JOSEPH H. HUNT
Assistant Attorney General
ALEX G. TSE
United States Attorney
MICHELLE R. BENNETT
Assistant Branch Director
JUSTIN M. SANDBERG, IL. BAR NO. 6278377
Senior Trial Counsel
MICHAEL GERARDI
CHRISTOPHER R. HEALY
REBECCA M. KOPPLIN
DANIEL RIESS
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, D.C. 20001
Telephone: (202) 514-5838
Facsimile: (202) 616-8202
Email: Justin.Sandberg@usdoj.gov
*Counsel for Federal Defendants*

**IN THE UNITED STATES DISTRICT COURT**

**FOR THE NORTHERN DISTRICT OF CALIFORNIA**

**OAKLAND DIVISION**

STATE OF CALIFORNIA, *et al.*

Plaintiffs,

STATE OF OREGON

Plaintiff-Intervenor,

v.

ALEX M. AZAR, II, Secretary of Health and Human Services, *et al.*,

Defendants,

and

THE LITTLE SISTERS OF THE POOR, JEANNE JUGAN RESIDENCE, *et al.*

Defendant-Intervenors.

Case No. 4:17-cv-5783-HSG

**DEFENDANTS' OPPOSITION TO PLAINTIFF-INTERVENOR STATE OF OREGON'S MOTION FOR PRELIMINARY INJUNCTION**

Hearing Date: August 22, 2019
Time: 2:00 p.m.
Courtroom: 2, 4th Floor
Judge: Hon. Haywood S. Gilliam, Jr.

**TABLE OF CONTENTS**

## TABLE OF AUTHORITIES

**Cases**

**Statutes**



**Regulations**

**Other Authorities**

## INTRODUCTION

Under the Patient Protection and Affordable Care Act ("ACA"), employers are required to cover, without cost sharing, preventive services for women that are recommended by guidelines supported by the Health Resources and Services Administration ("HRSA"), an agency within the Department of Health and Human Services ("HHS"). The ACA does not mention contraceptive coverage. However, HRSA issued guidelines recommending coverage of all FDA-approved contraceptives for women. The government recognized that some employers hold sincere religious objections to providing insurance coverage for some or all forms of contraception, but decided at that time to exempt only a small number of those employers—churches and their integrated auxiliaries—from the requirement. Other religious employers remained subject to the contraceptive mandate ("Mandate") and were left either to violate their sincerely held religious beliefs or to be liable for significant fines.

Years of litigation in dozens of cases followed. In *Burwell v. Hobby Lobby Stores, Inc.*, the Supreme Court held that the "contraceptive mandate imposes a substantial burden on the exercise of religion" in violation of the Religious Freedom Restoration Act ("RFRA"). 134 S. Ct. 2751, 2779 (2014). Rather than extending the exemption, however, HHS tried to "accommodate" other types of religious objectors. Its decision triggered further litigation and generated decisions in nine federal courts of appeals. Ultimately, the Supreme Court vacated those decisions and instructed the courts of appeals to give the parties time to try to resolve their differences. *See Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016).

On October 6, 2017, to address serious religious and moral objections and to conclude litigation, the Departments of HHS, Labor, and the Treasury ("the Agencies") issued interim final rules with requests for public comments ("IFRs") that kept the Mandate in place, but exempted religious and moral objectors. *See* 82 Fed. Reg. 47,792 (Oct. 13, 2017); 82 Fed. Reg.

47,838 (Oct. 13, 2017). After reviewing all the comments received on the IFRs, and making some changes in response, the Agencies promulgated final rules that superseded the IFRs. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,536 (Nov. 15, 2018) (the "Religious Exemption Rule"); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (the "Moral Exemption Rule") (collectively, "the Rules").

Oregon has now moved for a preliminary injunction that seeks to reverse this considered decision. The State demands that religious and secular groups facilitate services to which they deeply object on religious or moral grounds. Oregon contends that the Rules violate the procedural and substantive requirements of the Administrative Procedure Act ("APA"). However, the state fails to confront the implications of its position, which would apply equally to the longstanding exemption for churches and their integrated auxiliaries, and would thus expose churches to the Mandate for the first time.

Oregon's motion for a preliminary injunction should be denied. Oregon has not shown that it faces imminent irreparable harm, as demonstrated by the fact that it delayed seeking emergency injunctive relief until over five months after the Agencies promulgated the Final Rules, and because the Rules are already enjoined nationwide. The state is also not likely to succeed on the merits of any of its claims. Oregon errs in contending that the Agencies acted contrary to law by permitting only post-promulgation comments, because comments that were post-promulgation comments with respect to the enjoined IFRs are now pre-promulgation comments with respect to the Final Rules. In addition, the Rules are consistent both with the Women's Health Amendment and with other relevant ACA provisions. Furthermore, far from being arbitrary and capricious, the Agencies reasonably exercised their rulemaking authority to

protect a narrow class of sincere religious and moral objectors from being forced to facilitate practices that conflict with their beliefs. Finally, the balance of harms and public interest weigh against the Court granting preliminary injunctive relief to Oregon.

## BACKGROUND

### I. The Affordable Care Act and the Contraceptive-Coverage Mandate

The ACA requires most group health plans and health-insurance issuers that offer group or individual health coverage to provide coverage for certain preventive services without "any cost sharing requirements." 42 U.S.C. § 300gg-13(a). The Act does not specify the types of women's preventive care that must be covered. Instead, as relevant here, the Act requires coverage, "with respect to women," of such "additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration ["HRSA"]." *Id.* § 300gg-13(a)(4).

In August 2011, HRSA adopted the recommendation of the Institute of Medicine, a part of the National Academy of Sciences, to issue guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods, including oral contraceptives, diaphragms, injections and implants, emergency contraceptive drugs, and intrauterine devices. *See* 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). As a result, coverage for such contraceptive methods was required for plan years beginning on or after August 1, 2012. *See* 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011).

