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 13 **IN THE UNITED STATES DISTRICT COURT**
 14 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
 15 **OAKLAND DIVISION**
 16

17 STATE OF CALIFORNIA, <i>et al.</i> , 18 Plaintiffs, 19 v. 20 ALEX M. AZAR, II, Secretary of 21 Health and Human Services, <i>et al.</i> , 22 Defendants, 23 and 24 THE LITTLE SISTERS OF THE POOR, 25 JEANNE JUGAN RESIDENCE, <i>et al.</i> , 26 Defendant-Intervenors) Case No.: 4:17-cv-5783-HSG)) DEFENDANTS' OPPOSITION TO) PLAINTIFFS' MOTION FOR) PRELIMINARY INJUNCTION) (SECOND)) Date: January 11, 2019) Time: 10:00 a.m.) Courtroom: 2, 4 th Floor)))))
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INTRODUCTION

1
2 As part of the Patient Protection and Affordable Care Act (“ACA”), Congress required
3 employers to cover some recommended preventive services without cost sharing. That law does not
4 mention contraceptive coverage. But the Health Resources and Services Administration, an agency
5 within the Department of Health and Human Services (“HHS”), issued guidelines mandating
6 coverage of all FDA-approved contraceptives. At the same time, the government recognized that
7 some employers hold sincere religious objections to providing insurance coverage for some or all
8 forms of contraception, but decided to exempt only a fraction of those employers—churches and
9 their integrated auxiliaries—from the requirement. Other religious employers remained subject to
10 the contraceptive mandate (“Mandate”) and were left either to violate their sincerely held religious
11 beliefs or to be liable for significant fines.

12 Years of litigation in dozens of cases followed. In *Burwell v. Hobby Lobby Stores, Inc.*, the
13 Supreme Court held that the “contraceptive mandate imposes a substantial burden on the exercise of
14 religion” in violation of the Religious Freedom Restoration Act (“RFRA”). 134 S. Ct. 2751, 2779
15 (2014). But rather than extending the exemption, HHS tried “accommodating” other types of
16 religious objectors. That decision triggered further litigation and generated decisions in nine federal
17 courts of appeals. Ultimately, the Supreme Court vacated those decisions and instructed the courts
18 of appeals to give the parties time to try to resolve their differences. *See Zubik v. Burwell*, 136 S. Ct.
19 1557, 1560 (2016).

20 On October 6, 2017, to address serious religious and moral objections and to conclude
21 litigation, the Departments of HHS, Labor, and the Treasury (“the Agencies”) issued interim final
22 rules with requests for public comments (“IFRs”) that kept the Mandate in place, but exempted
23 religious and moral objectors. *See* 82 Fed. Reg. 47,792 (Oct. 13, 2017); 82 Fed. Reg. 47,838 (Oct.
24 13, 2017). After reviewing all the comments received on the IFRs, and making some changes in
25 response, the Agencies promulgated final rules superseding the IFRs. *See* Religious Exemptions and
26 Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,536
27 (Nov. 15, 2018) (the “Religious Exemption Rule”); Moral Exemptions and Accommodations for
28

1 Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (the
2 “Moral Exemption Rule”) (collectively, “the Rules”).

3 Plaintiffs—thirteen States and the District of Columbia—seek to reverse this considered
4 decision, demanding that religious and secular groups facilitate services to which they deeply object
5 on religious or moral grounds. They allege that the Rules violate the procedural and substantive
6 requirements of the Administrative Procedure Act. Their positions, if adopted, would apply equally
7 to sweep away the longstanding exemption for churches and their integrated auxiliaries, exposing
8 churches to the Mandate for the first time.

9 Plaintiffs’ motion for a preliminary injunction should be denied. Plaintiffs are not likely to
10 succeed on the merits of any of their claims. They err in contending that the Agencies acted contrary
11 to law by permitting only post-promulgation comments, because what were post-promulgation
12 comments with respect to the enjoined IFRs are now pre-promulgation comments with respect to the
13 Rules. In addition, the Rules are consistent both with the Women’s Health Amendment and with
14 other relevant ACA provisions. And far from being arbitrary and capricious, the Agencies
15 reasonably exercised their rulemaking authority to protect a narrow class of sincere religious and
16 moral objectors from being forced to facilitate practices that conflict with their beliefs. Plaintiffs
17 also have not shown that they face irreparable harm, and the balance of harms and public interest
18 weigh against the Court issuing an injunction.

