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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,

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. 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.

4:17-cv-05783-HSG

STATES' NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION, WITH MEMORANDUM OF POINTS AND AUTHORITIES

Date:	January 11, 2019
Time:	10:00 a.m.
Dept:	2, 4th Floor
Judge:	The Honorable Haywood S. Gilliam, Jr.
Trial Date:	Not set
Action Filed:	October 6, 2017

TO THE DEFENDANTS AND THEIR COUNSELS OF RECORD:

PLEASE TAKE NOTICE that on January 11, 2019, at 10:00 a.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 Rhode Island, the Commonwealth of Virginia, the State of Vermont, and the State of Washington (collectively, "the States") move under Local Rule 7-2 for a preliminary injunction staying implementation of the two final rules (Exemption Rules): 83 Fed. Reg. 57,536 (Nov. 15, 2018) (religious exemption) and 83 Fed. Reg. 57,592 (Nov. 15, 2018) (moral exemption).

Because the Rules violate the Administrative Procedure Act and will cause irreparable harm, the States bring this motion to request that this Court issue a preliminary injunction enjoining enforcement and implementation of the contraception Exemption Rules by Defendants Alex M. Azar, 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. 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 (collectively, Defendants).

This motion is based on this notice, the Memorandum of Points and Authorities, the Declarations of Nicole Alexander-Scott, MD, MPH, Bruce S. Anderson, Ph.D., John Arensmeyer, Keisha Bates, Mari Cantwell, Randie C. Chance, Dr. Jennifer Childs-Roshak, Kimberly Custer, Dr. Caryn Dutton, Laura E. Durso, Meagan Gallagher, Alfred J. Gobeille, Daniel Grossman, MD, Lisa M. Hollier, MD, MPH, FACOG, Professor Lisa Ikemoto, Dave Jones, Kevin Kish, Kathryn Kost, Myron Bradford Kreidler, Ruth Lytle-Barnaby, Heather P. Maisen, MSW, MPH, Nathan Moracco, Trinidad Navarro, Karen Nelson, Phuong H. Nguyen, Judy Mohr Peterson, Robert Pomales, Julie Rabinovitz, Karyl Rattay, Reverend Susan Russell, Amanda Skinner, Lauren J. Tobias, Jenna Tosh, Ph.D., Jennifer Welch, Jonathan Werberg, Massey Whorley, Walker A. Wilson, and Dr. Judy Zerzan-Thul this Court's file, and any matters properly before the Court.

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MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

A woman's access to contraceptive care—and decision whether and when to use it—is a fundamental precept of her freedom and equality. The ACA and its implementing regulations revolutionized women's access to preventive healthcare by guaranteeing "no cost" coverage of all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization, and contraceptive counseling. This guarantee empowered a woman to, in consultation with her own preferred medical provider, select the best contraception to meet her needs. Since 2012, over 62 million women have benefited from this law, with resulting societal benefits from greater female engagement in the workforce and economic self-sufficiency. Yet the federal Contraception Exemption Rules now allow any employer or insurer to dictate which contraceptive methods, if any, a woman may access, impacting her health care choices and decisions. 83 Fed. Reg. 57536 (Nov. 15, 2018); 83 Fed. Reg. 57592 (Nov. 15, 2018). The Rules thus "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. The States bring this motion to protect the rights of women and their families, as well as the States' public health and financial interests.

LEGAL AND FACTUAL BACKGROUND

I. PROVIDING CONTRACEPTIVE COVERAGE BENEFITS EVERYONE

The benefits of contraception to women—and ultimately society—are universal. Nearly two-thirds of all women use contraceptives.[1] 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 relative effectiveness, convenience, cost, accessibility, side effects, drug interactions and hormones, the frequency of sexual conduct, perceived risk of sexually transmitted infections, the desire for control, and a host of other factors. Kost Decl. ¶¶ 14-16; Ikemoto Decl. ¶ 6; Arensmeyer Decl. ¶ 6 ("Access to contraceptive coverage promotes the financial stability of female entrepreneurs and their employees"). As explained by the American

[1] *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.

College of Obstetricians and Gynecologists (ACOG), "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." Hollier Decl. ¶ 5; Kost Decl. ¶¶ 18, 42, 44; *see, e.g.*, Grossman Decl. ¶ 7 ("interpregnancy intervals of less than 18 months and high rates of unintended pregnancy are associated with adverse birth outcomes"); Kish Decl. ¶ 12. Further, as a result of the ACA's contraceptive-coverage requirement, women have saved an average of 20% annually in out-of-pocket expenses, including $248 savings for IUDs and $255 for the contraceptive pill. Grossman Decl. ¶ 9; *see also* Kost Decl. ¶ 31 ("Between fall 2012 and spring 2014 (during which time the coverage guarantee went into wide effect), the proportion of privately insured women who paid nothing out of pocket for the pill increased from 15% to 67%, with similar changes for injectable contraceptives, the vaginal ring and the IUD").

II. THE ACA REQUIRES THAT WOMEN'S PREVENTIVE SERVICES, INCLUDING CONTRACEPTIVES, BE PROVIDED

The ACA generally requires that group health insurance plans include women's "preventive care and screenings" and those plans "shall not impose any cost sharing" on the consumer. 42 U.S.C. § 300gg-13(a)(4). In response to this Congressional directive, the U.S. Department of Health and Human Services (HHS) commissioned the nonpartisan Institute of Medicine (IOM) to assemble a diverse, expert committee to determine what should be included in "preventive care" coverage.[2] Following rigorous, independent, and exhaustive review of the scientific evidence, the IOM issued its expert report with a comprehensive set of recommendations for implementing women's preventive healthcare services.[3] These recommendations addressed important 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

[2] Inst. Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, 1-2 (2011), https://cdn.cnsnews.com/documents/INSTITUTE%20OF%20MEDICINE-PREVENTIVE%20SERVICES%20REPORT.pdf [hereinafter "*IOM Report*"]

[3] *Id*. at 79-156 (chapter 5 generally).

reproductive capacity.[4] Significantly, the IOM recommended that private health insurance plans be required to cover all FDA-approved contraceptives without cost-sharing.[5] It considered these services essential so that women can avoid unwanted pregnancies and space their pregnancies to promote optimal birth and maternal health outcomes.[6] The IOM also explained that removing cost barriers is important because "the most effective contraceptive methods," such as "long-acting, reversible contraceptive methods" have "high up-front costs."[7]

Following the IOM's recommendations on coverage, Defendants promulgated regulations requiring that certain employers offering group health insurance plans cover all FDA-approved contraceptive methods. 45 C.F.R. § 147.130(a)(1)(iv); 29 C.F.R. § 2590.715-2713(a)(1)(iv); 26 C.F.R. § 54.9815-2713(a)(1)(iv). To effectuate these regulations, the Health Resources and Services Administration (HRSA) issued guidelines that included a list of each type of preventive service, and the frequency with which it should be offered.[8]

Since the ACA's contraceptive-coverage requirement took effect in 2012, women have saved $1.4 billion annually, and to date, 62.8 million women nationwide have benefited.[9] These savings have a corresponding impact on society, including the States. Kost Decl. ¶¶ 32-36; Cantwell Decl. ¶¶ 13-14 ("The ACA's implementation correlates with a decrease" in enrollment in state-funded programs). The ACA's requirement decreases the number of unintended pregnancies, and thereby the costs associated with those pregnancies. Kost Decl. ¶¶ 32-26. Furthermore, unintended pregnancy is associated with poor birth outcomes and maternal health complications, and thus, the contraceptive-coverage requirement also reduces the number of high-cost births and infants born in poor health. Hollier Decl. ¶¶ 4-6 ("[u]niversal coverage of

[4] *See id*. at 109; *id*. at 79-156.

