million (Religious Exemption Rule) and $8,760 (Moral Exemption Rule), Defendants fail to explicitly detail who will bear such costs. 83 Fed. Reg. at 57,538; 83 Fed. Reg. 57,593. The Rules fail to acknowledge both the populations most likely to be harmed by the Rules (*see infra* at 49-51) and the impact on the states' public fiscs. Ex. 57 (D10 00207358), Ex. 57 (D10 00207348-49), Ex. 57 (D10 00207409), Ex. 57 (D10 00207374).

5. Defendants Overlooked Congress's Intent that HRSA Assess the Efficacy and Safety of Preventive Care Measures

Through the ACA and the Women's Health Amendment, Congress mandated that an expert entity, HRSA, set guidelines for specific services that advance preventive care. 42 U.S.C.

§ 300gg-13(a). Congress identified HRSA as the arbiter of safe and efficacious women's preventive care for purposes of the ACA's coverage mandate. Since 2011, HRSA has fulfilled its duty by convening panels of nationally recognized experts to make and update recommendations for women's preventive care. In the IOM report and WPSI recommendations, our nation's preeminent medical experts guided the systematic and methodical reviews of medical and public health evidence that resulted in the HRSA guidelines. Defendants diverged from Congress's stated intent in promulgating their Exemption Rules by independently, albeit vaguely, concluding that some uncertainties with respect to the efficacy and safety of contraceptives exist. But as Congress explicitly stated, HRSA, the expert agency, is charged with promulgating guidelines that define "preventive services." The Exemption Rules jettison this required statutory process. Because Defendants relied on factors and a process that Congress did not intend it to consider, the new exemptions are arbitrary and capricious. *State Farm*, 463 U.S. at 43; *cf. Southwest Ctr. For Biological Diversity v. United States Forest Service*, 100 F.3d 1443, 1449 (9th Cir. 1996) (where agency "had no obligation to consider the views of other agencies" in issuing regulation, no APA violation).

B. Defendants' Justifications Are Implausible Because the Exemption Rules Are Not Tailored to Address the Purported "Problems" the Rules Identify

The Exemption Rules are not plausibly tied to the existing record because the purported problems Defendants have identified are not mitigated by the expanded exemptions. If the safety of contraceptives were broadly in question, as Defendants contend, the exemptions would not enhance protection for the entire population of women facing the alleged health risks. Instead, the Rules are limited to women who happen to be employed by organizations or insured by companies that would assert religious or moral objections to the contraceptive requirement.

Similarly, Defendants further justify the Exemption Rules by citing concerns (though no evidence) that access to contraceptive coverage may increase the prevalence of teen pregnancy. 83 Fed. Reg. at 57,554. Yet the new Exemption Rules do not relate to the age of the plan beneficiary. *See Del. Dep't of Nat. Res. & Envtl. Control v. EPA*, 785 F.3d 1, 17-18 (D.C. Cir. 2015) (setting aside a regulation because it was not tailored to address the identified problems).

Defendants also claim that the Exemption Rules are necessary because the contraception coverage requirement was not narrowly tailored to the populations of women most at-risk for unintended pregnancies, specifically women who are aged 18 to 24 years, unmarried, have a low income, are not high school graduates, and are members of racial or ethnic minorities. 83 Fed. Reg. at 57,547. As a threshold matter, Defendants' narrow view of who is entitled to contraceptive coverage runs counter to Congress's intent that health plans generally "shall" provide women's preventive care without cost-sharing. Congress did not limit this statutory benefit to a certain category of women. Defendants' position also runs counter to the ample record evidence of high rates of unintended pregnancies, regardless of age or population subgroup, and the risk of unintended pregnancy for sexually active couples that do not use a contraceptive method. *See e.g.*, Ex. 57 (D10 00207386) ("A typical woman in the United States wishing to have only two children will, on average, spend three decades—roughly 90% of her adult life—avoiding unintended pregnancy"); Ex. 1 (D1 0000666) (Sexually active couples forgoing any contraceptive method face an approximately 85% chance of pregnancy in a one-year period). And even taking Defendants' claim at face value, the Exemption Rules are still arbitrary and capricious because they are not narrowly tailored to any subgroups with particularly high risks.

The serious lack of alignment between the purported "problems" Defendants cited as a basis for the Exemption Rules and the scope of the new policy they seek to implement demonstrates that the Rules are arbitrary and capricious. *State Farm*, 463 U.S. at 43 (A rule is arbitrary and capricious if it "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."); *Bureau of Land Mgmt.*, 286 F. Supp. 3d at 1066-67 (finding that even if the agency had provided factual evidence to support its claim that the new regulations burdened small operators, a "blanket suspension" of the regulation was arbitrary and capricious because the suspension was "not properly tailored" to address the allegedly errant provision).