19 **BACKGROUND**

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

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

1 In August 2011, HRSA adopted the recommendation of the Institute of Medicine, a part of
2 the National Academy of Sciences, to issue guidelines requiring coverage of, among other things,
3 the full range of FDA-approved contraceptive methods, including oral contraceptives, diaphragms,
4 injections and implants, emergency contraceptive drugs, and intrauterine devices. *See* 77 Fed. Reg.
5 8,725, 8,725 (Feb. 15, 2012). As a result, coverage for such contraceptive methods was required for
6 plan years beginning on or after August 1, 2012. *See* 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011).

7 At the same time, the Agencies, invoking their statutory authority under 42 U.S.C. § 300gg-
8 13(a)(4), promulgated interim-final rules authorizing HRSA to exempt churches and their integrated
9 auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623; 77 Fed. Reg. at
10 8,725. Various religious groups urged the Agencies to expand the exemption to all religious not-for-
11 profit organizations and other organizations with religious or moral objections to providing
12 contraceptive coverage. *See* 78 Fed. Reg. 8,456, 8,459 (Feb. 6, 2013). Instead, in a subsequent
13 rulemaking, the Agencies offered only what they termed an “accommodation” for religious not-for-
14 profit organizations with religious objections to providing contraceptive coverage. *See* 78 Fed. Reg.
15 39,870, 39,874-82 (July 2, 2013). The accommodation allowed a group health plan established or
16 maintained by an eligible objecting employer to opt out of any requirement to directly “contract,
17 arrange, pay, or refer for contraceptive coverage,” *id.* at 39,874, by providing notice of its objection.
18 The regulations then generally required the employer’s health insurer or third-party administrator to
19 provide or arrange contraceptive coverage for plan participants. *See id.* at 39,875-80.

20 In the case of self-insured church plans, however, coverage by the plan’s third-party
21 administrator under the accommodation was voluntary.¹ Church plans are exempt from the
22 Employee Retirement Income Security Act of 1974 (ERISA) under section 4(b)(2) of that Act, and
23 the authority to enforce a third-party administrator’s obligation to provide separate contraceptive
24 coverage derives solely from ERISA. The Agencies thus could not require the third-party
25 administrators of church plans—and, by extension, many nonprofit religious organizations

26
27 ¹ A church plan can include a plan maintained by a “principal purpose” organization
28 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).

1 participating in those plans—to provide or arrange for such coverage or to impose fines or penalties
2 for failing to provide such coverage. *See* 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

3 Even apart from the exemption for churches and their integrated auxiliaries, the Mandate did
4 not apply to many employers. The ACA itself exempts from the preventive-services requirement,
5 and therefore from any contraceptive-coverage mandate imposed as part of that requirement,
6 “grandfathered” health plans (generally, those plans that have not made specified changes since the
7 Act’s enactment), *see* 42 U.S.C. § 18011, which cover tens of millions of people, *see* 83 Fed. Reg.
8 57,541 (Nov. 15, 2018) (estimating over 25 million individuals enrolled in such plans). And
9 employers with fewer than fifty employees are not subject to the tax imposed on employers that fail
10 to offer health coverage, *see* 26 U.S.C. § 4980H(c)(2), although such small employers that provide
11 non-grandfathered coverage must comply with the preventive-services requirement.

12 **II. Challenges to the Contraceptive-Coverage Mandate and Accommodation**

13 Many employers objected to the contraceptive-coverage mandate. In *Hobby Lobby*, the
14 Supreme Court held that RFRA prohibited applying the Mandate to closely held for-profit companies
15 with religious objections to providing contraceptive coverage. The Court held that the Mandate
16 “impose[d] a substantial burden on the exercise of religion” for employers with religious objections,
17 134 S. Ct. at 2779, and that even assuming a compelling governmental interest, application of the
18 Mandate to such employers was not the least restrictive means of furthering that interest, *id.* at 2780.
19 The Court observed that, at a minimum, the less-restrictive accommodation made available to not-
20 for-profit employers by the Agencies could be extended to closely held for-profit companies with
21 religious objections. *Id.* at 2782. The Court did not decide, however, “whether an approach of this
22 type complies with RFRA for purposes of all religious claims.” *Id.*

23 In response to *Hobby Lobby*, the Agencies promulgated rules extending the accommodation
24 to closely held for-profit entities with religious objections to providing contraceptive coverage. *See*
25 80 Fed. Reg. at 41,323-28. But numerous entities continued to challenge the Mandate. They argued
26 that the accommodation burdened their exercise of religion because they sincerely believed that the
27 required notice and the provision of contraceptive coverage in connection with their health plans
28

1 made them complicit in providing such coverage, in contravention of their faith.