[5] *Id*. at 102-10. Before the ACA, contraceptives accounted for between 30-44% of out-of-pocket healthcare spending for women. Kost Decl. ¶ 32.

[6] Inst. Medicine, *Report Brief: Clinical Preventive Services for Women: Closing the Gaps* 2 (2011), http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/preventiveservicesforwomenreportbrief_updated2.pdf [hereinafter *IOM Brief*].

[7] *IOM Report* at 108, 19, 20; Jones Decl. ¶ 20.

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

[9] Nat'l Women's Law Ctr, Fact Sheet, *Reproductive Rights & Health* (Nov. 2018), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-4.pdf; Rabinovitz Decl. ¶¶ 4-5.

contraceptives is cost effective and reduces unintended pregnancy and abortion rates" and "each dollar spent on publicly funded contraceptive services saves the U.S. health care system nearly $6."); Grossman Decl. ¶ 7; Rattay Decl. ¶¶ 7-10.

III. THE 2016 REGULATORY SCHEME CARVED OUT A PROPERLY TAILORED EXEMPTION AND ACCOMMODATION THAT MAINTAINED WOMEN'S ACCESS TO EQUAL HEALTHCARE COVERAGE WHILE BALANCING RELIGIOUS LIBERTY

The ACA itself does not create exemptions or accommodations. But over the past six years, Defendants have implemented tailored exemptions and accommodations in order to reconcile the sincerely held religious beliefs of specific employers and the compelling interest in access to contraception. *See* 75 Fed. Reg. 41726 (2010); 76 Fed. Reg. 46621 (2011); 77 Fed. Reg. 8725 (2012); 78 Fed. Reg. 39870 (2013); 79 Fed. Reg. 51092 (2014); 80 Fed. Reg. 41318 (2015). The federal government carefully crafted a narrowly tailored exemption for houses of worship, churches and their integrated auxiliaries, conventions, and associations of churches. *See* 76 Fed. Reg. 46621 (2011); 77 Fed. Reg. 8728 (2012); 78 Fed. Reg. 8456, 8458 (2013). This allowed these entities to seek an exemption from the contraceptive-coverage requirement consistent with the Internal Revenue Code. *See* 45 C.F.R. § 147.131(a) (defining "religious employers"); 26 C.F.R. § 54.9815-2713A(a).

In addition to this narrow exemption, in 2013, the federal government created an "accommodation" for religiously affiliated nonprofit organizations with objections to contraceptive coverage. 45 C.F.R. § 147.131(b); 78 Fed. Reg. 12739871, 398892-389897 (2013). Under the accommodation—a process unnecessary and inapplicable to exempt employers—a nonprofit employer certified its religious objection to the federal government or to the insurer, and then the insurer was responsible for providing separate contraceptive coverage for female employees. 45 C.F.R. § 147.131(b) & (c)(2). Upon notification, the government worked with the insurer to guarantee that women received coverage.[10] This process ensured a seamless, automatic mechanism for female employees and dependents to receive the statutorily entitled contraceptives

[10] The health insurer covered the contraceptive benefits and services, and, in turn, could be reimbursed with a fee for providing such benefits and services. 80 Fed. Reg. 41346 (2015).

that their nonprofit employers did not pay for or facilitate. 45 C.F.R. § 147.131(b).[11] In short, the accommodation process balanced the rights of female employees to equal health care coverage while safeguarding religiously affiliated nonprofit employers' ability to opt out of providing this coverage. *See* 80 Fed. Reg. 41318 (2015) (HHS regulation); 45 C.F.R. § 147.131(c)-(d); 158 Cong. Rec. S375 at H586 (daily ed. Feb. 8, 2012) (statement that the accommodation "represents a respectful balance between religious persons and institutions and individual freedom").

The religious accommodation was later expanded to include certain closely held for-profit organizations with religious objections to providing contraceptive care, consistent with *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014); 80 Fed. Reg. at 41318 (2015); 45 C.F.R. § 147.131(b)(4).

Crucially for this case, the Supreme Court declined to hold that the accommodation process violated the Religious Freedom Restoration Act of 1993 (RFRA), and instead instructed that: "the parties on remand should be afforded an opportunity to arrive at an approach going forward that accommodates [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.*" *Zubik v. Burwell*, 136 S. Ct. 1557, 1559-60 (2016) (emphasis added) (internal quotation marks and citation omitted). As this Court recognized, during the *Zubik* litigation, the 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, seeking input on whether and how the regulations could be changed to resolve the objections asserted by plaintiffs in *Zubik*, while still ensuring that the affected women receive full and equal health coverage. 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

[11] *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.

concluded 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. [12]

IV. DEFENDANTS PROMULGATED IFRS THAT ALLOW EMPLOYERS TO DEPRIVE FEMALE EMPLOYEES EQUAL ACCESS TO HEALTHCARE COVERAGE

On October 6, 2017, Defendants promulgated sweeping new rules upending women's access to 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 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 the contraceptive requirement to exempt themselves. The "Moral Exemption IFR" provided that nearly any employer can avoid providing these benefits to their employees if they have a "moral" objection. Like the Religious Exemption IFR, the Moral Exemption IFR extends to insurers and individuals, allowing those objectors to exempt themselves as well.

Significantly, under the IFRs, no employer needs to provide any accommodation to assure that women receive their statutorily entitled contraceptive coverage. The employer need not actually assert a religious or moral objection to the contraceptive-coverage requirement in order to opt out; nor do they need to notify the federal government. Rather, they "object" by simply exempting themselves from the statutory requirement—making the carefully structured accommodation process entirely voluntary and resulting in female employees simply not obtaining coverage *at all*. Notably, if any employer decided it has a religious or moral objection to providing contraception, there is no notice to the woman, or to the federal government. The only way a woman will discover that her employer has exempted itself from providing contraceptives is by examining her notice of benefits and coverage; she will otherwise receive no proactive notice.

[12] 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.

In determining the impact of the IFRs, Defendants specifically relied on state and local programs to fill in the gaps of coverage. 82 Fed. Reg. 47792, 47803 (2017) (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).