Indeed, the Rules are "a solution in search of a problem." *California*, 2019 WL 1877392, at *36 (citing *Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 837 (D.C. Cir. 2006)); *Arizona Cattle Growers Ass'n v. U.S. Fish & Wildlife*, 273 .3d 1229, 1244 (9th Cir. 2001);

Sorenson Commc'ns Inc. v. FCC, 755 F.3d 702, 708 (D.C. Cir. 2014). The broad scope of the Exemption Rules is not supported by the record. For example, Defendants concede that they are not aware of any publicly traded entities that have religious objections to providing contraceptive coverage, but they nevertheless expand the exemption to include such entities. 83 Fed. Reg. at 57,562. Similarly, Defendants cite only three employers to justify the entirety of the Moral Exemption Rule. 83 Fed. Reg. at 57,626 & n.74. And, Defendants have stipulated to injunctions barring them from enforcing contraceptive-coverage requirement against several employers, including "open-ended" injunctions that allow additional employers to join. *See* Dkt. Nos. 197 at 10 n. 4 (listing the stipulated injunctions); 197-1; Dkt. No. 234 at 30.

C. Defendants Failed to Meaningfully Respond to Comments Concerning the Rules' Impacts

In promulgating the Exemption Rules, Defendants ignored several key issues regarding contraceptive coverage. A rule is arbitrary and capricious if the agency "failed to consider an important aspect of the problem[.]" *State Farm*, 463 U.S. at 43. "For an agency's decisionmaking to be rational, it must respond to significant points raised during the public comment period." *Allied Local & Reg'l Mfrs. Caucus*, 215 F.3d at 80. And while Defendants need not address every comment, Defendants must address "significant" comments or those "which, if true, raise points relevant to the agency's decision." *City of Portland, v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007). Defendants failed to meet this standard.

1. Defendants Failed to Respond to Comments from Medical Associations Describing the Medical Consensus About Contraceptives' Efficacy

Defendants failed to respond to vital public comments submitted by medical professionals. Significantly, Defendants failed to respond to the letter submitted the American College of Obstetrics and Gynecologists (ACOG), joined by the American Academy of Pediatrics and the Society for Adolescent Health and Medicine, challenging the IFRs' inaccurate assessment of the potential health risks purportedly associated with contraception, including venous thrombosis (blood clots), cancer, and depression. 82 Fed. Reg. at 47,804; Ex. 46 (D10 00207106), Ex. 71 (D11 00328171-72) ("As with any medication, certain types of contraception may be

contraindicated for patients with certain medical conditions . . . . [P]atients and physicians, . . . , should determine the right contraceptive for a patients' health care needs."). The comment notes that the IFRs include several false and misleading statements, and "greatly exaggerate[] the harms of contraception." *Id*. at 00328171-72. Defendants failed to directly address the specific concerns that these organizations raised. 83 Fed. Reg. at 57,555.

This public comment is especially vital to this rulemaking process because these professional organizations are official partners in HHS's Women's Preventive Services Initiative process, and ACOG is a central stakeholder. Ex. 25 (D9 669078). The WPSI is responsible for reviewing and updating women's preventive care guidelines. The Departments, through the HRSA, launched the WPSI, and awarded ACOG a multi-year cooperative agreement to coordinate the guideline effort. Ex. 25 (D9 669074). Defendants failed to address ACOG and its partners' objections or to explain Defendants' inconsistent positions with respect to the health risks associated with contraception. Failure to respond to a public comment is grounds for setting aside the rule if "the points raised in the comments were sufficiently central that agency silence would demonstrate the rulemaking to be arbitrary and capricious." *N.M. Health Connections v. U.S. Dep't of Health & Human Servs.*, 312 F. Supp. 3d 1164, 1216 (D.N.M 2018) (citing *Natural Res. Def. Council, Inc. v. EPA*, 859 F.2d 156, 188 (D.C. Cir. 1988)).

Consistent with the ACOG comment letter, many other medical associations warned Defendants that the IFRs were predicated on an inaccurate assessment of the science and medicine concerning contraception, whereas the guidelines were developed based on the best clinical and scientific evidence. Objecting medical associations included the American Public Health Association (D10 00206908-909), Physicians for Reproductive Health (D10 00195097-98), the American Academy of Nursing (D10 00206990-91 & Ex. 80 (D11 0454730)), and the American College of Physicians (D10 00207148-49). *See also* Ex. 83 (D12 00697151) (Asian & Pacific Islander American Health Forum), Ex. 86 (D12 00715496-97) (Women's Health and Family Planning Association of Texas), Ex. 79 (D11 00435049) (National Center for Health Research), A.R. D11 00427847-50 (California Planned Parenthood Education Fund and Planned Parenthood Affiliates of California), Ex. 31 (D10 00206845-851) (National Health Law