At the same time, the Agencies, invoking their statutory authority under 42 U.S.C. § 300gg-13(a)(4), promulgated interim-final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623; 77 Fed. Reg. at 8,725. Various religious groups urged the Agencies to expand the exemption to all religious not-for-profit organizations and other organizations with religious or moral objections to providing contraceptive coverage. *See* 78 Fed. Reg. 8,456, 8,459 (Feb. 6, 2013). Instead, in a subsequent rulemaking, the Agencies offered only what they termed an "accommodation" for

religious not-for-profit organizations with religious objections to providing contraceptive coverage. *See* 78 Fed. Reg. 39,870, 39,874-82 (July 2, 2013). The accommodation allowed a group health plan established or maintained by an eligible objecting employer to opt out of any requirement to directly "contract, arrange, pay, or refer for contraceptive coverage," *id.* at 39,874, by providing notice of its objection. The regulations then generally required the employer's health insurer or third-party administrator to provide or arrange contraceptive coverage for plan participants. *See id.* at 39,875-80.

In the case of self-insured church plans, however, coverage by the plan's third-party administrator under the accommodation was voluntary.[1] Church plans are exempt from the Employee Retirement Income Security Act of 1974 (ERISA) under section 4(b)(2) of that Act, and the authority to enforce a third-party administrator's obligation to provide separate contraceptive coverage derives solely from ERISA. The Agencies thus could not require the third-party administrators of church plans—and, by extension, many nonprofit religious organizations participating in those plans—to provide or arrange for such coverage or to impose fines or penalties for failing to provide such coverage. *See* 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

Even apart from the exemption for churches and their integrated auxiliaries, the Mandate did not apply to many employers. The ACA itself exempts from the preventive-services requirement, and therefore from any contraceptive-coverage mandate imposed as part of that requirement, "grandfathered" health plans (generally, those plans that have not made specified changes since the Act's enactment), *see* 42 U.S.C. § 18011, which cover tens of millions of people, *see* 83 Fed. Reg. 57,541 (Nov. 15, 2018) (estimating over 25 million individuals enrolled in such plans). And employers with fewer than fifty employees are not subject to the tax imposed on employers that fail to offer health coverage, *see* 26 U.S.C. § 4980H(c)(2), although such small employers that provide non-grandfathered coverage must comply with the preventive-services

[1] A church plan can include a plan maintained by a "principal purpose" organization regardless of who established it. *See Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1655-63 (2017); *see also* 29 U.S.C. § 1002(33).

requirement.

## II. Challenges to the Contraceptive-Coverage Mandate and Accommodation

Many employers objected to the contraceptive-coverage mandate. In *Hobby Lobby*, the Supreme Court held that RFRA prohibited applying the Mandate to closely held for-profit companies with religious objections to providing contraceptive coverage. The Court held that the Mandate "impose[d] a substantial burden on the exercise of religion" for employers with religious objections, 134 S. Ct. at 2779, and that even assuming a compelling governmental interest, application of the Mandate to such employers was not the least restrictive means of furthering that interest, *id.* at 2780. The Court observed that, at a minimum, the Agencies could extend the less-restrictive accommodation made available to not-for-profit employers to closely held for-profit companies with religious objections to the Mandate but not the accommodation. *Id.* at 2782. The Court did not decide, however, "whether an approach of this type complies with RFRA for purposes of all religious claims." *Id.*

In response to *Hobby Lobby*, the Agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. *See* 80 Fed. Reg. 41,318, 41,323-28. But numerous entities continued to challenge the Mandate. They argued that the accommodation burdened their exercise of religion because they sincerely believed that the required notice and the provision of contraceptive coverage in connection with their health plans made them complicit in providing such coverage, in contravention of their faith.

A circuit split developed,[2] and the Supreme Court granted certiorari in several of the cases. The Court vacated the judgments and remanded the cases to the respective courts of appeals. *See Zubik*, 136 S. Ct. 1557 (2016) (per curiam). The Court "d[id] not decide whether [the plaintiffs'] religious exercise ha[d] been substantially burdened, whether the Government ha[d] a compelling

[2] *Compare, e.g., Priests for Life v. HHS*, 772 F.3d 229 (D.C. Cir. 2014) (accommodation does not substantially burden religious exercise), *vacated and remanded*, 136 S. Ct. 1557 (2016), *with Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927 (8th Cir. 2015) (accommodation violates RFRA), *vacated by HHS v. CNS Int'l Ministries*, 136 S. Ct. 2006 (2016).

interest, or whether the current regulations [we]re the least restrictive means of serving that interest." *Id.* at 1560. Instead, the Court required that, on remand, the Courts of Appeals afford the parties an opportunity to resolve the dispute. In the meantime, the Court precluded the government from "impos[ing] taxes or penalties on [the plaintiffs] for failure to provide the [notice required under the accommodation]." *Id.* at 1561.

In response to the Supreme Court's *Zubik* order, the Agencies requested public comment to determine whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while providing a mechanism for coverage for their employees. *See* 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies received over 54,000 comments, but could not find a way to amend the accommodation to both satisfy objecting organizations and provide seamless coverage to their employees. *See* FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).[3] The pending litigation—more than three dozen cases brought by more than 100 separate plaintiffs—thus remained unresolved.

In addition, some nonreligious organizations with moral objections to providing contraceptive coverage challenged the Mandate. That litigation also led to conflicting decisions by the courts. *Compare Real Alternatives, Inc. v. Secretary, HHS*, 867 F.3d 338 (3d Cir. 2017) (rejecting challenge), *with March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015) (issuing permanent injunction against the government).

## III. The Interim Final Rules

In an effort "to resolve the pending litigation and prevent future litigation from similar plaintiffs," the Agencies concluded that it was "appropriate to reexamine" the Mandate's exemption and accommodation. 82 Fed. Reg. at 47,799. Following that reexamination, in October 2017, the Agencies issued two interim final rules, or IFRs, that requested public comments and that expanded the exemption while continuing to offer the existing accommodation as an optional alternative. The first rule expanded the religious exemption to all nongovernmental plan sponsors,

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

as well as institutions of higher education in their arrangement of student health plans, to the extent that those entities have sincere religious objections to providing contraceptive coverage. *See id.* at 47,806. The Agencies relied in part on their consistent interpretation of the preventive-services provision to convey "broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines." *Id.* at 47,794.