2 A circuit split developed,² and the Supreme Court granted certiorari in several of the cases.
3 The Court vacated the judgments and remanded the cases to the respective courts of appeals. *See*
4 *Zubik*, 136 S. Ct. 1557 (2016) (per curiam). The Court “d[id] not decide whether [the plaintiffs’]
5 religious exercise ha[d] been substantially burdened, whether the Government ha[d] a compelling
6 interest, or whether the current regulations [we]re the least restrictive means of serving that interest.”
7 *Id.* at 1560. Instead, the Court held that, on remand, the Courts of Appeals afford the parties an
8 opportunity to resolve the dispute. In the meantime, the Court precluded the government from
9 “impos[ing] taxes or penalties on [the plaintiffs] for failure to provide the [notice required under the
10 accommodation].” *Id.* at 1561.

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

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

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25 ² *Compare, e.g., Priests for Life v. HHS*, 772 F.3d 229 (D.C. Cir. 2014) (accommodation does
26 not substantially burden religious exercise), *vacated and remanded*, 136 S. Ct. 1557 (2016), *with*
27 *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).

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

III. The Interim Final Rules

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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, 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, including Plaintiffs, *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

1 decisions. *Id.* at 47,843.

2 Invoking agency-specific statutory authority to issue interim final rules, 26 U.S.C. § 9833;
3 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92, the Agencies' use of interim final rules on three prior
4 occasions with respect to the preventive service requirements, and the APA's general "good cause"
5 exception, 5 U.S.C. § 553(b), the Agencies issued the IFRs without prior notice and comment. The
6 Agencies also solicited public comments for 60 days post-promulgation in anticipation of final
7 rulemaking. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838.

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

10 California and four other states sued, challenging the IFRs. They claimed that the IFRs (1)
11 fail to comply with the APA's notice-and-comment requirements; (2) are arbitrary and capricious,
12 an abuse of discretion, or otherwise contrary to law; (3) violate the Establishment Clause; and (4)
13 violate the Equal Protection Clause. Am. Compl., Nov. 1, 2017, ECF No. 24, ¶¶ 116-137.

14 The Court granted Plaintiffs' motion for preliminary injunctive relief on the first claim,
15 issuing a "nationwide" preliminary injunction against the IFRs. Order Granting Pls.' Mot. for a
16 Prelim. Inj., Dec. 21, 2017, ECF No. 105, at 28-29. As an initial matter, the Court rejected the
17 Agencies' arguments that Plaintiffs had not demonstrated standing and that venue was not proper in
18 the Northern District of California. *Id.* at 12-14, 16. Turning to the preliminary injunction factors,
19 the Court concluded that Plaintiffs were likely to succeed on their procedural APA claim. The Court
20 rejected the Agencies' arguments that they had statutory authority to depart from the APA's notice-
21 and-comment requirements. *Id.* at 19-21. The Court also dismissed the Agencies' determination
22 that the need to resolve protracted litigation, cure RFRA violations, and eliminate uncertainty over
23 this important issue constituted "good cause" for bypassing pre-promulgation notice and comment.
24 *Id.* at 21-24. The Court further held that absent an injunction, Plaintiffs would be irreparably harmed,
25 and that the balance of harms warranted preliminary injunctive relief. *Id.* at 25-28.

26 On December 13, 2018, the Ninth Circuit affirmed the Court's decision in part and vacated
27 it in part. *California v. Azar*, No. 18-15144, 2018 WL 6566752 (9th Cir. Dec. 13, 2018). That court
28 concluded that venue was proper in this district. *Id.* at *4. It also held that Plaintiffs had standing to

1 challenge the IFRs because the “states show[ed], with reasonable probability, that the IFRs will first
2 lead to women losing employer-sponsored contraceptive coverage, which will then result in
3 economic harm to the states.” *Id.* at *6. Next, the Court of Appeals decided that the Agencies “did
4 not have statutory authority for bypassing notice and comment” with respect to the IFRs, and that
5 doing so was not harmless. *Id.* at *13-14. The Ninth Circuit also found this Court did not abuse its
6 discretion in concluding that Plaintiffs had demonstrated irreparable harm and that the balance of
7 harms tipped in their favor, though it recognized that “[p]rotecting religious liberty and conscience
8 is obviously in the public interest.” *Id.* at *14-15. But the Court of Appeals held that the injunction
9 “must be narrowed to redress only the injury shown as to the plaintiff states.” *Id.* at *16.