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, at a minimum, were likely to succeed on their claim that Defendants violated the Administrative Procedure Act (APA) by issuing the IFRs without advance notice and comment, and that absent a preliminary injunction, the States would suffer irreparable substantive and procedural injuries, in addition to the equities and public interest tipping in the States' favor. Dkt. No. 105 at 17-28. This Court rejected Defendants' standing arguments because the States had demonstrated they would incur economic burdens, either to cover contraceptive services necessary to fill in the gaps left by the IFRs or for expenses associated with unintended pregnancies. *Id*. at 12-16.

On December 13, 2018, the Ninth Circuit largely upheld this Court's decision. *California v. Azar*, --F.3d -- , 2018 WL 6566752 (9th Cir. Dec. 13, 2018). The Ninth Circuit held that the States have standing to sue because the IFRs would "first lead to women losing employer-sponsored contraceptive coverage, which [would] then result in economic harm to the states." *Id*. at *6. The Court elaborated 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*. The Court highlighted that 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 also concluded that "loss of coverage [would] inflict economic harm to the states." *Id*. at *7. The Court noted that the RIA estimates that the direct cost of filling the coverage loss as $18.5 or $63.8 million per year and the rule identifies state and local programs as filling that gap; thus, the RIA "assumed that state and local governments will bear additional economic costs." *Id*. The Court concluded that the

"declarations submitted by the states further show that women losing coverage from their employers will turn to state-based programs or programs reimbursed by the state." *Id*.

On the merits, the Ninth Circuit concluded that the States were likely to succeed on their APA notice-and-comment claim. *California*, 2018 WL 6566752, at *9-13. The Court also concluded that the harm to the States was "not speculative; it is sufficiently concrete and supported by the record." *Id*. at *14.

VI. DEFENDANTS PROMULGATED FINAL RULES WHICH WILL SUPERSEDE THE IFRS

On November 15, 2018, Defendants promulgated the final Exemption Rules which will supersede the IFRs effective January 14, 2019 (Rules). 83 Fed. Reg. 57536; 83 Fed. Reg. 57592. These Rules are very similar to the IFRs. *See* Federal Defs.' Supplemental Br., Ninth Circuit No. 18-15144, Dkt. No. 125 at 6 ("the substance of the rules remains largely unchanged"); Little Sisters' Supplemental Br., Ninth Circuit No. 18-15144, Dkt. No. 128 at 2 (noting the final rule is "substantively identical" to the IFR). However, there are two noteworthy differences.

First, not only do Defendants continue to acknowledge that tens of thousands of women will likely lose contraceptive coverage as a result of the Rules, but, the RIA in the Rules estimates that even *more* women will be harmed by the expanded exemptions. *See, e.g.*, 83 Fed. Reg. at 57551 n. 26, 57578. Second, the Rules suggest that women can 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 57548, 57551; 83 Fed. Reg. at 57605, 57608.[13] Such a suggestion *demonstrates* that the Rules require women to take additional steps—outside of their employer-sponsored coverage—to access necessary care. 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. A majority of states do not have family planning programs at all. Kost Decl. ¶¶ 46-52 (explaining that publicly funded family planning programs and providers are already operating under restrictive conditions, further undermining these programs ability to serve those affected by the expanded exemptions); *see also* Custer Decl. ¶¶ 22-24. Moreover, the Title X program is ill-

[13] Defendants have proposed drastic changes to the Title X program, making it even more unsuitable as a stop-gap for the Rules. *See also* Second Am. Compl. ¶¶ 7, 54-55, 218-222.

equipped to replicate or replace the seamless contraceptive-coverage requirement.[14] Custer Decl. ¶ 3; Kost Decl. ¶¶ 40-41; Rattay Decl. ¶ 4; Skinner Decl. ¶ 9. This will have a spill-over effect to state programs. Cantwell Decl. ¶ 18; Custer Decl. ¶ 23; Dutton Decl. ¶ 28; Nelson Decl. ¶¶ 16, 20; Pomales Decl. ¶¶ 10-11; Skinner Decl. ¶ 5; Tobias Decl. ¶ 5; Welch ¶ 10. Further, in several states Title X clinics screen every patient for state family-planning eligibility. *See, e.g.*, Cantwell Decl. ¶ 18; Rabinovitz Decl. ¶ 3; Tobias Decl. ¶ 5. Thus the States' safety-net programs will see an increase in the number of consumers, resulting in economic harm to the States, as women continue to fall through the proverbial cracks in trying to seek out basic care.

LEGAL STANDARD

To obtain a preliminary injunction, the plaintiff must demonstrate that (1) it "is likely to succeed on the merits," (2) it "is likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in [its] favor," and (4) "an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Courts evaluate these factors on a "'sliding scale,'" such that serious questions on the merits and a balance of hardships that tip sharply towards the plaintiff can support a preliminary injunction, so long as the plaintiff also shows a likelihood of irreparable injury and that the injunction is in the public interest. *Arc of Cal. v. Douglas*, 757 F.3d 975, 983 (9th Cir. 2014).

ISSUE PRESENTED

Do the Exemption Rules violate the APA and irreparably harm the States and women, necessitating injunctive relief to maintain the status quo?

ARGUMENT

I. THE STATES ARE LIKELY TO SUCCEED ON THE MERITS

A. The Exemption Rules Are Invalid Under the APA Because They Are Not in Accordance with the Law and in Excess of Statutory Authority

The 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). Here,

[14] The Title X program is subject to discretionary funding. Kost Decl. ¶ 48. 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%. Kost Decl. ¶ 49.

Congress did not delegate to Defendants the ability to promulgate rules undermining the ACA's protection for women to access no-cost preventive services. *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001) (citing *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)).

1. The Rules Are Contrary to the Women's Health Amendment

The Rules cannot be reconciled with the text and purpose of the ACA—which seeks to promote access to women's healthcare, not limit it. *See Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 577-81 (E.D. Pa. 2017). The ACA's requirement that certain group health plans cover women's "preventive care and screenings" (42 U.S.C. § 300gg-13(a)(4)) was added by the Women's Health Amendment—the purpose of which was ensuring that women have equal access to healthcare and are not required to pay more than men for preventive care, including contraception. *See Hobby Lobby Stores*, 134 S. Ct. at 2788 (Ginsburg, J., dissenting); 158 Cong. Rec. S375 (noting that it is the female employee's decision, not the employer's, whether to use birth control or access the ACA's preventive health measures, despite the religious affiliation of her employer). The Women's Health Amendment sought to redress the "fundamental inequity" that women were systematically charged more for preventive services than men. 155 Cong. Rec. S12027 (Dec. 1, 2009) (statement of Sen. Gillibrand).[15] At that time, "more than half of women delay[ed] or avoid[ed] preventive care because of its cost." *Id.* Supporters of the amendment expected that eradicating discriminatory barriers to preventive care—including contraceptive care—would result in substantially improved health outcomes for women. *See, e.g.*, at S12052 (statement of Sen. Franken); *see also id.* at. S12059 (statement of Sen. Cardin) (noting that amendment will cover "family planning services"); *id.* (statement of Sen. Feinstein) (same).