The Agencies acknowledged that contraceptive coverage is "an important and highly sensitive issue, implicating many different views." 82 Fed. Reg. at 47,799. But "[a]fter reconsidering the interests served by the [m]andate," the "objections raised," and "the applicable Federal law," the Agencies "determined that an expanded exemption, rather than the existing accommodation, [wa]s the most appropriate administrative response to the religious objections raised by certain entities and organizations." *Id.* The Agencies also explained that the new approach was necessary because "[d]espite multiple rounds of rulemaking," and even more litigation, they "ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations" or resolved the pending legal challenges that had divided the courts. *Id.*

The second rule created a similar exemption for entities with sincerely held moral objections to providing contraceptive coverage; unlike the religious exemption, though, this rule did not apply to publicly traded companies. *See* 82 Fed. Reg. 47,838 (Oct. 13, 2017). This rule was issued "in part to bring the [m]andate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues," *id.* at 47,844, as well as similar efforts by states. *Id.* at 47,847. The IFR further reflected the Agencies' attempts to resolve legal challenges by moral objectors that had given rise to conflicting court decisions. *Id.* at 47,843.

Invoking agency-specific statutory authority to issue interim final rules, 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92, the Agencies' use of interim final rules on three prior occasions with respect to the preventive service requirements, and the APA's general "good cause" exception, 5 U.S.C. § 553(b), the Agencies issued the IFRs without prior notice and comment.

The Agencies also solicited public comments for 60 days post-promulgation in anticipation of final rulemaking. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838.

## IV. Plaintiffs' Challenge to the IFRs, the District Court's Opinion, and the Ninth Circuit's Ruling

California and four other states sued, challenging the IFRs. They claimed that the IFRs (1) failed to comply with the APA's notice-and-comment requirements; (2) were arbitrary and capricious, an abuse of discretion, or otherwise contrary to law; (3) violated the Establishment Clause; and (4) violated the Equal Protection Clause. Am. Compl., Nov. 1, 2017, ECF No. 24, ¶¶ 116-137. The Court granted Plaintiffs' motion for preliminary injunctive relief on the first claim, issuing a "nationwide" preliminary injunction against the IFRs. Order Granting Pls.' Mot. for a Prelim. Inj., Dec. 21, 2017, ECF No. 105, at 28-29. On December 13, 2018, the Ninth Circuit affirmed the Court's decision in part and vacated it in part. *California v. Azar*, No. 18-15144, 2018 WL 6566752 (9th Cir. Dec. 13, 2018). The Ninth Circuit held that Plaintiffs had standing to challenge the IFRs because the "states show[ed], with reasonable probability, that the IFRs will first lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states." *Id.* at *6. Next, the Court of Appeals decided that the Agencies "did not have statutory authority for bypassing notice and comment" with respect to the IFRs, and that doing so was not harmless. *Id.* at *13-14. The Ninth Circuit also found this Court did not abuse its discretion in concluding that Plaintiffs had demonstrated irreparable harm and that the balance of harms tipped in their favor, though it recognized that "[p]rotecting religious liberty and conscience is obviously in the public interest." *Id.* at *14-15. But the Court of Appeals held that the injunction "must be narrowed to redress only the injury shown as to the plaintiff states." *Id.* at *16.

## V. The Final Rules

After considering, for over 11 months, the more than 110,000 comments on the IFRs, on November 15, 2018, the Agencies issued final versions of the religious exemption and the moral exemption rules. The Final Rules address the significant comments received by the Agencies.

Changes were made in response to questions and concerns raised in various comments, while the fundamental substance of the exemptions was finalized as set forth in the IFRs.

As was true of the IFRs, the final religious exemption rule is "necessary to expand the protections for the sincerely held religious objections of certain entities." 83 Fed. Reg. at 57,537. It "minimize[s] the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing." *Id.* The rule "do[es] not remove the contraceptive coverage requirement generally from HRSA's Guidelines." *Id.* What it does do is "finalize exemptions [for] the same types of organizations and individuals for which exemptions were provided in the Religious [IFR]: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals." *Id.* "In addition, the [religious exemption] maintain[s] a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators." *Id.*

In response to comments on the religious IFR, the Agencies made numerous clarifying or technical changes in the final religious exemption rule. For example, the final rule clarified the prefatory language to the exemptions "to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections." *Id.; see also id.* (listing modifications). The Agencies also "revise[d] the exemption applicable to health insurance issuers to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement." *Id.*

The final moral exemption rule continues to fulfill the purpose that it did in interim form: to "protect sincerely held moral objections of certain entities and individuals." 83 Fed. Reg. at 57,592. The Agencies considered public comments asking for the moral exemption to be expanded to publicly traded or government entities, but declined to do so. *Id*. at 57,616-19. Importantly, like the religious exemption rule, the moral exemption rule "do[es] not remove the contraceptive coverage requirement generally from HRSA's guidelines." *Id.* at 57,593. And "[t]he changes to the rule[ ] being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage." *Id.*

## VI. Plaintiffs' Second Amended Complaint and Second Motion for a Preliminary Injunction

Plaintiffs (joined by nine other states) filed a second amended complaint as well as a second motion for a preliminary injunction. Second Am. Compl., Dec. 18, 2018, ECF No. 170; States' Notice of Mot. and Mot. for Prelim. Inj., with Memorandum of Points and Authorities (Second PI Mem.), December 19, 2018, ECF No. 174. In the new complaint, Plaintiffs raised claims under the APA, the Establishment Clause, and the Equal Protection Clause. Second Am. Compl. ¶¶ 235-260. They sought a preliminary injunction of the Final Rules on their APA claims, but not their constitutional claims. *See* ECF No. 174. The court issued the preliminary injunction on January 13, 2019, enjoining the Agencies from implementing the Final Rules in the Plaintiff states. *California v. Azar*, 351 F. Supp. 3d 1267, 1300 (N.D. Cal. 2019). That decision is on appeal in the Ninth Circuit. *California v. Little Sisters of the Poor et al.*, No. 19-15072 (9th Cir. 2019).

## VII. Oregon's Intervention and the Present Motion for Preliminary Injunction

On January 7, 2019, the State of Oregon filed a Motion to Intervene, *see* ECF No. 210, which was granted by the Court on February 1, 2019. ECF No. 274. Oregon then filed its Intervenor-Complaint, ECF. No. 287, and a motion to join the Plaintiffs' preliminary injunction motion.

ECF No. 288. The Court denied this motion, because it was filed after the Court had already granted Plaintiffs' preliminary injunction motion. ECF No. 297. Oregon filed the instant Motion for a Preliminary Injunction on March 3, 2019. ECF No. 312.