Program), Ex. 36 (D10 00206916) (Guttmacher Institute), Ex. 74 (D11 00373535-36) (County of Santa Clara), Ex. 28 (D10 00195113-15) & Ex. 53 (D10 00207185-87) (National Partnership for Women & Families), Ex. 60 (D10 00207671-73) (National Latina Institute for Reproductive Health), Ex. 64 (D10 00208995-96) (National Family Planning & Reproductive Health Association), Ex. 33 (D10 00206889-91) (Lift Louisiana), Ex. 34 (D10 00206899-901) (National Network of Abortion Funds), 00206998-00207000 (Power to Decide), Ex. 39 (D10 00206981-83) (Wisconsin Alliance for Women's Health), Ex. 43 (D10 00207037-38) (NARAL Pro-Choice America), Ex. 62 (D10 00207745-47) (Reproductive Rights and Justice Practicum at Yale Law School), Ex. 66 (D10 00209051-53) (Yale Students for Reproductive Justice), Ex. 48 (D10 00207134-36) (Ibis Reproductive Health), Ex. 76 (D11 00396711-13) (Colorado Consumer Health Initiative). And according to one member of the IOM committee convened by HHS, the new rules are "not based upon sound scientific or empirical evidence." Ex. 58 (D10 00207496-502). Defendants' failure to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made," renders the result "arbitrary and capricious." *State Farm*, 463 U.S. at 43; *see also Humane Soc. of U.S. v. Locke*, 626 F.3d 1040, 1049 (9th Cir. 2010).

2. Defendants Failed to Respond to Comments Outlining the Negative Financial and Health Impacts of Unintended Pregnancy

A significant cross-section of stakeholders commented that the expanded exemptions would undercut access to contraception and create significant burdens associated with unintended pregnancies, including negative financial and health impacts of unintended pregnancies on women and their families—impacts which Defendants previously recognized as significant. Ex. 79 (D11 00435049), A.R. D11 00427850, Ex. 42 (D10 00207019), Ex. 31 (D10 206845-46), A.R. D11 00435091, Ex. 28 (D10 00195106), Ex. 58 (D10 00207498), Ex. 30 (D10 00195137-40), Ex. 64 (D10 00208989), Ex. 60 (D10 00207659-61), Ex. 55 (D10 00207242), Ex. 57 (D10 00207310-11), Ex. 57 (D10 00207320-21), Ex. 57 (D10 00207328-29), Ex. 57 (D10 00207334-35), Ex. 57 (D10 00207402-03), Ex. 85 (D12 00715480), Ex. 61 (D10 00207709), Ex. 72 (D11 00328183); *see, e.g.*, 77 Fed. Reg. at 8,727 ("[s]tudies show a greater risk of preterm birth and low birth

weight among unintended pregnancies compared with pregnancies that were planned"). Additionally, several commenters discussed the importance of contraception, noting it:

- "enables women to be equal participants in the social, political, and economic life of the nation," Ex. 51 (D10 00207159-61); Ex. 45 (D10 10 00207072-76) (IFRs harm women's health, equality, and economic security); Ex. 77 (D11 00396717-19) (IFRs undermine women's human rights); Ex. 38 (D10 00206967-73) (noting that even women of faith reported that considerations such as their health or the health of their children took precedence over their religion's view of contraception), Ex. 68 (D10 00209103-06) (no-cost contraception coverage is vital to women of all faith);
- is important to women's professional and educational opportunities, Ex. 62 (D10 00207737-40), Ex. 67 (D10 00209066-67) (discussing adverse impacts of unintended pregnancies on women, children, and society);
- is vital for women in rural areas, Ex. 29 (D10 00195127);
- is important for women of color, Ex. 29 (D10 00195127); Ex. 65 (D10 00209032-36) (IFRs will have a disparate impact on women of color); and
- is crucial for the LGBT community, Ex. 32 (D10 00206861-65), Ex. 37 (D10 00206954-56) (discussing impact on LGBT community), Ex. 52 (D10 00207178-79) (IFRs will increase health disparities faced by LGBT community), Ex. 61 (D10 00207707-10) (IFRs strip women and LGBT community of coverage guaranteed by federal law).

Defendants wholesale bundled these concerns before summarily dismissing them:

> Other commenters . . . assert[ed] that the expanded exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more unintended pregnancies, births spaced more closely, and workplace, economic, or societal inequality.

