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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,
Defendants-Intervenors.

4:17-cv-05783-HSG

STATES' REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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

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INTRODUCTION

At the heart of the States' motion is a Congressional enactment: the Women's Health Amendment to the Patient Protection and Affordable Care Act (ACA), which gave women across the country guaranteed access to preventive healthcare. Congress sought to ensure that women receive full and equal health coverage appropriate to their medical needs. To that end, the Women's Health Amendment—or the statutory "Mandate," as Defendants and Intervenors call it—provides that health plans "shall" provide women's "preventive care and screenings" without "impos[ing] any cost sharing." 42 U.S.C. § 300gg-13(a)(4). The only delegation of authority to Defendants—through the Health Resources and Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services (HHS)—was limited to determining the *scope* of those additional preventive services (and not *who* must provide those services). *Id*. On two separate occasions, Congress considered but declined to amend the ACA to permit employers and insurers to deny coverage based on religious beliefs or moral convictions.

The States do not bring an "all-or nothing" choice to this Court. On the contrary, all that the States seek is for the federal government to "ensur[e] that women covered by [religious employers'] health plans receive full and equal health coverage, including contraceptive coverage," while protecting the religious beliefs of employers. *Zubik v. Burwell*, 136 S.Ct. 1557, 1559-60 (2016). The new rules fail the directives of *Zubik*, and therefore they should be enjoined.

ARGUMENT

I. THE STATES HAVE STANDING[1]

Only the Little Sisters challenge the States' standing. Dkt. No. 197 at 9. However, the Ninth Circuit concluded that the Rules "will first lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states." *California*, 2018 WL 6566752 at *6; *see also e.g.*, Kost Decl. ¶¶ 54, 61, 69, 77, 85, 93; Whorley Decl. ¶¶ 8, 10, 11; Cantwell Decl. ¶¶ 17, 18; Tosh Decl. ¶¶ 26-28, 34; Nelson Decl. ¶ 15; Rattay Decl. ¶¶ 5, 7, 8.

[1] Defendants also reassert their argument that venue is improper. Dkt. No. 198 at 10. The Ninth Circuit squarely concluded that "venue is proper in the Northern District of California." *California v. Azar*, --F.3d -- , 2018 WL 6566752 at *4 (9th Cir. Dec. 13, 2018).

"Just because a causal chain links the harm to the states does not foreclose standing." *California*, 2018 WL 6566752 at *6. Further, the "states need not have already suffered economic harm" and there is "no requirement that the economic harm be of a certain magnitude." *Id*. The Rules themselves predict tens of thousands of women will lose contraceptive coverage, and suggest that women seek coverage through state-funded programs. *Id*.; *see also* 83 Fed. Reg. 57,536, 57,548 (Nov. 15, 2018); *id*. at 57,551 n.26; *id*. at 57,578; 83 Fed. Reg. 57,592, 57,605 (Nov. 15, 2018); *id*. at 57,608. Thus, as the Ninth Circuit has already concluded, the States have standing. *California*, 2018 WL 6566752 at *6-8.[2]

II. THE STATES ARE LIKELY TO SUCCEED ON THE MERITS

A. The Rules Are Not in Accordance with the Women's Health Amendment

The Women's Health Amendment requires that health plans provide preventive services to women without cost sharing. 42 U.S.C. § 300gg-13(a)(4). While Congress did not provide a fixed list of covered preventive services, it "mandated" that preventive services according to recommendations of medical experts at HRSA "shall" be provided. *See 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)").[3]

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."[4] Congress delegated to HRSA the responsibility to develop "comprehensive guidelines" "for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4).[5] Thus, HRSA's limited role is to craft Guidelines

[2] Furthermore, the States have "standing to seek judicial review of governmental action that affects the performance of [their] duties." *Central Delta Water Agency v. United States*, 306 F.3d 938, 950 (9th Cir. 2002); Kish Decl. ¶¶ 12-14; Jones Decl. ¶¶ 10, 23-24.