During the same time, Congress rejected a competing amendment that would have permitted broad moral and religious exemptions to the ACA's coverage requirements—the same moral and religious exemptions that are reflected in the IFRs and the Rules. *Hobby Lobby*, 134 S. Ct. at 2775 n.30; *id.* at 2789-2790 (Ginsburg, J., dissenting); 159 Cong. Rec. S2268 (Mar. 22,

[15] *See id.* at S12051 (statement of Sen. Franken) (similar); *see also id.* at 12027 (statement of Sen. Gillibrand) ("women of child-bearing age spend 68 percent more in out-of-pocket heath care costs than men"); *see id.* at S12051 (statement of Sen. Dodd) (similar).

2013). These Rules thus contravene Congressional intent by disregarding what the Women's Health Amendment accomplished and adopting by regulation what Congress rejected.

While the Women's Health Amendment delegates to HRSA the responsibility of setting forth the "comprehensive guidelines," Defendants were not provided with the authority to carve out broad exemptions to exempt employers from this statutory requirement. HRSA was delegated the responsibility to define *what* types of preventive services shall be included—not *who* must abide by the statute. Further, Defendants may not exercise their discretion in a manner that effaces the provision's core purpose. *See Michigan v. EPA*, 135 S. Ct. 2699, 2708 (2015) (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."). Defendants' implementation of the ACA's directive eliminates the provision's core purpose and is therefore invalid under the APA. *See, e.g.*, *Nw. Envtl. Def. Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 681-86 (9th Cir. 2007) (setting aside agency action that is contrary to governing law).

Moreover, the Rules cannot be reconciled with the plain language of the ACA. They are, in fact, 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 plain that the "preventive care" for "women" "shall" be provided. Nothing in the statute allows exemptions for broad categories of employers, plan sponsors, issuers, or individuals.

2. The Rules Are Contrary to Other Provisions Within the ACA

First, Section 1554 of the ACA forbids the HHS Secretary from promulgating "any regulation" that "creates any unreasonable barriers" to medical care *or* "impedes timely access to health care services." 42 U.S.C. § 18114, (1), (2). Here, inclusion of women's preventive services as a core part of the ACA's essential health benefits requirement, 42 U.S.C. § 18022, was critical to fulfilling Congress's goals of ensuring complete coverage of preventive care, better

health outcomes for women, and an end to discrimination against women in health care. By forcing women to go outside their employer-sponsored healthcare provider, the Rules are creating barriers and impeding timely access to crucial care. Women may need to pay out of pocket for such care, which will have a direct impact on healthcare. Kost Decl. ¶ 24 ("[e]xtensive empirical evidence demonstrates what common sense would predict: eliminating costs leads to more effective and continuous use of contraception"). The Rules increase the impediment to contraceptive access, and that, "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." Kost Decl. ¶ 37; Custer Decl. ¶¶ 19-21. Defendants' suggestion that women "simply" seek out services at a Title X clinic, or through some other governmental program, further demonstrates the barriers they are creating given that such clinics are already unable to meet the demands of the current low-income population they were designed to serve. 83 Fed. Reg. at 57548, 57551; Kost Decl. ¶¶ 48-51 (explaining the burdens of the proposed Title X rule).[16]

Second, Section 1557 of the ACA states that an "individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity" on the basis of sex. 42 U.S.C. § 18116; 20 U.S.C. § 1681; *see also Ferrer v. CareFirst, Inc.*, 265 F.Supp. 3d 50, *52-54 (D.D.C. 2017) (denial of full coverage resulted in women having to pay hundreds of dollars out of pocket for lactation services, violating the ACA). The Rules selectively authorize denial of coverage for women's preventive coverage only. Women are forced into a Hobson's choice: accept incomplete medical coverage unequal to that received by male colleagues or forgo employer-provided or university-provided coverage and try to purchase out-of-pocket a comprehensive healthcare package. *Cf.* Kish Decl. ¶ 12. The Rules' express authorization of employers' exempting themselves from providing full and equal coverage to their female employees directly violates Section 1557. 45 C.F.R. § 92.1.

[16] *See* Comment Letter of California, et al., available at https://www.regulations.gov/document?D=HHS-OS-2018-0008-161828.

3. The Rules Are in Excess of Statutory Jurisdiction

Defendants, like any federal agency, "literally [have] no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); 5 U.S.C. § 706(2)(C). In determining whether Defendants exceeded their statutory authority, this Court must undertake a two-step process. *American Library Ass'n v. FCC*, 406 F.3d 689, 698-99 (D.C. Cir. 2005). First, the Court must ascertain whether the statute "has directly spoken to the precise question at issue;" if the statute is unambiguously clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984). Second, if the statute admits of some ambiguity, then courts must determine whether the agency's interpretation is "reasonable." *Id*. at 844. In assessing whether an agency's interpretation is "reasonable," courts apply normal canons of statutory construction, and may therefore look not only to the law's text, but to its structure, purpose, and legislative history. *Id*. at 845. A regulation is invalid when it adopts an interpretation so unreasonable that it directly conflicts with the statute it purports to implement. *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 91-92, 101-102 (2002) (holding agency interpretation unreasonable where it conflicts with the law's "remedial scheme" and Congress's intent).

As discussed above, the Women's Health Amendment is unambiguously clear that Defendants did not have the authority under the ACA to enact the Rules. They are, in fact, contrary to several provisions within the ACA, including the guarantee to women of no-cost preventive care and screenings, the guarantee that access to healthcare not be blocked, and the guarantee of nondiscrimination on the basis of sex.

Even if the Women's Health Amendment is ambiguous, Defendants' interpretation of the ACA is unreasonable based on the ACA's text, structure, purpose, and legislative and regulatory history. In implementing the ACA Congress recognized that contraceptive coverage is a necessary component of equality between men and women because it allows women to control their health, education, and livelihoods. Kost Decl. ¶¶ 44-45. Denying women access to this coverage denies them equal opportunity to aspire, achieve, participate in and contribute to society