83 Fed. Reg. at 57,548; *see also* 83 Fed. Reg. at 57,606. Defendants then concluded that the exemptions do not impermissibly burden third parties because they incorrectly assumed that the

ACA does not require contraceptive care without cost sharing,[42] and thus "if some third parties do not receive contraception coverage from private parties who the government chose not to coerce, that result exists in the absence of government action." *Id*. at 57549; 83 Fed. Reg. at 57,606. Defendants' willingness to dismiss summarily the central grounds for promulgating the prior rules is the opposite of a "reasoned explanation." *Encino Motorcars*, 136 S. Ct. at 2126. Defendants' failure to meaningfully acknowledge, engage, and to respond to these significant issues raised by numerous commenters further renders the Rules arbitrary and capricious. *Del. Dep't of Nat. Res. & Envtl. Control*, 785 F.3d at 15; *see also Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt*., 698 F.3d 1101, 1125 (9th Cir. 2012). In fact, in issuing a preliminary injunction, Judge Chen recently concluded that Defendants' failure to adequately consider the patient and public health costs of unintended pregnancies renders a rule arbitrary and capricious. *See California*, 2019 WL 1877392, at *29-32.

3. Defendants Failed to Respond to Comments Concerning the Exemption Rules' Impact on Patients Experiencing Domestic Violence

Numerous commenters discussed the benefits of contraceptive use and its impact on domestic violence. For instance, the Black Women's Health Imperative commented that decreased access to contraceptives leads to an increase in unintended pregnancies and women facing an unintended pregnancy are more likely to experience domestic violence during pregnancy. Ex. 69 (D10 00209110), Ex. 78 (D11 00396759-60); *see also* Ex. 28 (D10 00195106), Ex. 58 (D10 00207498), Ex. 57 (D10 00207320). A domestic violence survivor and counselor stated:

> I worked in a domestic violence shelter and was myself receiving services from an organization that supported survivors. Time and time again, I had to provide emotional support to women who had been forced or coerced by their partners into having unwanted sex. I was also a victim of such sexual exploitation. When sex is used to get a woman pregnant in order to inhibit her ability to leave an abusive partner (it happens far more often than we'd like to believe), birth control is one way that a woman can take back some control over her life.

[42] Contrary to this assumption, this Court noted that it "knows of no Supreme Court, court of appeal or district court decision that did not presume that the ACA requires specified categories of health insurance plans and issuers to provide contraceptive coverage at no cost to women." Dkt. No. 234 at 37.

Ex. 70 (D10 00262440); *see also* 77 Fed. Reg. at 8,728 & n.12 (Defendants previously recognizing that contraception improves the social and economic status of women, including affording them greater freedom to make marriage decisions); Ex. 9 (D4 000401 (IOM Report) (women facing an unintended pregnancy "are more likely than those with intended pregnancies to receive late or no prenatal care, to smoke and consume alcohol during pregnancy, to suffer from perinatal mood disorders, and to experience domestic violence during the pregnancy")); Ex. 24 (D9 668960). Yet discussion of domestic violence appears nowhere in the Exemption Rules. Defendants' failure to consider this important aspect of the issue renders the Exemption Rules arbitrary and capricious. *State Farm*, 463 U.S. at 43; *Del. Dep't of Nat. Res. & Envtl. Control*, 785 F.3d at 15.

III. THE EXEMPTION RULES AND THE IFRS VIOLATE THE ESTABLISHMENT CLAUSE[43]

The Religious Exemption Rule and the Religious IFR violate the Establishment Clause because, in the name of religious accommodation, it strips third parties—employees, students, and dependents—of health insurance to which they are entitled by law, imposing substantial costs and burdens on them. Government conduct may not have a primary effect, which advances a particular religious practice. *Catholic League for Religious & Civil Rights v. City & Cty. of S.F.*, 624 F.3d 1043, 1054-55 (9th Cir. 2010) (en banc) (citing *Lemon v. Kurtzman*, 403 U.S. 602, 612-13 (1971)).[44] Conduct unlawfully advances religion by favoring religion at the expense of the rights, beliefs, and health of others. *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334-35 (1987) ("At some point, accommodation may devolve into 'an unlawful fostering of religion.'").

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[43] Because the States' APA claims demonstrate that this Court should set aside the Exemption Rules, this Court need not even reach the Constitutional claims. *See In re Ozenne*, 841 F.3d 810, 814 (9th Cir. 2016) ("as a fundamental rule of judicial restraint, [the court] must consider nonconstitutional grounds for decision before reaching any constitutional questions" (internal quotation marks and citations omitted)).

[44] The Supreme Court has "repeatedly emphasized [its] unwillingness to be confined to any single test or criterion in this sensitive area," but generally applies the *Lemon* test to evaluate Establishment Clause violations. *Kreisner v. City of San Diego*, 1 F.3d 775, 780 (9th Cir. 1993) (citing *Lynch v. Donnelly*, 465 U.S. 668, 669 (1984)).