[3] *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").

[4] About HRSA, https://www.hrsa.gov/about/index.html (last visited Jan. 5, 2019). Notably, HRSA's expertise is in *providing* access to medical care; it has no expertise in crafting religious or moral exceptions to such care.

[5] The Women's Health Amendment does not attempt to enumerate the *specific* services or treatments within the broad category of "preventive services." It would be untenable both legally and practically to expect Congress—a body of non-medically trained individuals—to expressly

carrying out the purpose of the Women's Health Amendment and determining the scope of preventive care services. HRSA does not have the authority to decide which employers are exempt from providing such preventive care. Having included all FDA-approved contraceptives within women's "preventive care"—first, based on the Institute of Medicine's recommendations in 2011 and then, based on American College of Obstetricians and Gynecologists' recommendations in 2016—HRSA cannot now declare that some employers need not provide that statutorily-required care. *See Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001) (agency may not issue regulation unless it has "textual commitment of authority" to do so); *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("an agency literally has no power to act . . . unless and until Congress confers power upon it").

Defendants argue that pursuant to the Women's Health Amendment, they have the authority to "narrow the scope of the Mandate." Dkt. No. 198 at 18, 20; 83 Fed. Reg. at 57,540 (claiming that Defendants have broad authority "to administer these statutes.") This is not an accurate reading of the statute; when Congress wants to grant broad rulemaking authority to an agency, it does so.[6] It did not here. *See City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) ("Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge agency discretion").[7] Defendants' interpretation also runs afoul of

do so, particularly in an evolving discipline such as medicine, where new treatments and therapies are developed and added (and sometimes deleted from or rendered obsolete) to the physician's toolkit every year. HRSA itself notes that since the Guidelines were originally established in 2011 "there have been advancements in science and gaps identified in the existing guidelines." *See* https://www.hrsa.gov/womens-guidelines-2016/index.html (last visited Jan. 7, 2019).

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

[7] Defendants' unreasonably place undue reliance on the phrase "as provided for" and specifically on the word "as" to confer authority to HRSA to create Rules permitting categories of employers to exempt themselves from the Women's Health Amendment. Dkt. No. 198 at 18. As

separation-of-powers principles and, practically speaking, would render Defendants' authority limitless. *Am. Trucking*, 531 U.S. at 485 (agency "may not construe the statute in a way that completely nullifies textually applicable provisions meant to limit its discretion").[8] Under their interpretation, HRSA—and by extension HHS—could exempt all employers from the Women's Health Amendment altogether because HRSA and HHS have the authority to "narrow the scope" of who must abide by the statutory requirements. That assertion is not supported by the plain text of the statute or the legislative history; indeed, such a notion would defeat the statute itself.

Defendants point out that grandfathered plans are excluded from the contraceptive-coverage requirement, as if this somehow weakens the statutory requirement. Dkt. No. 198 at 4, 23; *see also* Dkt. No. 197 at 3, 5, 12, 14; Dkt. No. 199 at 9 n.6. Congress expressly considered which employers to exempt under grandfathered plans, and it did not choose to exempt employers with religious or moral objections. This Court should decline to add statutory exemptions beyond what Congress expressly provided. *See Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993) ("*Expressio unius est exclusio alterius*"); *United States v. Johnson*, 529 U.S. 53, 58 (2000) ("When 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.").[9]

Notably, both before and after the implementation of the ACA, Congress considered legislation to add broad exemptions to the contraceptive-coverage requirement and in every

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one court explained, "'as' is used in anticipation of HRSA issuing guidelines and not to the conclusion that the ACA implicitly provides the Agencies with the authority to create non-statutory exemptions." *Pennsylvania*, 281 F. Supp. 3d at 579.

[8] *See also Schein v. Archer & White Sales*, -- S. Ct. --, 2019 WL 122164, at *5 (Jan. 8, 2019) (the parties and the Court "may not engraft [their] own exceptions onto the statutory text.").