based on their individual talents and capabilities. *Id.* (2011 study found that a majority of women reported that access to contraception had enabled them to take better care of their families (63%), support themselves financially (56%), stay in school or complete their education (51%), or get or keep a job or pursue a career (50%)); *see also* Ikemoto Decl. ¶ 6; see also *See Hobby Lobby Stores*, 134 S. Ct. at 2785-2786 (Kennedy, J., concurring) (government has a compelling interest in ensuring women equal access to healthcare coverage as their male colleagues); Kost Decl. ¶¶ 38-45 (describing harms to women as a result of the Rules, including unintended pregnancies, being unable to space and time pregnancies, and effect on the overall health of women), ¶ 42 (isolating contraceptive coverage in this way interferes with the ability of healthcare providers to treat women holistically); ¶ 45 ("Low-income women, women of color and women aged 18-24 are at disproportionately high risk for unintended pregnancy, and millions of these women rely on private insurance coverage—particularly following implementation of the ACA"); Tosh Decl. ¶¶ 11-12; Grossman Decl. ¶ 6; Bates Decl. ¶¶ 3-4. As a result of these Rules, women will be forced to struggle to pay for it themselves, to forgo contraceptive coverage or switch to less expensive contraceptives that may be less effective for them, risking an unintended pregnancy, or to try to seek out services from some entity other than their employer, such as the state. Kost Decl. ¶¶ 25-34, 54. These harms uniquely impact women in that they affect women's ability to pursue additional education, spend additional time in their careers, and have increased earning power over the long term—precisely the problem Congress sought to cure with the Women's Health Amendment. Tosh Decl. ¶ 25; Ikemoto Decl. ¶ 6; Arensmeyer Decl. ¶ 4; Bates Decl. ¶¶ 3, 6. Thus, the Rules must be held unlawful and set aside as being in excess of statutory authority. 5 U.S.C. § 706(2)(C).

Defendants' reliance on RFRA to enact the Rules is erroneous. 83 Fed. Reg. at 57541. Of course, RFRA simply does not apply to the Moral Exemption Rule because RFRA does not extend to moral beliefs. Nor does RFRA justify the Religious Exemption Rule. As a threshold matter, "person," as defined in RFRA, does not extend to for-profit publicly traded corporations. 42 U.S.C. § 2000bb-1(a). Moreover, RFRA does not give Defendants license to allow employers to deprive women of their statutorily entitled benefits. To the extent that an employer has a

religious objection, Defendants must still ensure that female employees are not deprived of their entitlement to equal access to medical care and coerced to participate in the religious beliefs of their employer. Russell Decl. ¶¶ 5, 6. The Rules here substantially burden third parties—denying female employees (and the female dependents of all employees) access to preventive care and services—based on the religious beliefs of the employer. RFRA cannot justify the broad scope of either the Moral or Religious Exemption Rule.

B. The Exemption Rules Are Invalid Because Defendants Violated the APA by Permitting Only Post-Promulgation Comments

Defendants evaded their obligations under the APA by promulgating rules without proper notice and comment. The APA requires agencies to provide the public notice and an opportunity to be heard *before* promulgating a regulation. 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).

Here, it is undisputed that Defendants bypassed the notice and comment requirements of the APA. Instead, Defendants issued IFRs, took comments after the IFRs became effective, and then promulgated Final Rules.[17] "It is antithetical to the structure and purpose of the APA" "to implement a rule first, and then seek comment later." *Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005); *see also, e.g., Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983) ("[p]ermitting the submission of views after the effective date is no substitute for the right of interested persons to make their views known to the agency in time to influence the rule in a meaningful way"); *Natural Resources Defense Council, Inv. v. EPA*, 683 F.2d 752, 768 (3rd Cir. 1982) ("post-promulgation notice and comment procedures cannot cure the failure to provide such procedures

[17] As this Court previously concluded, and the Ninth Circuit affirmed, Defendants do not have statutory authority to bypass notice and comment. *See* Dkt. No. 105 at 17-25; *California*, 2018 WL 6566752, at *9-13.

prior to the promulgation of the rule at issue"). "If a period for comments after issuance of a rule could cure a violation of the APA's requirements, an agency could negate at will the Congressional decision that notice and an opportunity for comment must precede promulgation." *Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3rd 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." *Id*. "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." *Id*.

As this Court and the Ninth Circuit already concluded, Defendants lacked good cause for failing to give any notice to the public or allowing for public comment *before* these rules took immediate effect. Dkt. No. 105 at 17-25; *California*, 2018 WL 6566752, at *9-13. Defendants' post-promulgation acceptance of comments is no substitute. Notice and comment is particularly important in legally and factually complex circumstances like those presented here—it allows affected parties to explain the practical effects of a rule before implementation, and ensures that the agency proceeds in a fully informed manner, exploring less harmful alternatives. *Alcaraz v. Block*, 746 F.2d 593, 611 (9th Cir. 1984); *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1483-1484 (9th Cir. 1992). Because Defendants failed to follow the APA's notice and comment procedures, the Rules are invalid.

C. The Rules Are Arbitrary and Capricious Because Defendants Failed to Provide an Adequate Justification for Their Reversal of Policy

An agency must provide a "concise general statement of [a regulation's] basis or purpose". 5 U.S.C. 553(c). "[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). The agency must "articulate a 'rational connection between the facts found and the choice made.'" *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974). Where an agency departs from a prior policy, it must at a minimum "display awareness that it *is* changing position." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Jicarilla Apache Nation v. U.S. Dept. of Interior*, 613 F.3d at 1112, 1119 (D.C. Cir. 2010) (holding that an agency that neglects to explain its departure from established precedent acts

arbitrarily and capriciously"). In addition, a more "detailed justification" is necessary where there are "serious reliance interests" at stake or the new policy "rests upon factual findings that contradict those which underlay its prior policy." *F.C.C.*, 556 U.S. at 515; *see also State Farm*, 463 U.S. at 48-51 (regulation rescinding prior regulation after change in presidential administration was arbitrary and capricious where agency failed to address prior fact findings). And a change in administration does not authorize an unreasoned reversal of course. *See State v. U.S. Bureau of Land Mgmt.*, 277 F.Supp.3d. 1106, 1123 (N.D. Cal. 2017) ("New presidential administrations are entitled to change policy positions, but to meet the requirements of the APA, they must give reasoned explanations for those changes and address the prior factual findings underpinning a prior regulatory regime." (quotation marks and brackets omitted)). Where the agency action is "arbitrary" or "capricious," the court must invalidate it. 5 U.S.C. § 706(2)(A).

Given the number of women nationwide who rely on the contraceptive-coverage requirement, the government must provide greater justification for the Rules. *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015). Defendants failed to do so. The Rules are arbitrary and capricious because they constitute a complete reversal of prior agency policy without a detailed justification for such a substantial shift. The factual record remains unchanged since the prior regulations were promulgated. And millions of women across the country have relied on the ACA's contraceptive-coverage requirement since 2012. Dkt. Nos. 170-1 & 170-2.[18] The Rules cite a number of reasons for the change, none of which meet the heightened standard. See, e.g., 83 Fed. Reg. at 57537; 83 Fed. Reg. at 57593. For instance, the prior regulations found a compelling government interest in ensuring that women have access to contraceptive coverage. *See Hobby Lobby Stores*, 134 S. Ct. at 2785-86 (Kennedy, J., concurring). The Rules summarily announce that there is not a compelling interest in ensuring women's access to contraceptive

[18] Nat'l Women's Law Ctr, Fact Sheet, *Reproductive Rights & Health* (Nov. 2018), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-4.pdf; Rabinovitz Decl. ¶¶ 4-5.

coverage, yet provide no support for this complete about-face. 83 Fed. Reg. at 57545, 57546-57548; 83 Fed. Reg. at 57605.