## ARGUMENT

### I. The Nationwide Injunction Currently in Place and Oregon's Delay in Seeking Injunctive Relief Fatally Undermines Its Claim of Irreparable Injury.

Oregon cannot show irreparable injury because the nationwide injunction currently in place provides it with all the redress it seeks. *See Pennsylvania v. Trump*, No. 2:17-cv-4540-WB, Order, ECF No. 135 (Jan. 14, 2019). Indeed, Oregon only argues that it will suffer irreparable harm "if the nationwide injunction is lifted." *See* PI Mot. at 28. The requirement that a party show irreparable harm restricts this Court's authority to enter a duplicative injunction with respect to Oregon. *See e.g.*, *Hawai'i v. Trump*, 233 F. Supp. 3d 850, 853 (D. Haw. 2017) ("[T]he Western District of Washington's nationwide injunction already provides the State with the comprehensive relief it seeks in this lawsuit. As such, the State will not suffer irreparable damage.").

An injury that is expressly contingent on a future event is, by definition, not an imminent, irreparable injury. *See Henke v. Dep't of Interior*, 842 F. Supp. 2d 54, 59 (D.D.C. 2012) ("Injury that is hypothetical or speculative does not rise to the level of irreparable harm."); *accord In re Excel Innovations, Inc.*, 502 F.3d 1086, 1098 (9th Cir. 2007) ("Speculative injury cannot be the basis for a finding of irreparable harm."). Because Oregon cannot show irreparable harm, the Court should at the very least stay consideration of this motion unless and until the *Pennsylvania* nationwide injunction is stayed, narrowed, or vacated. Unless and until that happens, however, Oregon will not suffer irreparable harm absent an injunction from this Court, and there is accordingly no basis for the Court to resolve Oregon's motions for preliminary injunction at this time.

Additionally, the fact that Oregon waited over five months after the Agencies promulgated the Final Rules—and over eighteen months after the Agencies issued the IFRs—to seek an injunction undermines its claim that it will suffer irreparable harm if the Court declines to grant the preliminary injunction.[4] "A delay in seeking a preliminary injunction is a factor to be considered in weighing the propriety of relief." *Lydo Enters., Inc. v. City of Las Vegas*, 745 F.2d 1211, 1213 (9th Cir. 1984). This is because a preliminary injunction "is sought upon the theory that there is an urgent need for speedy action to protect the plaintiff's rights. By sleeping on its rights a plaintiff demonstrates the lack of need for speedy action." *Id*. (citation omitted). It is thus well established in this Circuit that a "[p]laintiff's long delay before seeking a preliminary injunction implies a lack of urgency and irreparable harm." *Oakland Tribune, Inc., v. Chronicle Publ'g Co*., 762 F.2d 1374, 1377 (9th Cir. 1985); *see also Garcia v. Google, Inc*., 786 F.3d 733, 766 (9th Cir. 2015) (affirming district court's conclusion that a several-month long delay in seeking injunction "undercut [plaintiff's] claim of irreparable harm"); *Hi-Rise Tech., Inc. v. Amateurindex.com*, 2007 WL 1847249, at * 4 (W.D. Wash. June 27, 2007) ("Such a long delay in seeking relief weighs against granting a temporary restraining order or a preliminary injunction.").

[4] The Court has determined that *Plaintiffs* are likely to suffer irreparable harm absent preliminary injunctive relief. Defendants respectfully maintain that no irreparable harm will befall Plaintiffs if the Rules are allowed to go into effect. But here, by contrast with Plaintiffs, Oregon's significant delay undercuts any notion that it will suffer irreparable harm absent a preliminary injunction. *See also California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) ("That the states promptly filed an action following the issuance of the IFRs also weighs in their favor.") (citing *Oakland Tribune*, 762 F.2d at 1377).

Despite this established principle, when the Agencies promulgated the IFRs in October 2017, Oregon chose not to file suit and did not attempt to join the present action. Nor did Oregon choose to file suit or attempt to join this action when the Agencies promulgated the Final Rules in November 2018. Instead, Oregon waited for more than an additional five months before filing a motion in this Court contending that absent emergency injunctive relief, it would suffer irreparable harm. That contention is fatally undermined by Oregon's unexplained delay. Moreover, Oregon's preliminary injunction motion, in overwhelming part, repeats *verbatim* the arguments made by Plaintiffs in their Motion for Preliminary Injunction. *Compare* ECF No. 174, *with* ECF No. 312. Even Oregon's section on irreparable harm is largely identical to the Plaintiffs' brief. *Compare* ECF No. 312 at 28-30 *with* ECF No. 174 at 28-31. Where Oregon has not only filed late for preliminary relief, but has not even bothered to write a motion particular to its state's own circumstances, this Court should conclude that Oregon has failed to satisfy its burden to establish irreparable harm.

## II. Oregon Is Unlikely to Succeed on the Merits.

### a. Oregon Is Not Likely to Succeed on Its Claim That the Rules Are Procedurally Deficient Under the APA.

Oregon contends that the Agencies' use of a post-promulgation comment period after issuing the IFRs renders the Final Rules invalid under the APA. *See* PI Mem. at 23-24. The Agencies maintain that because they had independent statutory authority to issue the IFRs, and had good cause to do so as well, post-promulgation comments were proper. *See* ECF No. 51 at 14-18 (arguing in favor of independent statutory authority to issue the IFRs, and in favor of the Agencies' determination of good cause). But even assuming that the IFRs were procedurally improper, the Final Rules now at issue were issued after receiving and carefully considering

public comments (and at a time after the IFRs were enjoined). Therefore, the APA's notice-and-comment requirements were satisfied with respect to these Final Rules.