[9] Furthermore, grandfathering these plans was 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); *Hobby Lobby*, 134 S. Ct. at 2801 ("[T]he grandfathering provision is 'temporary, intended to be a means for gradually transitioning employers into mandatory coverage.'") (Ginsburg, J., dissenting); *see also* Kaiser Family Foundation, Employer Health Benefits 2017 Annual Survey 207 (Sept. 19, 2017), https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/ (last visited May 21, 2018) (showing decline in percentage of workers enrolled in a grandfathered plan).

instance, the legislation failed. *See, e.g.*, 158 Cong. Rec. S539 (Feb. 9, 2012) (S. Amdt. 1520, Section (b)(1)), 112th Congress (2011-2012) (arguing 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").[10] Congress did provide a specific statutory exemption for those who have a religious objection to participating in aid-in-dying procedures (42 U.S.C. § 18113), but did not adopt such an exemption to contraceptive coverage. Thus, this Court need not speculate about whether Congress intended to allow broad religious or moral objections; it did not. This Court should reject Defendants' attempt to accomplish by regulation what Congress itself expressly declined to do.

B. The 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 (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. Kost Decl. ¶ 26 (without coverage, contraceptives cost $50 per month or upwards of $600 per year); *id*. at ¶ 25 (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); Grossman Decl. ¶¶ 6, 9; Childs-Roshak Decl. ¶ 25. Women who lose contraceptive coverage will 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. Ikemoto Decl. ¶ 5; Kost Decl. ¶¶ 16, 41 (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

[10] *See also Hobby Lobby*, 134 S. Ct. at 2775 n.30; *id.* at 2789-2790 (Ginsburg, J., dissenting); 159 Cong. Rec. S2268 (Mar. 22, 2013).

to switch to a less expensive, but less effective, contraceptive method given the requirement to pay out-of-pocket. Kost Decl. ¶ 27; Grossman Decl. ¶¶ 8-9. These numerous steps 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. Moreover, it is directly contrary to Congress's intention to remedy the problem that women across the country were paying significantly more out-of-pocket for preventive care and thus often failed to seek critical preventive services. *Priests for Life*, 772 F.3d at 235; *Burwell v. Hobby Lobby*, 134 S. Ct. 2751, 2785-2786 (2014) (Kennedy, J., concurring).

Defendants largely fail to respond to this clear statutory violation, except to blithely contend that the Rules do not "impose affirmative barriers on access to contraception." Dkt. No. 198 at. 20. Congress was clear in its command that HHS not take action impeding access to healthcare. Undeniably, these regulations will result in women losing healthcare coverage—which even Defendants admit (83 Fed. Reg. 57,581)—and as a result, women losing coverage will need to seek out that care from somewhere else—a fact that Defendants also admit and that the Ninth Circuit recognized (*id* at 57,548, 57,551; *id* at 57,605, 57,608; *California*, 2018 WL 6566752 at *7). Defendants cannot ignore the statutory command of Congress.

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

The 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. The U.S. Equal Employment Opportunity Commission has already concluded that offering coverage for preventive prescription drugs and services but not contraception constitutes discrimination on the basis of sex. *See* Commission Decision on Coverage of Contraception, EEOC, 2000 WL 33407187 (Dec. 14, 2000).

Defendants assert that the Rules do not violate the ACA's nondiscrimination requirement because any discrimination "flow[s] from the statute," not from the Rules. Dkt. No. 198 at 19; *see also* Dkt. No. 199 at 11. This logic turns the statutory nondiscrimination requirement on its head. Congress expressly provided that an individual shall not be "excluded from participation

in, 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. Defendants' Rules inflict the very exclusion, denial, and discrimination that § 18116 prohibits. The Rules single out a healthcare service utilized *exclusively* by women and permit employers to unilaterally exempt themselves from providing that service. There is no requirement that the States produce a "smoking gun" piece of evidence demonstrating invidious intent, as Defendants suggest. Dkt. No. 198 at 19. It is sufficient that the Rules on their face broadly permit employers to exempt themselves from abiding by a statutory requirement, thereby denying women full and equal participation in the health plan, in direct violation of the nondiscrimination statute.