Further, there is no justification for the *scope* of the Rules. Defendants fail to justify expanding the universe of employers, or its extension of the exemption (as opposed to the accommodation). For example, the religious exemption is now available for publicly traded entities, even though Defendants readily admit that they are not aware of any publicly traded entities that have objected to providing contraceptive coverage on the basis of religious belief. 83 Fed. Reg. at 57562. Nevertheless, the Rules now make it easy for any such entity to opt out of contraceptive coverage for any reason, including economic, because there is no notice required and no oversight by the Defendants. Nor is there notice to an employee, outside of her regularly provided evidence-of-coverage packet, including for new employees. Thus, unless a woman combs through her statement of benefits, she will not know that her employer has exempted itself from the contraceptive-coverage requirement, thereby depriving her of her statutorily entitled benefits. Although the Rules refer to the *Hobby Lobby* and *Zubik* decisions, the Supreme Court has never suggested that such a broad exemption, encompassing religious and moral objections for nearly any employer at the detriment to women, is necessary.

In addition, the Rules rely on information about women's health that is "unfounded." Kost Decl. ¶¶ 12-13 (explaining flawed data and analysis); Chance Decl. ¶¶ 6-19 (discussing the problematic and arbitrary methods and estimates Defendants used to determine the likely number of women affected by the unavailability of contraception due to the Rules, and suggesting that actual number of affected women could be far greater). At the same time, the Rules ignore other public health interests, such as the use of contraceptive medicines for non-birth control purposes. Hollier Decl. ¶ 5; Bates Decl. ¶ 3.

The Rules note that contraceptive coverage is not mandated by Congress, only by the implementing regulations. 83 Fed. Reg. at 57540. Yet, the ACA relied on HRSA to define the scope of preventive services and in turn, HRSA's guidelines state that preventive services include all FDA-approved contraceptive methods (along with other critical preventive services for

women). 42 U.S.C. § 300gg-13(a)(4).[19] Further, the legislative history of the Women's Health Amendment demonstrates that Congress expected contraceptives to fall within its ambit. *See, e.g.*, 55 Cong. Rec. S12027 (Dec. 1, 2009) (statement of Sen. Gillibrand) ("more than half of women delay[ed] or avoid[ed] preventive care because of its cost").[20] "[T]he Women's Health Amendment 'will require insurance plans to cover at no cost basic preventive services and screenings for women." Br. amici curiae of Senators Murray, et al., *Burwell v. Hobby Lobby Stores, Inc*. (Jan. 28, 2014).[21] The Rules also ignore the IOM Report's core findings that providing no-cost coverage of the full range of contraceptives is critical to women's health and wellbeing. *Org. Vill. of Kake v. U.S. Dept. of Agric.*, 795 F.3d 956, 966 (9th Cir. 2015) (agency action is arbitrary where agency's explanation is counter to the evidence before the agency). Finally, the Rules attempt to justify the reduction in coverage by pointing to federal and state programs that already provide women access to contraception. But this was true when the contraceptive-coverage requirement was promulgated and thus cannot provide a reasoned justification for the reversal in course. 83 Fed. Reg. at 57605, 57608; 83 Fed. Reg. at 57548. Further, these programs "simply cannot replicate or replace the gains in access made by the contraceptive coverage guarantee." Kost Decl. ¶ 46.

Additionally, through the course of this litigation, Defendants have contended that that no employer will utilize these Rules. *See California v. Azar*, 18-15144, Fed. Def.'s Br. (Dkt #11), at 28-34 (9th Cir. 04/09/2018). If so, there is no rational justification for upending the prior regulatory framework.

In short, the Rules are arbitrary and capricious and therefore invalid. 5 U.S.C. § 706(2)(A). The facts have remained relatively unchanged since the prior regulations were promulgated, yet

[19] Health Res. & Serv. Admin., *Women's Preventive Services Guidelines*, https://www.hrsa.gov/womens-guidelines/index.html; *See also* Women's Preventive Services Initiative Report, https://www.womenspreventivehealth.org/final-report/.

[20] *See id.* at S12051 (statement of Sen. Franken) (similar); *see also, e.g.*, at S12052 (statement of Sen. Franken) (Noting the amendment expected to eradicate discriminatory barriers to preventive care—including contraceptive care—to result in substantially improved health outcomes for women); *see also id.* at. S12059 (statement of Sen. Cardin) (noting that amendment will cover "family planning services"); *id.* (statement of Sen. Feinstein) (same).

[21] http://sblog.s3.amazonaws.com/wp-content/uploads/2014/02/hobby-lobby-conestoga-amicus-brief.pdf

the Rules constitute a significant change in policy. As such, Defendants have acted arbitrarily and capriciously and the Rules should be found unlawful. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (declining to defer to agency provided insufficiently reasoned explanation for "why it deemed it necessary to overrule its previous position."); *see also F.C.C.*, 556 U.S. at 535-536 (Kennedy, J., concurring).

II. ABSENT AN INJUNCTION, THE STATES WILL SUFFER IRREPARABLE HARM

The Rules will inflict irreparable harm upon the States. *Winter*, 555 U.S. at 22; *California*, 2018 WL 6566752, at *14 (affirming this Court's conclusion that "potentially dire public health and fiscal consequences" will result without an injunction). The threat of harm here is imminent. *Caribbean Marine Servs. Co., Inc. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988). Every day the Rules are in effect will be another day that employers can eliminate contraceptive coverage for employees and their dependents, without any separate notice. *See, e.g.*, Werberg Decl. ¶¶ 4-9.[22] For workers and beneficiaries in existing health plans, contraceptive coverage could be dropped with 60-days notice that the employer is revoking its use of the accommodation process, or when a new plan year begins. 26 C.F.R. § 54.9815-2713A(a)(5); 29 C.F.R. § 2590.715-2713A(a)(5); 45 C.F.R. § 147.131(c)(4); 26 C.F.R. § 54.9815-2715(b); 29 C.F.R. § 2590.715-2715(b); 45 C.F.R. § 147.200(b). This loss of coverage will mean that women no longer have seamless access to their essential healthcare benefits. This will result in a lack of continuity of care. Rabinovitz Decl. ¶ 7. The States will also suffer concrete and irreparable injury, including to those already covered through plans using the accommodation. *See* Durso Decl. (results of a Freedom of Information Act request for all accommodated employers).