The Supreme Court has consistently held that government conduct that shifts the burden for religious exercise to third parties is a violation of the Establishment Clause. In *Caldor*, 472 U.S. at 709, the Court held that a Connecticut statute guaranteeing employees the right not to work on a chosen Sabbath Day violated the Establishment Clause because "the statute takes no account of the convenience or interests of the employer or those of other employees who do not observe a Sabbath." Further, the statute did not provide any exceptions to the "right not to work" on a chosen Sabbath, causing the employer "substantial economic burdens" and the "imposition of significant burdens on other employees required to work in place of the Sabbath observers." *Id.* at 709. Similarly, in *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 (1989) (plurality op.), the Court held that a tax-exemption for religious periodicals violated the Establishment Clause because it "burden[ed] nonbeneficiaries by increasing their tax bills by whatever amount was needed to offset the benefit bestowed on subscribers to religious publications." *Id.* at 18 n.8. The Court explained that religious exemptions from general laws are permissible when they do not "impose substantial burdens on non-beneficiaries while allowing others to act according to their religious beliefs." *Id.*

Further, in considering whether an exemption from a generally applicable rule sought under RLUIPA violates the Establishment Clause, the Court has recognized that it "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries."[45] *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005). In *Cutter*, three prisoners complained that prison officials failed to grant exemptions for their religious practices, in violation of RLUIPA.[46] The prisoners

[45] *See* Elizabeth Sepper, *Religious Exemptions, Harm to Others, and the Indeterminacy of A Common Law Baseline*, 106 Ky. L.J. 661, 662 (2018) ("[T]he Supreme Court has regularly rejected exemptions that would transfer the burdens of religious compliance from objectors to other third parties."); Micah Schwartzman et. al., *The Costs of Conscience*, 106 Ky. L.J. 781, 791 (2018); Frederick Mark Gedicks & Rebecca G. Van Tassell, *RFRA Exemptions from the Contraception Mandate: An Unconstitutional Accommodation of Religion*, 49 Harv. C.R.-C.L. L. Rev. 343, 361 (2014).

[46] RFRA and RLUIPA have virtually identical language and fulfill the same purpose. *Compare* 42 U.S.C. § 2000bb-1 *with* 42 U.S.C. § 2000cc-1. RLUIPA applies "the same standard as set forth in RFRA." *Holt*, 135 S. Ct. at 860 (citations omitted), and RLUIPA's legislative history indicates that it is to be interpreted by reference to RFRA and First Amendment jurisprudence. *See* 146 Cong. Rec. S7774, S7776 (July 27, 2000) ("The term 'substantial burden' as used in this Act is not intended to be given any broader interpretation than the Supreme Court's articulation of

argued that they were denied access to religious materials, denying them opportunities for group worship, and forbidding them to adhere to the dress mandates of their religion. *Id*. In that case, the religious exemption did not violate the Establishment Clause because "it d[id] not override other significant interests," like the safety of other prisoners and prison staff. *Id*. at 722; *see also Hobby Lobby*, 573 U.S. at 730 n.37 (citing *Cutter* approvingly in holding that "[i]t is certainly true that in applying RFRA 'courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.'" (*Cutter*, 544 U.S. at 720)).[47]

Here, the Religious Exemption Rule and the Religious IFR violate the Establishment Clause because, if implemented, it will significantly burden female employees and female covered dependents. As a result of the Rule, employers can exempt themselves from the contraceptive mandate, thereby ensuring that their female employees and female dependents will not receive their statutorily guaranteed full and equal benefits.[48] Instead, under these Exemption Rules, female employees and female covered dependents must obtain contraceptive coverage outside their employer-sponsored health plan at their own expense or the state's expense *or* forgo contraceptives altogether, with little to no warning.

Further, as in *Caldor*, there are no exceptions under the Religious Exemption Rule or the Religious IFR for circumstances like the health of the female employees and female dependents. 472 U.S. at 709. Some women use contraceptives if they have a health condition for which "pregnancy is contraindicated," such as congenital heart disease. *Hobby Lobby*, 573 U.S. at 743 (Kennedy, J., concurring). Hormonal contraceptives also provide long-term benefits against certain cancers like endometrial and ovarian cancer. Ex. 1 (D1 0000670), Ex. 9 (D4 00405), Ex.

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the concept of substantial burden on religious exercise").

[47] "Nothing in [RFRA] shall be construed to affect, interpret, or in any way address that portion of the First Amendment prohibiting laws respecting the establishment of religion (referred to in this section as the 'Establishment Clause')." 42 U.S.C. § 2000bb-4; *see also Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290, 302 (2000) ("The principle that government may accommodate the free exercise of religion does not supersede the fundamental limitations imposed by the Establishment Clause.").

[48] In contrast, in *Hobby Lobby*, the Supreme Court held that there was no "detrimental third party effect" because the government still ensured that women received contraceptive coverage through the exemption and accommodation process. *Hobby Lobby*, 573 U.S. at 730 n. 37. This is no longer the case under the Religious Exemption Rule.

22 (D9 667792), Ex. 57 (D10 207319-20). But the Religious Exemption Rule fails to consider any such circumstances or interests. *See Caldor*, 472 U.S. at 709 (Religious concerns may not "automatically control over all secular interests at the workplace."). And, as discussed above, the suggestion that affected women can still obtain contraceptive coverage through Title X is illusory. *See infra* at 31-32.