D. The Broad Religious Exemption Rule is Not Mandated by RFRA

Relying in large part on *Hobby Lobby*, Defendants argue that the Religious Exemption Rule is necessary to ensure compliance with the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. §§ 2000bb-2000bb-4.[11] In *Hobby Lobby*, the Court held that the contraceptive-coverage requirement could not be applied to closely held for-profit companies that objected on religious grounds to providing contraceptive coverage. But, the Court emphasized that the effect of its decision "on the women employed by [Hobby Lobby] would be precisely zero" because the government could expand an already existing accommodation that relieved objecting religious nonprofit employers from the contraceptive-coverage requirement while still ensuring that the affected women received legally required coverage. 134 S. Ct. at 2760, 2763. The Court did not equate closely held organizations with churches and did not require that those entities be entirely exempt from the contraceptive-coverage requirement. Thus, Defendants' Rules go far beyond what the Supreme Court contemplated or required. *See also Zubik*, 136 S. Ct. at 1559-60.[12]

[11] Defendants are not entitled to deference in their RFRA analysis. *See Gonzales v. Oregon*, 546 U.S. 243, 258-259 (2006).

[12] Little Sisters' argument that rules cannot distinguish between churches and other religious objecting entities, like Hobby Lobby, is erroneous. Dkt. No. 197 at 10-11. While *Larson* forbids denominational preference; it does not require—or even hint—that non-churches must be treated precisely the same as houses of worship. *Larson v. Valente*, 456 U.S. 228, 246 (1982). Indeed, such a requirement would have lasting consequences far beyond this case.

In essence, Defendants assert that the accommodation on which *Hobby Lobby* relied is itself a violation of RFRA. In so doing, they insist that employers have a right not only to be relieved of the obligation to provide contraceptive coverage themselves, but also to prevent the government from arranging for third parties to fill the resulting gap. If accepted, that claim would deny tens of thousands of women the health coverage to which they are entitled under federal law, and subject them to the very harms that the statute is designed to eliminate.[13] The States do not question the sincerity of religious employers' beliefs. But as eight courts of appeals have held, Defendants' RFRA argument stretches too far. *See* Order Granting States' Preliminary Injunction, Dkt. No. 105 at 27 n.17 (summarizing cases); *see also Pennsylvania*, 281 F. Supp. 3d at 579-581 (Rules not required under RFRA where prior accommodation process did not impose substantial burden). To the extent RFRA applies, Defendants must harmonize RFRA with the Women's Health Amendment so as not to run afoul of congressional intent. They cannot simply prioritize one federal statute over the other. *Ass'n of Am. R.R. v. S. Coast Air Quality Mgmt. Dist.*, 622 F.3d 1094, 1097 (9th Cir. 2010) (when two federal laws purportedly conflict, courts must strive to harmonize the two laws). In our diverse and pluralistic nation, the right to the free exercise of religion does not encompass a right to insist that the government take measures that "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *Hobby Lobby*, 134 S. Ct. at 2787 (Kennedy, J., concurring).

As this Court previously held, it is "likely that the prior framing of the religious exemption and accommodation permissibly ensured [ ] protection" for employers' religious beliefs. Dkt. No. 105 at 27. This Court explained that it "view[ed] as likely correct the reasoning of the eight Circuit Courts of Appeal . . . which found that the procedure in place prior to the 2017 IFRs did

[13] Such a claim has far-reaching implications. Under RFRA, an entity must demonstrate a "substantial" burden; a burden does not rise to the level of being "substantial" when it places a de minimus burden on an adherent's religious exercise. This is particularly important given our modern administrative state. Here, the accommodation permits an employer to avoid providing, paying for, referring, contracting, or facilitating access to contraception. 78 Fed. Reg. 39,870, 39,878 (July 2, 2013). To obtain the accommodation, a religious entity need only provide a letter or two-page form notifying the government or its insurer of its religious objections to providing contraceptive coverage for women. All subsequent action is taken by third parties.

not impose a substantial burden on religious exercise." *Id.*[14] The broad religious exemption contained in the Rules is not required under RFRA.