First, lack of access to contraception will likely cause unintended pregnancies to rise, triggering a chain of events with widespread repercussions. When contraception is provided at no

[22] While *some* states have contraceptive equity laws, those laws are only applicable to state-regulated insurers—not self-funded insurers, which cover millions of women nationwide. Emily Bazar, *For Millions of Insured Americans, State Health Laws Don't Apply*, The Washington Post (Nov. 16, 2017), https://www.washingtonpost.com/national/health-science/for-millions-of-insured-americans-state-health-laws-dont-apply/2017/11/16/138f4476-cab7-11e7-b506-8a10ed11ecf5_story.html?noredirect=on&utm_term=.f2b609de3f19 (61% of covered workers are in self-funded plans). Of the states that do have these laws, they do not all require no-cost contraceptive coverage or coverage of all 18 FDA-approved methods. 83 Fed. Reg. at 57612 (acknowledging state laws do not apply to self-insured plans and vary in scope).

cost under the ACA, women are free to use the most effective methods, resulting in lower rates of unintended pregnancy, abortion, and birth among adolescents. Kost Decl. ¶¶ 7-9, 14-15, 17-19, 32; *Id*. at ¶ 25 (A long-acting reversible contraceptive (LARC) "costs nearly a month's salary or a woman working full time at the federal minimum wage"); Grossman Decl. ¶ 9 ("women now save an average of 20% annually in out-of-pocket expenses, including $248 savings for IUDs and $255 for the contraceptive pill"); Hollier Decl. ¶ 6; Ikemoto Decl. ¶ 5; Tosh Decl. ¶ 26; Nelson Decl. ¶ 30. The converse is true under the Rules. As the cost of contraception increases, women are more likely to use less effective methods, use them inconsistently or incorrectly, or not use them at all—and the result is a higher rate of unintended pregnancies. Kost Decl. ¶¶ 29, 39-42; Hollier Decl. ¶ 6; Grossman Decl. ¶¶ 8-9 ("women from advantaged groups (income over $75,000) were far more likely to actually use a LARC method when they preferred LARC"); Ikemoto Decl. ¶ 5; Jones Decl. ¶ 15; Tosh Decl. ¶ 36; Nelson Decl. ¶ 30; Rattay Decl. ¶ 7; Lytle-Barnaby Decl. ¶ 28; Skinner Decl. ¶ 20. Significantly, the risk of unintended pregnancy is greatest for the most vulnerable women: young, low-income, minority women, without high school or college education. IOM Report at 103; Kost Decl. ¶ 45.

The consequences of unintended pregnancies felt by the States and their residents are both immediate and far-reaching. Over half of unintended pregnancies end in miscarriage or abortion. Tosh Decl. ¶ 26. For pregnancies carried to term, intervals between pregnancies of less than 18 months are associated with poor obstetric outcomes, including maternal health problems, premature birth, birth defects, low birth weight, and low mental and physical functioning in early childhood. Kost Decl. ¶ 42; Grossman Decl. ¶ 7; Jones Decl. ¶ 18; Nelson Decl. ¶ 30; Tosh Decl. ¶ 25; Rabinovitz Decl. ¶¶ 4-5. All these outcomes—whether miscarriages, abortions, or live births (particularly high-risk births)—cost the States in both the short-term and long-term. The States are burdened not only with funding a significant portion of the medical procedures associated with unintended pregnancies and their aftermath, Kost Decl. ¶¶ 54, 61 (California), 69 (Connecticut), 77 (Delaware), 85 (District of Columbia), 93 (Hawaii); 101 (Illinois), 109 (Maryland), 117 (Minnesota), 125 (New York), 133 (North Carolina), 141 (Rhode Island), 149 (Vermont), 157 (Virginia), 165 (Washington); Tosh Decl. ¶¶ 26-28; Rattay Decl. ¶ 6; Peterson

Decl. ¶ 6; Welch Decl. ¶ 13; Wilson Decl. ¶ 5; Tobias Decl. ¶ 4; Zerzan-Thul Decl. ¶¶ 10-11; Alexander-Scott Decl. ¶ 3; Maisen Decl. ¶11; Moracco Decl. ¶ 5; Gobeille Decl. ¶¶ 6-7, but also with the lost opportunities for affected women to advance professionally and educationally and to contribute as taxpayers. Kost Decl. ¶ 44; Hollier Decl. ¶ 5; Arensmeyer Decl. ¶ 4; Nelson Decl. ¶ 31; Bates Decl. ¶¶ 3, 6. These lifelong consequences for women and their families are severe; for the States, such harm is irreparable because it cannot be undone with a successful result at the end of the litigation. The only way to avoid this disruption is to ensure that the ACA's guarantee of no-cost contraceptive coverage is maintained while this litigation proceeds. *Leigh v. Salazar*, 677 F.3d 892, 902 (9th Cir. 2012) ("Preliminary injunctions normally serve to prevent irreparable harm by preserving the status quo" pending adjudication of the action on the merits).

Second, if the Rules are not enjoined, the States are likely to face increased costs of providing contraception to their residents. This is particularly true in states, like Virginia and Minnesota, which do not have a contraceptive equity laws, and states with contraceptive equity laws that are not equivalent to the ACA contraceptive-coverage requirement, like those laws in North Carolina, Hawaii, and Rhode Island. Whorley Decl. ¶ 8; Alexander-Scott Decl. ¶ 3; Anderson Decl. ¶ 4; 83 Fed. Reg. at 57612 (acknowledging that of the states with contraceptive equity laws, "only four states have laws that match the federal requirements in scope"). Unlike other states, where the effect of the Rules is limited to patients covered under self-insured plans, Nelson Decl. ¶ 12, in Virginia there is no state requirement that insurance plans provide no-cost contraceptive coverage. Whorley Decl. ¶ 8. Many women who lose coverage in Virginia will turn to Plan First, Virginia's limited-benefit family-planning program, which only provides contraceptive coverage for women in families below 200% of the federal poverty level. *Id.* at ¶¶ 3, 4, 10. The increase in Plan First enrollees—and in women seeking services from hospital systems that are Plan First providers—will cause fiscal harm to Virginia. *Id.* at ¶¶ 10, 11.