The Agencies provided the notice and comment period required under APA § 553 with respect to the Final Rules. Section 553 requires that an agency provide notice, an opportunity to be heard, and publication of a final rule no less than 30 days before it is to go into effect. 5 U.S.C. § 553. Oregon had that full and timely notice and ample opportunity for comment, and it participated in that process. *See* Dec. 5, 2017 Comment by State Attorneys General, *available at* https://www.regulations.gov/contentStreamer?documentId=CMS-2014-0115-58168&attachmentNumber=1&contentType=pdf. Indeed, the Agencies received and considered more than 110,000 public comment submissions across both rules, and detailed their consideration of those submissions in the final rulemakings. *See* 83 Fed. Reg. 57,540 (religious rule); 83 Fed. Reg. at 57,596 (moral rule). The Agencies also made numerous changes in response to those comments, *see* 83 Fed. Reg. 57,556-73; 83 Fed. Reg. 57,613-26 (highlighting comments, responses, and changes). Although Oregon may disagree with those changes, or with the Rules generally, it is not the place of Plaintiff-Intervenor, nor this Court, to substitute its judgment for that of the Agencies. *See Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Instead, the Court should consider whether the Agencies examined the relevant data and articulated a satisfactory explanation for their action, including a "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Most of the cases Oregon cites address challenges to interim final rules, not final rules promulgated after notice and comment, and are thus inapposite. In *Paulsen*, for example, the court enjoined an IFR but specifically contrasted that case with others in which "interested

parties received some notice that sufficiently enabled them to participate in the rulemaking process before the relevant agency adopted the rule." *Paulsen v. Daniels*, 413 F.3d 999, 1007 (9th Cir. 2005). Here, Oregon had a full opportunity for notice and comment. In *Levesque*, similarly, the First Circuit voided an interim final rule for failure to provide notice and comment, but let the final rule stand. *See Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983). Likewise, in *NRDC*, the Third Circuit upheld a challenge to an interim rule that indefinitely suspended the implementation of certain Clean Water Act Amendments. *See NRDC v. EPA*, 683 F.2d 752, 768 (3d Cir. 1982). Although in that case, the court's remedy included enjoining a later rule to "further suspend" the amendments, this aspect of the court's ruling was not based on any procedural inadequacy of the "further suspension" rules. *See id*. at 757. Instead, the court enjoined both rules because the question on which the public commented, *i.e.*, whether to "further suspend" the amendments, was not the question that would have been asked had the APA's procedures been followed. The question "would have been whether the amendments, which had been in effect for some time, should be suspended, and not whether they should be further postponed." *Id*. at 768.

Unlike in *NRDC*, the question posed to the public for comment here was the same question that would have been posed had the IFR been an NPRM. Moreover, the IFRs were enjoined shortly after they went into effect, remedying any procedural defect. Thus, even given this Court's prior conclusion that the IFRs were procedurally defective, the proper remedy is one that Oregon already received—notice of a proposed rule and an opportunity to comment on that same rule. *See Sharon Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979). Because Oregon had the opportunity to submit a comment in response to the IFRs—and did so—it has suffered no procedural injury. On the contrary, the Final Rules amply "present[ed] evidence of a level of

public participation and a degree of agency receptivity that demonstrate that a 'real public reconsideration of the issued rule has taken place." *Levesque*, 723 F.2d at 188. The Ninth Circuit has left in place final rules despite the invalidation of prior interim rules for failure to provide notice and comment. *See Paulsen*, 413 F.3d at 1008 (invalidating an interim rule for failure to comply with notice-and-comment procedures and holding that the rule in effect was the final rule, where the rule previously in force erroneously interpreted a statutory provision); *Buschmann v. Schweiker*, 676 F.2d 352 (9th Cir. 1982) (invalidating interim rule and accepting parties' agreement that final rule was valid). Moreover, the Ninth Circuit has also recognized that even where an agency has been found to have improperly dispensed with notice-and-comment procedures, the proper remedy is to offer the lost opportunity to comment rather than enjoining the final rules. *See Western Oil & Gas Ass'n v. EPA*, 633 F.2d 803, 812-13 (9th Cir. 1980) (in a case in which petitioners had not been afforded the opportunity to comment on an EPA rule, "the proper remedy . . . is a reenactment of the deliberative process with correct provision for the petitioners' participation"). That participation has already been afforded to Oregon, which has thus suffered no procedural injury. For these reasons, Oregon is unlikely to succeed on the merits of its claim that the Rules are procedurally invalid.

**b. Oregon Is Unlikely to Succeed on Its Substantive APA Claims.**

i. The Rules are Not Contrary to the Women's Health Amendment.

Oregon's argument that the Rules violate the Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4), fails because the ACA grants HRSA, and in turn the Agencies, significant discretion to shape the content and scope of any preventive-services guidelines adopted pursuant to § 300gg-13(a)(4). Although this Court ruled against the Agencies with respect to this question in the Plaintiffs' preliminary injunction motion, the Agencies respectfully urge this Court to reconsider its position. *See Askins v. U.S. Dep't of Homeland Sec.*, 899 F.3d 1035, 1042 (9th

Cir. 2018) (the law of the case doctrine "does not preclude a court from reassessing its own legal rulings in the same case"); *City of Los Angeles, Harbor Div. v. Santa Monica Baykeeper*, 254 F.3d 882, 888 (9th Cir. 2001) (doctrine is "is discretionary, not mandatory and is in no way a limit on a court's power") (internal citations and punctuation omitted).

The ACA does not specify the types of preventive services that must be included in such guidelines. Instead, as relevant here, it provides only that, "with respect to women," coverage must include "such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA]." Id. § 300gg-13(a)(4). Several textual features of § 300gg-13(a) demonstrate that this provision grants HRSA broad discretionary authority.

First, unlike the other paragraphs of the statute, which require preventive-services coverage based on, *inter alia*, "current recommendations of the United States Preventive Services Task Force," recommendations "in effect . . . from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention," or "the comprehensive guidelines" that HRSA had already issued with respect to preventive care for children, the paragraph concerning preventive care for women refers to "comprehensive guidelines" that did not exist at the time. *Compare id.* § 300gg-13(a)(1), (2), (3), *with id.* § 300gg-13(a)(4). That paragraph thus necessarily delegated the content of the guidelines to HRSA.

Second, nothing in the statute mandates that the guidelines include contraception at all, let alone include all types of contraception for all types of employers with covered plans. On the contrary, the statute provides only for coverage of preventive services "as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph." *Id.* § 300gg-13(a)(4). The use of the phrase "for purposes of this paragraph" makes clear that HRSA should

consider the particular context of the directive in shaping the guidelines, and the use of the phrase "as provided for" indicates that HRSA has discretion to define not only the services to be covered under that directive, but also the manner or reach of that coverage. *See also* 83 Fed. Reg. at 57,540 n.10; 57,541 (discussing the Agencies' interpretation of the word "as" to confer discretion to the Agencies). That suggestion is further reinforced by the absence of the words "evidence-based" or "evidence-informed" in this subsection, as compared with § 300gg-13(a)(1), (3), which confirms that Congress authorized HRSA to consider factors beyond the scientific evidence in deciding whether to support a coverage mandate for particular preventive services.