E. The Rules Violate the APA Procedural Requirements

The Rules violate the APA for failing to provide adequate notice-and-comment. Before promulgating a regulation, the APA requires agencies to first publish in the Federal Register a notice of proposed rulemaking and then give the public an opportunity to participate in the rulemaking by submitting written comments. 5 U.S.C. § 553. Defendants skirted this deliberative rule-making process by initially promulgating these rules as Interim Final Rules, making them immediately effective. Then, Defendants sought comment on those already-effective rules, and received over 100,000 comments. Notwithstanding the volume of comments, Defendants issued Final Rules that were nearly identical to the Interim Final Rules that they initially promulgated.

Defendants ask this Court to interpret the APA as allowing them to "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 (3d Cir. 1979). If this Court adopts Defendants' interpretation, it would permit an agency to skirt the requirement for advance notice and comment by simply issuing an interim final rule, making the new rules effective immediately, and then accepting post-promulgation comment. Agencies would no longer have any incentive to issue a notice of proposed rulemaking, or to seriously consider submitted comments since the rules will already be in effect. Following this formula, agencies will suffer consequences only if a member of the public rushes to court and obtains an injunction. This Court should not incentivize

[14] It is not the States' position, as Defendants' claim, that the prior framework was improper or unlawful. Throughout this litigation, the States have asserted that the prior regulatory framework appropriately adheres to the Women's Health Amendment while also complying with RFRA. Under the carefully crafted prior system, Defendants provided a narrow automatic exemption from the contraceptive-coverage requirement for "'churches, their integrated auxiliaries, and conventions or associations of churches,' as well as 'the exclusively religious activities of any religious order,'" a category of employers defined in the Internal Revenue Code. *Hobby Lobby*, 134 S. Ct. at 2763 (quoting 26 U.S.C. § 6033(a)(3)(A)(i) and (iii)); *see* 45 C.F.R. 147.131(a). That exemption was adopted "against the backdrop of the longstanding governmental recognition of a particular sphere of autonomy for houses of worship." 80 Fed. Reg. 41,325 (July 14, 2015); *see* 76 Fed. Reg. 46,623 (Aug. 3, 2011). The States have no objection to this narrowly crafted exemption and do not seek to "sweep [it] away" as the Defendants assert. Dkt. No. 198 at 2.

agencies to thwart the will of Congress and deprive the public of its right to properly noticed rulemaking. The solution for Defendants was easy: This Court concluded that Defendants did not have good cause to bypass notice and comment; Defendants could have immediately—on December 21, 2017—withdrawn the IFRs and issued Notices of Proposed Rulemaking and thereafter proceed with the Notice of the Final Rules. Defendants provide no explanation why such a solution is not feasible or is contrary to law. Nor do they cite any authority that permits them to simply promulgate a final rule, despite judicial conclusions that the nearly identical IFRs were improperly issued.

Moreover, contrary to Defendants' assertions that they made "numerous changes in response to the comments" (Dkt. No. 198 at 11), by their own admissions, the Rules are effectively the same. *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). Indeed, Defendants made only minor technical changes. 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593. As outlined below, their Final Rules, like the interim rules, failed to account for the numerous healthcare consequences that will befall women and then failed to respond to comments pointing out such consequences. *See infra* at 11.

Intervenors contend that the States' challenge would invalidate all of the previous IFRs implementing the ACA. Dkt. No. 197 at 19. Not so. Because not all of the previous IFRs are before this Court, it need not consider the circumstances of their rulemaking. *See* Dkt. No. 170.