Therefore, the Religious Exemption Rule and the Religious IFR violate the Establishment Clause because they place a significant burden on female employees and female dependents.

IV. THE EXEMPTION RULES AND THE IFRS VIOLATE THE EQUAL PROTECTION CLAUSE

The Equal Protection component of the Fifth Amendment prohibits the federal government from denying equal protection of the laws. Although the ACA requires coverage for many different types of preventive services, the Exemption Rules and the IFRs single out women's healthcare—specifically, the Rules target contraceptive coverage. In so doing, these Rules create an explicit and constitutionally impermissible gender-based classification. *See Caban v. Mohammed*, 441 U.S. 380 (1979); *Int'l Union v. Johnson Controls*, 499 U.S. 187 (1991); *Arce v. Douglas*, 793 F.3d 968, 977 (9th Cir. 2015). The Rules do not create generally applicable religious or moral exemptions; they explicitly target contraceptive coverage, essential for women's reproductive health—and a necessary component of equality between men and women because it allows women to control their health, education and livelihoods. *See Hobby Lobby*, 573 U.S. at 737 (Kennedy, J., concurring); *Johnson Controls*, 499 U.S. at 211 ("It is no more appropriate for the courts than it is for individual employers to decide whether a woman's reproductive role is more important to herself and her family than her economic role").

Because the Exemption Rules and the IFRs create a gender-based classification by singling out women's healthcare coverage, Defendants must demonstrate an "exceedingly persuasive justification" for the IFRs and the Exemption Rules. *United States v. Virginia*, 518 U.S. 515, 531 (1996); *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982). The Supreme Court has "repeatedly recognized that neither federal nor state government acts compatibly with the equal protection principle when a law . . . denies to women, simply because they are women, full citizenship stature-equal opportunity to aspire, achieve, participate in and contribute to society

based on individual talents and capacities." *Virginia*, 518 U.S. at 532 (court must "carefully inspect[] official act that closes a door or denies opportunity to women"). In such instances, the government must meet a "demanding" standard of review. *Id*. at 533. The government must show "at least that the [challenged] classification serves important government objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.'" *Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1690 (2017); *see also Nevada Dep't of Human Res. v. Hibbs*, 538 U.S. 721, 728-29 (2003) ("heightened scrutiny" analysis requires that the government's justification not rely on overbroad generalizations about women).

Defendants cannot meet this rigorous standard. First, the Exemption Rules and the IFRs do not serve an important government interest. The Moral Exemption Rule and the Moral IFR is purportedly needed to ensure that non-religious entities can exercise their moral objections to providing women's healthcare services. As support for such a rule, Defendants cite only three employers: two who filed suit against the prior regulatory scheme (March for Life and Real Alternatives, Inc.) and one who submitted a comment letter (Americans United for Life). 83 Fed. Reg. at 57,626 & n.74. Accommodating requests from these three lone employers does not amount to an "important" government interest such that it supersedes the rights of millions of women to access statutorily guaranteed healthcare. *See, e.g.*, *Virginia*, 518 U.S. at 541-42, 550.[49] Nor can Defendants demonstrate an "important government interest" to support the expansive breadth of the Religious Exemption Rule. This Rule's vast expansion of the available exemption

[49] To the extent Defendants rely on historical letters penned by the Founding Fathers to religious organizations, the Supreme Court has repeatedly recognized that in considering a gender discrimination case, the Court must bear in mind that "[o]ur nation has had a long and unfortunate history of sex discrimination." *Virginia*, 518 U.S. at 531 (explaining that women did not count among "We the People" and even after gaining the right to vote, the government could "withhold from women opportunities accorded men" for any reason); *Hibbs*, 538 U.S. at 729. As Justice Kennedy explained, "The nature of injustice is that we may not always see it in our times. The generations that wrote and ratified the Bill of Rights and Fourteenth Amendment did not presume to know the extent of freedom in all of its dimensions and so they entrusted future generations a charter protecting the right of all persons to enjoy liberty as we learn its meaning." *Obergefell v. Hodges*, 135 S. Ct. 2584, 2598 (2015). Thus, reliance on these historical letters cannot justify the IFRs' and Exemption Rules' vast expansion to accommodate objections to the detriment of millions of women.

from "churches" to *all* employers, including publicly traded companies and insurers, is without justification in the ACA or RFRA. *See supra* at 16-33.