Accordingly, § 300gg-13(a)(4) must be understood as a positive grant of authority for HRSA to develop the women's preventive-services guidelines and for the Agencies, as the administering Agencies of the applicable statutes, to shape that development. *See* 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. That is especially true for HHS, as HRSA is a component of HHS and is subject to the HHS Secretary's general supervision. *See* 47 Fed. Reg. 38,409 (Aug. 31, 1982). The text of § 300gg-13(a)(4) thus authorized HRSA to adopt guidelines for coverage that include an exemption for certain employers, and nothing in the ACA prevents HHS from supervising HRSA in the development of those guidelines. Indeed, since their first rulemaking on this subject in 2011, the Agencies have consistently interpreted the broad delegation to HRSA in § 300gg-13(a)(4) to include the authority to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623.

In light of this statutory and regulatory backdrop, the Agencies' exercise of authority to expand the exemption is, at the very least, a reasonable construction of the statute entitled to

deference. *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

ii. RFRA Both Authorizes and Requires the Religious Exemption Rule.

Even apart from § 300gg-13(a)(4), RFRA independently authorizes the religious exemption. RFRA prohibits the government from "substantially burden[ing] a person's exercise of religion" unless the application of the burden to that person is "the least restrictive means" of furthering a "compelling governmental interest." 42 U.S.C. § 2000bb-1(b). Under *Hobby Lobby*, RFRA requires the government to eliminate the substantial burden imposed by the contraceptive-coverage mandate. The expanded religious exemption is a permissible—and in the case of some objecting employers, required—means of doing so.

In *Hobby Lobby*, the Supreme Court held that the contraceptive coverage mandate, standing alone, "imposes a substantial burden" on objecting employers. 134 S. Ct. at 2779. And the Court further held that application of the mandate to objecting employers was not the least restrictive means of furthering any compelling governmental interest, because, at a minimum, the accommodation was a less restrictive alternative that could be extended to the objecting employers in that case. *See id.* at 2780-83. But the Court did not decide whether the accommodation would satisfy RFRA for all religious claimants; nor did it suggest that the accommodation is the only permissible way for the government to comply with RFRA and the ACA, even assuming the existence of a compelling governmental interest. *See id.* at 2782. Moreover, as the Agencies noted, other lawsuits have shown that "many religious entities have objections to complying with the accommodation based on their sincerely held religious beliefs." 82 Fed. Reg. at 47,806.

The Agencies reasonably decided to adopt the religious exemption to satisfy their RFRA obligation to eliminate the substantial burden imposed by the mandate. *See* 83 Fed. Reg. at 57,544-48. Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive coverage mandate, per *Hobby Lobby*—RFRA does not prescribe the remedy by which the government must eliminate that burden. The prior administration chose to attempt to do so through the complex accommodation it created, but nothing in RFRA compelled that novel choice or prohibits the current administration from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. Indeed, if the Agencies had simply adopted an exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because the Agencies should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result here based merely on path dependence.

The Agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the litigation over whether the accommodation violates RFRA. *See* 82 Fed. Reg. at 47,798; *see also Ricci v. DeStefano*, 557 U.S. 557, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate-impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban); *cf. Walz v. Tax Comm'n*, 397 U.S. 664, 669 (1970) (recognizing "room for play in the joints" when accommodating exercise of religion).

To be sure, if providing an exemption for an objecting religious employer would prevent the contraceptive-coverage mandate from achieving a compelling governmental interest as to that employer, then RFRA would not authorize that exemption. *See Hobby Lobby*, 134 S. Ct. at

2779-80. But the Agencies expressly found that application of the mandate to objecting entities neither serves a compelling governmental interest nor is narrowly tailored to any such interest. That is so for multiple reasons, including that: Congress did not mandate coverage of contraception at all; the preventive-services requirement was not made applicable to "grandfathered" plans; the prior rules exempted churches and their related auxiliaries, and also effectively exempted entities that participated in self-insured church plans; multiple federal, state, and local programs provide free or subsidized contraceptives for low-income women; and entities bringing legal challenges to the mandate have been willing to provide coverage of some, though not all, contraceptives. *See* 83 Fed. Reg. 57,546-48. Accordingly, the Agencies reasonably exercised their discretion in adopting the exemption as a valid means of complying with their obligation under RFRA to eliminate the substantial burden imposed by the contraceptive-coverage mandate, whether or not the accommodation is a valid means of compliance.

Of course, that is especially true because the accommodation *does* violate RFRA for at least some employers, because it uses plan that the employers themselves sponsor to provide contraceptive coverage that they object to on religious grounds, which they sincerely believe makes them complicit in providing such coverage. *See* 82 Fed. Reg. at 47,798, 47,800. In light of that sincere religious belief, forcing objecting employers to use the accommodation plainly imposes a substantial burden under *Hobby Lobby*. *See Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927, 939-43 (8th Cir. 2015), *vacated and remanded sub nom.*, *HHS v. CNS Int'l Ministries*, 136 S. Ct. 2006 (2016) (mem.); *Priests for Life v. HHS*, 808 F.3d 1, 16-21 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from denial of rehearing en banc). Indeed, after extensive study, the previous administration determined that it could identify no means short of an exemption that

would resolve all religious objections; and on further examination the Agencies determined that denying the exemption was not narrowly tailored to achieving any compelling interest. *See supra* pp. 9-10, 30. It thus was not just reasonable, but required, for the Agencies to satisfy their RFRA obligations concerning the contraceptive-coverage mandate by providing an exemption rather than just the accommodation.

iii. The Rules Otherwise Comply with the ACA.