F. The Rules Are Arbitrary and Capricious

After Congress enacted the ACA, Defendants diligently pursued providing cost-free contraceptive coverage for American women. This pursuit was grounded in the scientific conclusions of the IOM report, which found that providing no-cost access to the full range of FDA-approved contraceptive methods, as well as education and counselling about contraception, are essential to prevent unintended pregnancies and the consequent negative impacts on both

mothers and children—a conclusion that was reaffirmed in 2016 by HHS, and remains the standard today under HHS's own Guidelines.[15]

The Rules summarily reject the agencies' prior evidence-based policy and now make contraceptive coverage optional. *See* 83 Fed. Reg. at 57,593-94 (leaving the "moral" objection broad and virtually limitless, thereby permitting most employers to exempt themselves). 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 1112, 1119 (D.C. Cir. 2010) (holding that an agency that neglects to explain its departure from established precedent acts arbitrarily and capriciously). Defendants and Intervenors accuse the States of simply not liking Defendants' conclusion, but in fact Defendants fail to recognize the serious reliance interests at stake. Those interests require Defendants to provide a more "detailed justification" of its change of policy. *F.C.C.*, 556 U.S. at 515. A detailed justification is also required here because the new policy "rests upon factual findings that contradict those which underlay its prior policy." *Id*.

Defendants and Intervenors contend that the Rules' discussion of the abrupt change of course is adequate. Dkt. No. 198 at 14-15; Dkt. No. 199 at 8. But the Rules provide no new facts and no meaningful discussion that would discredit their prior factual findings establishing the beneficial and essential nature of contraceptive healthcare for women, or for their creation of an entirely new Rule—a broad moral exemption rule. As Defendants acknowledge, the Rules contain a mere four pages addressing the reversal of direction. Dkt. No. 198 at 14; 83 Fed. Reg. at 57,552–56. That discussion restates some public comments questioning the importance of contraception and then declines to "take a position on the variety of empirical issues." 83 Fed. Reg. at 57,555; *see also id*. at 57,556. Notwithstanding this shallow foundation, the Rules summarily conclude that "significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when [they] declined to extend the exemption to certain objecting organizations and individuals." *Id*. at 57,555.

[15] *See* https://www.hrsa.gov/womens-guidelines/index.html; https://www.hrsa.gov/womens-guidelines-2016/index.html (last visited Jan. 6, 2019).

F.C.C. requires Defendants not only to explain their current position, but to explain *why* they have changed from their prior position, including why they added an entirely new "moral" exemption rule. Breezily declaring that there is "uncertainty and ambiguity" is insufficient. Given the overwhelming evidence of the importance of contraceptive coverage, Defendants cannot make that coverage essentially optional without a careful, detailed consideration of relevant facts and evidence. Indeed, had Defendants done a careful, detailed consideration of the relevant facts and evidence, they would not have issued such broad exemptions, particularly given Defendants' own prior findings about the need for coverage. 77 Fed. Reg. 8,725, 8,728 (2012); Supplemental Br. for Resp'ts at 1, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam) (No. 14-1418), 2016 WL 1445915, at *1. Defendants object that the States improperly rely on declarations rather than the administrative record. Dkt. No. 198 at 16. But the importance, reliability, and efficacy of contraceptives has been clearly established by Defendants themselves over the many years they required the provision of contraceptive coverage.[16]

Defendants also minimize the effect of the Rules, by stating that the contraceptive mandate remains in effect. Dkt. No. 198 at 14. This ignores that any employer could claim a "moral objection" by simply ceasing to provide coverage—thereby transmuting contraceptive coverage from a requirement into an option. Order Granting Preliminary Injunction, Dkt. No. 105 at 25-26. The Rules demonstrate an awareness of their change in policy yet fail to recognize the consequences of that reversal of course or to provide a sufficiently reasoned explanation for "why [they] deemed it necessary to overrule [their] previous position." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). As a result, the Rules are arbitrary, capricious, and "cannot carry the force of law." *Id*. at 2127.