Second, even if Defendants could demonstrate an important government interest, Defendants cannot demonstrate that the "means employed" are "substantially related" to the purported "important government interest." *Sessions*, 137 S. Ct. at 1690. Defendants have undertaken several actions that severely limit women's ability to access their statutorily guaranteed healthcare benefits and services, without showing that such actions are substantially related to achieving Defendants' purported important goals. *See, e.g.*, *Orr v. Orr*, 440 U.S. 268, 280-81 (1979) (classification did not substantially relate to objectives where it was gratuitous in that there was a feasible solution, with little additional burden on the State that would eliminate discrimination and would still achieve the government's objectives). Defendants have (1) vastly expanded the exemption to include (a) religious objections of *all* employers, including publicly traded for-profit corporations; and (b) moral objections of nearly all employers and (2) eliminated the prior safety net that ensured that women would obtain their statutorily entitled benefits and services, even if their employer exercised its objection. These Rules and IFRs fail the "means test" because they are much broader than necessary to achieve any purported goal with respect to accommodating employers and fail to account for the compelling interest of providing full and equal healthcare to women.

V. THE EXEMPTION RULES WERE IMPROPERLY PROMULGATED

Defendants evaded their obligations under the APA by promulgating rules without proper notice and comment. Nevertheless, Defendants claim that their failure to abide by the APA is cured as to the Final Exemption Rules because the public could comment on the IFRs post-promulgation. 83 Fed. Reg. at 57,552. Such a claim runs contrary to the plain language of the APA and, practically speaking, would provide an end-run for agencies to avoid compliance with the APA, which requires agencies to provide the public notice and an opportunity to be heard *before* promulgating a regulation.

Several courts, including the Ninth Circuit, have addressed how a post-promulgation comment period undermines the purposes of § 553: to reintroduce the public voice when a matter

has been delegated to unrepresentative agencies, and to educate the agency while it is in the process of developing its policies. *See Alcaraz v. Block*, 746 F.2d 593, 611 (9th Cir. 1984); *Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005) ("It is antithetical to the structure and purpose of the APA . . . to implement a rule first, and then seek comment later"); *see also, e.g.*, *Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979) ("Provision of prior notice and comment allows effective participation in the rulemaking process while the decisionmaker is still receptive to information and argument"). Procedural error is not taken lightly in the administrative context, where substantive challenges are difficult due to an agency's discretion to make policy contrary to the comments it receives; therefore, procedural error is only harmless where the mistake "clearly had no bearing on the procedure used or the substance of decision reached." *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th Cir. 1992).

As a result, several circuit courts have held that post-promulgation comments may not replace pre-promulgation comments, or have placed limits on the situations in which such a replacement will stand. *See, e.g.*, *Nat. Res. Def. Council v. Nat'l Highway Safety Admin.*, 894 F.3d 95 (2nd Cir. 2018); *United States v. Brewer*, 766 F.3d 884 (8th Cir. 2014); *United States v. Reynolds*, 710 F.3d 498 (3d Cir. 2013); *United States v. Dean*, 604 F.3d 1275 (11th Cir. 2010); *U.S. Steel Corp. v. EPA*, 595 F.2d 207 (5th Cir. 1979). In so doing, courts express concern that post-promulgation comments effectively nullify Congress's intent that agencies receive and consider public comments before issuing regulations. *See Pennsylvania*, 351 F. Supp. 3d at 813-14 (this practice "would allow [an agency] to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued . . . . We cannot countenance such a result.") (citing *NRDC*, 683 F.2d at 767); *Sharon Steel Corp*., 597 F.2d at 381 ("If a period for comments after issuance of a rule could cure a violation of the APA's requirements, an agency could negate at will the Congressional decision that notice and an opportunity for comment must proceed promulgation."); *U.S. Steel Corp*, 595 F.2d at 214 (finding judicial acceptance of this process would render § 553's notice and comment provisions unenforceable).

Courts rejecting the equivalence of public comments received before and after a regulation goes into effect have highlighted the status quo bias that agencies exhibit toward a regulation already in effect. *See, e.g.*, *Levesque v. Block*, 723 F.2d 175, 187 (1st Cir. 1983) (finding comments "must come at a time when they can feasibly influence the final rule," before it has become the status quo); *Sharon Steel Corp.*, 597 F.2d at 381 ("After the final rule is issued, the petitioner must come hat-in-hand and run the risk that the decisionmaker is likely to resist change"). To counter this bias, some courts require that the agency provide affirmative evidence that it considered post-promulgation comments with an "open mind." *See, e.g.*, *Guedes v. Bureau of Alcohol, Tobacco, Firearms, and Explosives*, 920 F.3d 1, 13 (D.C. Cir. 2019). Here, Defendants cannot meet this burden, having barely altered the Exemption Rules beyond their admission that more women would be harmed than the IFRs predicted, and having failed to meaningfully respond to the comments. *See supra* 46-51. Nor is it reasonable to conclude that comments submitted for IFRs and those submitted for Exemption Rules necessarily address the same question. *See Pennsylvania*, 351 F. Supp. 3d at 814 (holding the issuance of IFRs "fundamentally changed" the question submitted to the public from whether the rule should be changed at all to whether the rule should be finalized, in case addressing same rules as instant litigation) (citing *NRDC*, 683 F.2d at 767). In short, post-promulgation comments prevent the public from submitting comments to the most accurate question at the time the agency will be most receptive and are thus inconsistent with § 553. Defendants' failure to abide by the APA in promulgating the Final Exemption Rules renders them unlawful.