The Final Rules do not violate the ACA's nondiscrimination requirement, 42 U.S.C. § 18116, or its prohibition on unreasonable barriers to healthcare, *id.* § 18114. *See* PI Mem. at 19-21. With respect to § 18116, the Rules do not discriminate on the basis of sex, facially or otherwise. The Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing an exemption for those with religious and conscience objections. But the Rules and Guidelines do not require any coverage of male contraceptives. *See* 78 Fed. Reg. at 8,456, 8,458 n.3 (Feb. 6, 2013). Nor could they: the statutory provision requiring coverage for additional preventive services supported by HRSA pertains only to such services for "women." 42 U.S.C. § 300gg-13(a)(4). Thus, the Rules do not treat men more favorably, and any sex-based distinctions flow from the statute requiring coverage of additional preventive services for women only. Moreover, any distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection by an individual's employer to facilitating contraceptive coverage.

No other factor reflects any invidious intent to discriminate on the basis of sex. Nor does the Agencies' conclusion regarding the lack of a compelling interest in these circumstances demonstrate an intention to discriminate against women: the Rules explain the non-discriminatory reasons for the conclusion and address medical evidence in the course of doing so, *see, e.g.*, 83 Fed. Reg. at 57,546-48, and the conclusion is not inconsistent with applicable precedent, *Hobby Lobby*, 134 S. Ct. at 2766, 2780 (noting that the Tenth Circuit held that enforcing the contraceptive mandate against objecting employers did not serve a compelling

interest but "find[ing] it unnecessary to adjudicate this issue"). The final religious exemption rule accommodates religion by "expand[ing] exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage." 83 Fed. Reg. at 57,540. The final moral exemption rule is designed to protect sincerely-held "moral convictions" by exempting those with such convictions from facilitating the provision of contraceptive services. *Id*. at 57,596. The government may permissibly accommodate deeply-held moral convictions and has furthered this important interest in a variety of contexts since the founding. *See Welsh v. United States*, 398 U.S. 333 (1970); *United States v. Seeger*, 380 U.S. 163 (1965); *Doe v. Bolton*, 410 U.S. 179 (1973); 83 Fed. Reg. at 57,594 n.1. Indeed, Oregon, as well as some of the plaintiff states, protect moral beliefs in healthcare. *See, e.g.*, Or. Rev. Stat. Ann. § 435.435; Cal. Health & Safety Code § 123420; Md. Code Ann., Health – Gen. § 20-214.

With respect to § 18114, Oregon argues—also without legal authority—that the Rules create an unreasonable barrier to medical care. PI Mem. at 20-21. However, the Rules merely narrow the scope of the Mandate rather than impose affirmative barriers on access to contraception. *Cf. Harris v. McRae*, 448 U.S. 297, 316 (1980) ("[A]lthough government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those not of its own creation[, such as indigency]."). Worse, under Plaintiffs' interpretation, § 18114 would mandate the provision of all "appropriate medical care," rendering the ACA's extensive discussion of Essential Health Benefits surplusage. *See generally* 42 U.S.C. §§ 18021, 18022.

iv. The Rules Are Not Arbitrary and Capricious.

Oregon contends the Rules are arbitrary and capricious because the Agencies did not provide adequate justification for their reversal in policy. *See* PI Mem. at 24-28. It alleges that the Agencies have not sufficiently justified "such a substantial shift" in policy, have not justified the scope of the Rules, have relied on "unfounded" information, and have ignored the structure

and legislative history of the Women's Health Amendment. *Id*. But Oregon's argument overlooks the actual basis for the decision and substitutes Oregon's judgment for that of the Agencies. The Agencies recognized that the decision whether to expand the religious exemption (and to create a moral exemption) required them to "balance the various policy interests at stake," 83 Fed. Reg. at 57,556, *i.e.*, interests in contraceptive coverage on the one hand, and interests in freedom of religion and conscience on the other. They did just that, and decided as a matter of policy to enact "rules [that] will provide tangible protections for religious liberty" and conscience, thereby "impos[ing] fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the [Mandate] imposes a substantial burden on their religious exercise." *Id.*; *see also* 83 Fed. Reg. at 57,613 (moral exemption). In so doing, the Agencies reached a different balance than they had previously. But neither that fact, nor Oregon's contrary policy preference—nor anything else—renders the decision arbitrary or capricious.

"The scope of review under the 'arbitrary and capricious' standard is narrow," St*ate Farm*, 463 U.S. at 43, and while its requirements can change depending on the circumstances, the Agencies satisfy that standard even as articulated in *FCC v. Fox Television Stations, Inc*., 556 U.S. 502 (2009). The *Fox Television* articulation of the standard is itself not overly demanding; it simply requires an agency to provide a "reasoned explanation" for treating differently "facts and circumstances that underlay or were engendered by the prior policy." *Id*. at 516. An agency that changes policy need not demonstrate "that the reasons for the new policy are *better* than the reasons for the old one," but only that "the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better." *Id.* at 515.

The Agencies did just that. The Final Rules contain voluminous explanations of the Agencies' previous positions, their current positions, recognition that their positions changed, discussions of both sides of the issue from public comments, and extensive reasoning why the Agencies support their final conclusion. Over the course of four pages of the Federal Register, 83 Fed. Reg. at 57,552-56; *see also* 83 Fed. Reg. at 57,609-13 (moral rule), the Agencies discuss the efficacy and health effects of contraceptive use as well as the effect, if any, the Mandate had on contraceptive use. Thus, the Agencies did not ignore any prior findings or reliance interests. *See* PI Mem. at 25-26. Rather, after reviewing a litany of competing comments and scientific studies regarding the efficacy and health benefits of contraceptives, *see* 83 Fed. Reg. at 57,552-55 nn.28-50, the Agencies concluded that an "examination of the record and review of the public comments has reinforced the Departments' conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals." *Id*. at 57,555. The Agencies' conclusion was not to eliminate the Mandate altogether, but to expand the exemptions to a number of entities that are dwarfed by those who will still be subject to the Mandate itself. This further demonstrates the Agencies did not ignore factors they had considered in the past.

The Agencies' view of the medical evidence is accorded deference because it falls within HHS's expertise. *Nat'l Wildlife Fed. v. Nat'l Marine Fisheries Serv.*, 422 F.3d 782, 798-99 (9th Cir. 2005). It cannot be deemed arbitrary and capricious given the highly deferential character of that standard. Similarly, the Agencies addressed any reliance interests that may have arisen, concluding, after reviewing applicable studies and comments, that "it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use,"

given that "there is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing." 83 Fed. Reg. at 57,556.