III. ISSUING AN INJUNCTION TO PRESERVE THE STATUS QUO WOULD PROPERLY BALANCE THE EQUITIES AND SERVE THE PUBLIC INTEREST

While prior ACA regulations accommodated sincere religious beliefs and ensured full and equal health coverage for women—and the Supreme Court suggested such an approach (*Zubik*,

[16] *See, e.g.*, 76 Fed. Reg. at 46,623 (recognizing the need to extend "any coverage of contraceptive services under the HRSA Guidelines to as many women as possible"); 78 Fed. Reg. at 39,872–73 (discussing many benefits of contraception for women).

136 S. Ct. at 1560)—the Rules do not attempt to do both, but plainly prioritize one over the other. As the Ninth Circuit agreed, the States have demonstrated irreparable harm, warranting injunctive relief. *California*, 2018 WL 6566752, at *15. An injunction will prevent the immediate harm, including the "potentially dire public health and fiscal consequences" from curtailing the important public interest of access to contraceptive care. *Id*. This Court, too, has recognized the important public interest of "ensuring coverage for contraception and sterilization services" reflected in the ACA. Dkt. No. 105 at 15-16; *California*, 2018 WL 6566752, at *14.

In the face of judicial recognition of the important public interest at stake and widespread harm that would result from these massively expansive new exemptions, the Defendants and Intervenors fail to demonstrate that the public interest will be harmed by enjoining their effort to upend the carefully and deliberately crafted accommodation and exemption system currently in place. In fact, the Ninth Circuit seemed to question Defendants' allegations of purported harm given that Defendants had agreed to stay the district court proceedings rather than proceed on the merits, to enable a speedier resolution on the question of the Rules' legality. *California*, 2018 WL 6566752, at *11 n.5. Certainly these specific Intervenors will suffer no harms because they already have obtained permanent injunctions barring enforcement against them. *Little Sisters v. Azar*, 13-cv-02611 (D. Colo. May 29, 2018) (granting stipulated permanent injunction); Dkt. No. 199 at 4. And, the Defendants have stipulated to several other injunctions, including one that permits future objectors to join. Dkt. No. 197 at 7. Given that the Defendants' purported reason for their Rules was based on resolving ongoing litigation, it is disingenuous for them to claim additional employers will be harmed by an injunction maintaining the status quo when they are actively stipulating to permanent injunctions with those litigating entities. Simply put, the Defendants have offered nothing to cast doubt on the urgent need for a preliminary injunction.

IV. A NATIONWIDE INJUNCTION IS NECESSARY TO REDRESS THE INJURY SHOWN

The Ninth Circuit did not categorically prohibit nationwide injunctions and certainly did not prohibit them in this case. *California*, 2018 WL 6566752 at *15-17. Rather, the Court instructed that evidence was necessary to demonstrate the appropriateness of nationwide relief. *Id*. at *17. On the prior record, the Ninth Circuit recognized that "the record before the district court was

voluminous on the harm to the plaintiffs," but not "developed as to the economic impact on other states." *Id*. at *16. And thus, the injunction should have been "narrowed to redress only the injury shown as to the plaintiff states." *Id*. But a nationwide injunction is *not* foreclosed where there is a "showing of nationwide impact or sufficient similarity to the plaintiff states." *Id*. at *17; *see also NW Enviro. Defense Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 680-81 (9th Cir. 2007) (In the context of the APA, courts retain "broad equitable powers" "to grant any ancillary relief necessary to accomplish complete justice"). The States have heeded the Court's instruction and provided ample evidence—which is not controverted or even meaningfully discussed by any of the oppositions.