Although Virginia and other states like it will be particularly impacted, all states will face rising costs. In California, women (and men) are eligible to enroll in the state's Family Planning, Access, Care, and Treatment (Family PACT) program if they have a family income at or below 200% of the federal poverty level, no other source of family planning coverage, and a medical

necessity for family planning services. Cantwell Decl. ¶ 7; Tosh Decl. ¶¶ 23, 29; Nguyen Decl. ¶ 10. Eligible women are likely to seek services from Family PACT when their employers slash coverage for contraception from the benefits of self-funded plans. Cantwell Decl. ¶¶ 15, 16; Tosh Decl. ¶ 34; Rabinowitz Decl. ¶¶ 3, 8-10; Nguyen Decl. ¶ 13. The same is true in Connecticut, Vermont, New York, Maryland, Minnesota, Washington, and Delaware, as well as in other states that have state family planning programs. Kost Decl. ¶¶ 63-166. The government—including the States—will be left to pick up the tab.[23] Cantwell Decl. ¶ 17; Tosh Decl. ¶¶ 34-35; Nelson Decl. ¶¶ 15-16, 35; Rattay Decl. ¶ 8; Lytle-Barnaby Decl. ¶ 28; Skinner Decl. ¶¶ 21-22; Tobias Decl. ¶ 5; Gallagher Decl. ¶¶ 18-19; Zerzan-Thul Decl. ¶ 8; Navarro Decl. ¶ 14; Anderson Decl. ¶ 4; Maisen Decl. ¶ 11; Kreidler Decl. ¶ 15; Gobeille Decl. ¶ 6; Peterson Decl. ¶ 6. Indeed, the Rules direct women to Title X clinics; however, not only are these clinics designed for low-income women and lack the capacity to serve a new patient population, but in California, all Title X clinics screen for Family PACT and in New York Title X clinics are the same clinics that provide the state's Family Planning Program services. Cantwell Decl. ¶ 18; Tobias Decl. ¶ 5. Thus, directing women to Title X means more women will be enrolled in the state's programs.

Even a slight uptick in such costs will cause irreparable harm to the States. *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 724 (9th Cir. 1999) ("magnitude of the injury" is not determinative); *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014) (court erred by attempting to evaluate the severity of the harm, rather than determining whether the harm was irreparable).

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST FAVOR ISSUING AN INJUNCTION TO PRESERVE THE STATUS QUO

The balance of the equities and the public interest support issuing a preliminary injunction. *See Winter*, 555 U.S. at 24; *California*, 2018 WL 6566752, at *14-15 (affirming this Court's

[23] A good example is Maryland, where, the Medicaid Family Planning Waiver program provides contraceptive coverage to women up to 200% of the federal poverty level. In fiscal year 2016, the average monthly enrollment was 12,852 individuals. Women in low-income jobs whose employers exempt themselves from contraceptive coverage may qualify for this program, thereby shifting the costs of contraceptives for these women to the State. Nelson Decl. ¶¶ 22-25. In addition, Maryland's Medicaid and Children's Health Insurance Plans provide coverage for women up to 138% of the federal poverty level and for children to 300% of the federal poverty level. Eligible women whose employers avail themselves of this broad exemption may turn to these programs for contraceptive coverage for themselves and/or their children, thereby shifting the costs of their care to the State. Nelson Decl. ¶¶ 26-28.

conclusion that the balance of equities and public interest weigh in favor of an injunction). Particular attention should be given to preserving the status quo. *Chalk v. U.S. Dist. Court Cent. Dist. Cal.*, 840 F.2d 701, 704 (9th Cir. 1988). Here, the status quo is the ACA's contraceptive-coverage requirement, and the carefully and deliberately crafted accommodation and exemptions. *Dep't of Parks & Recreation for State of Cal. v. Bazaar Del Mundo Inc.*, 448 F.3d 1118, 1124 (9th Cir. 2006) (status quo is "the last uncontested status that preceded the parties' controversy").

Absent a preliminary injunction, the Rules will take effect on January 14, 2019, immediately enabling an employer to drop ACA-required contraceptive coverage upon 30-days notice that it is invoking the accommodation process, upon 60-days notice that it is revoking its use of the accommodation process, or when a new plan year begins. 26 C.F.R. § 54.9815-2713A; 29 C.F.R. § 2590.715-2713A(a)(5); 45 C.F.R. § 147.131(c)(4); 26 C.F.R. § 54.9815-2715(b); 29 C.F.R. § 2590.715-2715(b); 45 C.F.R. § 147.200(b). And because an employer need not notify the federal government of its decision, without a preliminary injunction, the parties to this litigation will not know which employers stop providing the required coverage, thus impeding the Court from preventing harm once the rules take effect.

The Ninth Circuit found that the record supported the "potentially dire public health and fiscal consequences as a result of a process as to which [plaintiffs] had no input" and highlighted the public interest in access to contraceptive care. *California*, 2018 WL 6566752, at *15. And this Court has recognized the importance of the public interest at stake—"the interest in ensuring coverage for contraception and sterilization services" as provided by the ACA, in previously issuing a preliminary injunction. Dkt. No. 105:15-16; *California*, 2018 WL 6566752, at *14.

While the immediate enforcement of the Rules will inflict grave and lasting harm upon the States and their residents, Defendants will suffer little harm if the Rules are enjoined. The ACA's accommodation and exemptions would still be available as this matter is litigated to its conclusion. *League of Wilderness Defenders/Blue Mountains Biodiversity Project. v. Connaughton*, 752 F.3d 755, 765 (9th Cir. 2014) (the balance of equities generally tips in favor of plaintiffs when the harms they face if an injunction is denied are permanent, while the harms defendants face if an injunction is granted are temporary).

As the Ninth Circuit held, the public interest is served by compliance with the APA. *California*, 2018 WL 6566752, at *14 (citing *Alcaraz*, 746 F.2d at 610). As argued above, the Final Rules violate the APA. The Court should grant the preliminary injunction.

IV. THE COURT SHOULD ISSUE A NATIONWIDE INJUNCTION

A nationwide injunction is necessary to ensure complete relief to the plaintiff States. Residents of the States work for out-of-state employers, including in states that are not parties to this lawsuit. Pomales Decl. ¶ 9. Some plaintiff States are home to students who are on their parents' employer-sponsored health plans, and those parents and employers are out-of-state. Pomales Decl. ¶ 9; Childs-Roshak Decl. ¶ 16.[24] Additionally, reproductive healthcare providers in plaintiff States serve residents of other states who travel to receive care. Tosh Decl. ¶ 33; Custer Decl. ¶ 8. These scenarios demonstrate that this Court cannot simply draw a line around the plaintiff States and impose an injunction only as to those States to ensure complete relief.

Additionally, in compliance with the Ninth Circuit's opinion, the States have attached additional evidence demonstrating that absent a nationwide injunction, irreparable harms will be felt outside the plaintiff States. *California*, 2018 WL 6566752, at *17 (Nationwide injunctive relief appropriate where evidence shows "nationwide impact or sufficient similarity to plaintiff states"). For instance, every State has hundreds of thousands of women who have benefitted from the contraceptive-coverage requirement and are at risk of losing this benefit. Dkt. Nos. 170-1, 170-2. The plaintiff States have submitted evidence demonstrating additional harms to their own States and harm to other States. Pomales Decl. ¶¶ 10-11; Dutton Decl. ¶¶ 27-28; *see supra* at 21, 23.

CONCLUSION

The States respectfully request that the Court grant this motion for preliminary injunction and enjoin implementation of the Exemption Rules.

[24] *See also* National Center for Education Statistics, https://nces.ed.gov/programs/digest/d17/tables/dt17_309.20.asp?current=yes (reflecting, for example, that California is home to 25,000 out-of-state students; New York to 35,000).

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Respectfully submitted,

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