In short, the Agencies thoroughly and rationally explained their views on the efficacy and health effects of contraceptives and any reliance interests engendered by the Mandate. In doing so, they demonstrated why, in their judgment, the policy interests in favor of expanding the exemptions outweigh the interests in leaving the contraceptive coverage mandate unchanged: the evidence on the benefits of contraceptives and the Mandate is more mixed—and the religious and conscientious objections to complying with the Mandate more substantial—than previously acknowledged. Accordingly, the record before the Agencies justified a different balancing of "the various policy interests at stake." *Id*.

Oregon's more specific objections fare no better. It contends that the Agencies provided no justification for the scope of the Rules. *See* PI Mem. at 26. But this is simply untrue—the Rules provide multiple pages of discussion regarding the scope of the Rules, comments that the Agencies received regarding the scope of the Rules, and the Agencies' response to those comments. *See* 83 Fed. Reg. at 57,542-44. Oregon further points out that the Agencies are not aware of particular publicly traded entities that have objected to providing contraceptive coverage on the basis of religion. *See* PI Mem. at 26. But the Agencies discuss this objection specifically: they note that "in a country as large as the U.S., comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or the majority shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious

character." 83 Fed. Reg. at 57,562. For this reason, the Agencies determined that they should equalize the availability of religious exemptions for for-profit entities that are not closely held. *See id.* at 57,562-63. It is clear that Oregon's real issue is that it disagrees with the Agencies' conclusion, not that the Rules lack a rational justification in violation of the APA. Disagreement is not an injury for which the APA can provide relief. Moreover, even if (contrary to fact) the Agencies had not provided sufficient justification for extending the exemption to publicly traded companies, that could be a basis only for enjoining the portion of the Religious Exemption Rule that applies to such companies, not the Rules in their entirety.

Second, Oregon claims that the Rules "rely on information about women's health that is 'unfounded'" according to Plaintiffs' declarants. But Oregon has not argued that the decision runs counter to the conclusions of the record, simply that it runs counter to evidence provided by Plaintiffs' declarants. PI Mem. at 26. This is irrelevant. The Agencies' decision is consistent with the record evidence, as is evident from a review of the studies cited by the Agencies. 83 Fed. Reg. at 57,552-55 nn.28-50. The Agencies made clear they were not taking a "definitive position" on "evidentiary issues" concerning contraception broadly—they were only considering whether expanding the religious and moral exemptions is appropriate in light of numerous competing public comments citing various studies on those issues. *Id*. at 57,556. Under the APA, the Agencies' decision should be reviewed on the basis of the administrative record. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985) ("The task of the reviewing court is to apply the appropriate APA standard of review to the agency decision based on the record the agency presents to the reviewing court.") (internal citation omitted). Although there are "limited exceptions" that "operate to identify and plug holes in the administrative record," *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005), they do not apply here. *See id.*

(extra-record admissions are necessary only (1) "to determine 'whether the agency has considered all relevant factors and has explained its decision, (2) if the agency has relied on documents not in the record, (3) when supplementing the record is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith.'") (internal citation and quotation marks omitted). Oregon's use of the declarations submitted by Plaintiffs goes far beyond that. Oregon relies on these declarations to attempt to show that the Agencies erred in the exercise of their judgment about the efficacy and health benefits of contraceptives and number of women affected. This is improper. As the Ninth Circuit has explained, "[c]onsideration of the [extra-record] evidence to determine the correctness or wisdom of the agency's decision is not permitted, even if the court has also examined the administrative record." *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980).

Finally, Oregon claims that the Agencies' extension of exemptions ignored the legislative history of the Women's Health Amendment and the conclusions of the Institute of Medicine report. *See* PI Mem. at 26-27. For the reasons discussed below in section [next section], the Agencies' action does not violate the Women's Health Amendment, § 300gg-13(a)(4). Oregon apparently assumes that imposing anything less than a categorical, exemption-free contraceptive-coverage requirement is irrational—yet Oregon does not argue that the exemption for churches is improper and, indeed, several plaintiffs confer broad religious exemptions to their own state contraceptive-coverage laws. See "State Laws and Policies: Insurance Coverage of Contraceptives," *available at* https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives (stating that Oregon has a "limited" religious exemption). Oregon is not irrational to provide such exemptions, and neither are the Agencies.

## VIII. The Balance of Equities and Public Interest Make Injunctive Relief Inappropriate.

Oregon argues that the balance of equities favors expanding the preliminary injunction to include Oregon, because doing so would "preserv[e] the status quo." PI Opp. at 31. But the status quo in this case is a preliminary injunction that does not include Oregon. Where the federal government is a party, the balance of equities and public interest inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). As discussed, Oregon has not alleged sufficient harm to establish irreparable harm. On the other side of the ledger, the government suffers irreparable institutional injury whenever its laws are set aside by a court. *See Maryland v. King*, 133 S. Ct. 1, 3 (2012) (Roberts, C.J., in chambers). Moreover, the government and the public at large have a substantial interest in protecting religious liberty and conscience. *See Kikumura v. Hurley*, 242 F.3d 950, 963 (10th Cir. 2001) (allegation of RFRA violation satisfies irreparable-harm requirement); *Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996) (same).

Even if Oregon's supposition were correct, however, churches have long been able to claim an exemption from the Mandate—the Rules simply equalize the availability of the exemptions for others with similar sincerely held religious beliefs or moral convictions. "RFRA is inconsistent with the insistence of an agency such as HHS on distinguishing between different religious believers . . . when it may treat both equally by offering both of them the same accommodation." *Hobby Lobby*, 134 S. Ct. at 2786. The government, the public, and employers with burdened beliefs have a strong interest in having the Rules implemented.

## CONCLUSION

For these reasons, the Court should deny Oregon's motion for a preliminary injunction.

Dated: May 14, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

ALEX G. TSE
United States Attorney

MICHELLE R. BENNETT
Assistant Branch Director

/s/ *Justin M. Sandberg*
JUSTIN M. SANDBERG, IL Bar No. 6278377
Senior Trial Counsel
MICHAEL GERARDI
CHRISTOPHER R. HEALY
REBECCA M. KOPPLIN
DANIEL RIESS
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, D.C. 20001
Telephone: (202) 514-5838
Facsimile: (202) 616-8202
Email: Justin.Sandberg@usdoj.gov
*Counsel for Federal Defendants*