VI. DEFENDANTS VIOLATED THE APA BY FAILING TO PROVIDE NOTICE AND COMMENT BEFORE PROMULGATING THE IFRS

Defendants evaded their obligations under the APA by promulgating the IFRs without proper notice and comment. The APA requires agencies to provide the public notice and an opportunity to be heard before formulating, amending, or repealing a rule. 5 U.S.C. §§ 551(5), 553. The agency must publish in the Federal Register a notice of proposed rulemaking that includes "(1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or

substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). After the notice has issued, "the agency shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c).

In narrow circumstances, the APA exempts agencies from this notice and comment process where they can show "good cause" that the process would be either "impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(B). The burden is on the agency to demonstrate good cause, and courts have interpreted the exception narrowly. *See, e.g.*, *Lake Carriers' Ass'n v. EPA*, 652 F.3d 1, 6 (D.C. Cir. 2011) (exception "'must be narrowly construed and only reluctantly countenanced'"). An agency's legal conclusion that good cause has been shown is entitled to no deference. *Sorenson Commc'ns*, 755 F.3d at 706.

It is undisputed that Defendants bypassed the APA's notice and comment requirements in promulgating the IFRs and they, therefore, had the burden to demonstrate good cause for such action. As this Court and the Ninth Circuit already concluded, Defendants failed to demonstrate good cause for not providing notice and allowing public comment *before* these rules took effect. Dkt. No. 105 at 17-25; *California*, 911 F.3d at 575-81. As noted immediately above, Defendants' post-promulgation acceptance of comments is no substitute. Notice and comment are particularly important in legally and factually complex circumstances like those presented here—they allow affected parties to explain the practical effects of a rule before implementation, and ensure that the agency proceeds in a fully informed manner, exploring less harmful alternatives. *Riverbend Farms*, 958 F.2d at 1483-1484; *Alcaraz*, 746 F.2d at 611. Because Defendants failed to follow the notice and comment procedures, the IFRs are invalid.

VII. THE EXEMPTION RULES AND THE IFRS SHOULD BE SET ASIDE AS INVALID

Under the APA, a reviewing court shall ". . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law; [or] without observance of procedure required by law." 5 U.S.C. § 706(2)(A) & (D). Thus, by statute, Congress has directed reviewing courts as to what the remedy must be: the Court must "set aside" unlawful rules. This Court should follow Congress's express

instruction. *See, e.g.*, *State v. Ross*, 358 F. Supp. 3d 965, 1050-51 (N.D. Cal. 2019); *Klamath-Siskiyou Wildlands Cir. v. Nat'l Oceanic & Atmospheric Admin.*, 109 F. Supp. 3d 1238, 1241 (N.D. Cal. 2015); *Nat. Res. Def. Council v. EPA*, 489 F.3d 1364, 1374 (D.C. Cir. 2007). Here, the Exemption Rules and the IFRs must be set aside because they are unlawful.

VIII. THE STATES ARE ENTITLED TO DECLARATORY AND INJUNCTIVE RELIEF

This Court may grant declaratory relief because an actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a). The central question is "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1174-75 (9th Cir. 2002). Here, an actual controversy exists about the validity of the Exemption Rules and the IFRs.

The States are also entitled to injunctive relief. On January 13, 2019, this Court preliminarily enjoined the Exemption Rules, finding that:

> Plaintiffs have shown that they are likely to succeed, or at a minimum have raised serious questions going to the merits, on their claim that the Religious Exemption and the Moral Exemption are inconsistent with the Women's Health Amendment, and thus violate the APA. Plaintiffs also have shown that they are likely to suffer irreparable harm as a result of this violation, that the balance of hardships tips sharply in their favor, and that the public interest favors granting the injunction.

Dkt. No. 234 at 21-24. The standard for a permanent injunction is the same except that the States, as they have shown above, must demonstrate actual success on the merits. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 32 (2008); *W. Watersheds Project v. Abbey*, 719 F.3d 1035, 1054 (9th Cir. 2013). In the event the Court requests evidence to support the issuance of a permanent injunction, that evidence will once again show that a balance of harms and public interest support issuance of injunctive relief. *See* Dkt. No. 275 at 2 (directing the parties to focus their briefing on the substantive merits and seeking only "a concise explanation of the remedies they seek, and the legal basis for that relief."); *see Ross*, 358 F. Supp. 3d at 1050-51.

CONCLUSION

The Court should grant the States' motion for summary judgment.

Dated: April 30, 2019

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