The record is now well "developed as to the economic impact on other states." *California*, 2018 WL 6566752 at *16. The record includes evidence that the Rules will have significant public health and fiscal consequences in all states. Kost Decl. ¶¶ 55-166 (Plaintiffs), 54 & Ex. B (all 50 states); Dkt. Nos. 170-1 & 170-2. Nationwide, if unable to access contraceptive coverage through their employer or university, some women would rely on publicly funded services. *Id*. Women who do not meet eligibility requirements of public programs would be at increased risk of unintended pregnancy. *Id*. Nationwide, both the immediate and long-term costs of the resulting unintended pregnancies would fall to the States. *Id*. The record before the Court provides more than ample evidence of economic impact on other States and demonstrates "sufficient similarity" to the "voluminous" evidence of harm to the Plaintiff States. *California*, 2018 WL 6566752 at *16, 17. Specifically, the record shows "sufficient similarity" in all States in terms of state spending on family planning, unmet need for publicly supported contraception across many States, and millions of dollars of public spending on unintended pregnancies. *Id*. The Women's Health Amendment was not designed to be implemented in some states and not others; this "Swiss cheese" approach runs directly counter to Congressional intent.

Under the Ninth Circuit's instructions, an injunction "must be no broader and *no narrower* than necessary to redress the injury shown by the plaintiff states." *California*, 2018 WL 6566752 at *16 (emphasis added). The Court is thus authorized to issue an injunction enjoining the Exemption Rules to "prevent the economic harm extensively detailed in the record," including a

nationwide injunction, because the record supports that scope of relief. *Id.* Just as the States have heeded the Ninth Circuit's instructions, the Court, too, should heed the instruction to issue an injunction no narrower than required to redress the injury shown by uncontroverted evidence.

The record also shows that absent a nationwide injunction, the States will not receive complete relief. Defendants fail to challenge the States' evidence showing that drawing a line around only the Plaintiff States would not fully alleviate the harm to the Plaintiff States. Absent a nationwide injunction, women (or covered dependents) in the Plaintiff States who are employed by an out-of-state employer might not continue receiving coverage. [17] Absent a nationwide injunction, students in Plaintiff States who receive healthcare on their out-of-state parents' plan would be affected by the Rules and may lose coverage. Pomales Decl. ¶¶ 9-11; Childs-Roshak Decl. ¶ 16; *e.g.*, Mot. at 25 n.24 (California is home to 25,000 out-of-state students); *see Bresgal v. Brock*, 843 F.2d 1163, 1171 (9th Cir. 1987) (district court did not abuse its discretion in granting nationwide relief where plaintiff laborers may travel to forestry jobs in other parts of the country). And Defendants have already conceded in the Rules themselves that 126,400 women *nationwide* will be negatively affected. 83 Fed. Reg. at 57,581. But, they fail to address the evidence of economic harm to the Plaintiff States resulting from increased costs if reproductive healthcare providers must serve more out-of-state residents because of the Rules. Tosh Decl. ¶ 33; Custer Decl. ¶ 8. This is a real prospect given the Rules' endorsement of these providers as an alternative to employer coverage of contraception. A nationwide injunction is required to redress demonstrated nationwide harm and to provide complete relief to the Plaintiff States.

CONCLUSION

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

[17] Significant numbers of Maryland, Virginia, Delaware, and District of Columbia residents, in particular, travel each day to jobs in neighboring states—500,000 Maryland residents, or 18% of the workforce; 353,000 Virginia residents, or 10% of the workforce; and 65,000 Delaware residents, or 16% of the workforce. U.S. Census Bureau, Out-of-State and Long Commutes: 2011, American Community Survey Reports, at 10 & tbl. 6 (Feb. 2013), https://www.census.gov/prod/2013pubs/acs-20.pdf. The District of Columbia has the highest percentage of workers—25.2% of the workforce—who commute to another state to work. *Id.*

Dated: January 8, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

Case Name: **State of California v. Health and Human Services, et al.** No. **4:17-cv-05783-HSG**

I hereby certify that on January 8, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

STATES' REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on January 8, 2019, at Sacramento, California.

Michele Warburton	*s/ Michele Warburton*
Declarant	Signature

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