10 **V. The Final Rules**

11 After considering, for over 11 months, the more than 110,000 comments on the IFRs, on
12 November 15, 2018, the Agencies issued final versions of the religious exemption and the moral
13 exemption rules. The final rules address the significant comments received by the Agencies.
14 Changes were made in response to questions and concerns raised in various comments, while the
15 fundamental substance of the exemptions was finalized as set forth in the IFRs.

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

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

13 The final moral exemption rule continues to fulfill the purpose that it did in interim form: to
14 “protect sincerely held moral objections of certain entities and individuals.” 83 Fed. Reg. at
15 57,592. The Agencies considered public comments asking for the moral exemption to be expanded
16 to publicly traded or government entities, but declined to do so. *Id.* at 57,616-19. Importantly, like
17 the religious exemption rule, the moral exemption rule “do[es] not remove the contraceptive
18 coverage requirement generally from HRSA’s guidelines.” *Id.* at 57,593. And “[t]he changes to
19 the rule[] being finalized will ensure clarity in implementation of the moral exemptions so that
20 proper respect is afforded to sincerely held moral convictions in rules governing this area of health
21 insurance and coverage, with minimal impact on HRSA’s decision to otherwise require
22 contraceptive coverage.” *Id.*

23 **VI. Plaintiffs’ Second Amended Complaint and Second Motion for a Preliminary**
24 **Injunction**

25 Plaintiffs (joined by nine other states) have filed a second amended complaint as well as a
26 second motion for a preliminary injunction. Second Am. Compl., Dec. 18, 2018, ECF No. 170;
27 States’ Notice of Mot. and Mot. for Prelim. Inj., with Memorandum of Points and Authorities
28 (Second PI Mem.), December 19, 2018, ECF No. 174. In this new complaint, Plaintiffs raise

1 claims under the APA, the Establishment Clause, and the Equal Protection Clause. Second Am.
 2 Compl. ¶¶ 235-260. But they seek a preliminary injunction of the Final Rules only on their APA
 3 claims, not their constitutional claims. Specifically, they argue that the Rules violate the text of the
 4 ACA, were issued without proper notice and comment, and inadequately explain the changes they
 5 make. Second PI Mem. at 9-20. They also argue that the other preliminary injunction factors
 6 weigh in their favor and that the Court should issue a nationwide injunction. *Id.* at 20-25.

ARGUMENT

I. Venue Is Not Proper In This District

9 On appeal, the Ninth Circuit rejected the Agencies' argument that venue was not appropriate
 10 here because California can be deemed to "reside" only in the Eastern District of California, where
 11 Sacramento, the seat of state government, is located. *California*, 2018 WL 6566752, at *4. The Ninth
 12 Circuit's conclusion is based on an overly narrow reading of the term "entity" in 28 U.S.C. § 1391
 13 to exclude a state. Properly construed, venue should be limited to the district court where a state is
 14 deemed to "reside," and California resides in the Eastern District of California. The Ninth Circuit's
 15 ruling in the preliminary injunction appeal notwithstanding, the Court should not further entertain
 16 this suit, and should instead dismiss or transfer the dispute to the Eastern District of California.⁴

II. Plaintiffs Are Unlikely to Succeed on the Merits

A. Plaintiffs Are Unlikely to Succeed on Their Claim That the Rules Are Procedurally Deficient Under the APA.

19 Plaintiffs claim that the Agencies' use of a post-promulgation comment period after issuing
 20 the IFRs renders the Final Rules invalid under the APA. *See* Second PI Mem. at 15. The Agencies
 21 maintain that because they had independent statutory authority to issue the IFRs, and had good cause
 22 to do so as well, post-promulgation comments were proper.⁵ *See* ECF No. 51 at 14-18 (arguing in
 23

24 ⁴ Defendants acknowledge that the Ninth Circuit concluded that Plaintiffs have pleaded facts
 25 sufficient to allege Article III standing for purposes of a procedural injury. That said, Defendants
 26 note that the test for establishing standing is more demanding for non-procedural injuries, and reserve
 27 the right to object to any potential preliminary relief for any plaintiff that has not established standing.

28 ⁵ Although this Court ruled against the Agencies with respect to their independent statutory
 authority to issue the IFRs and their assertion of good cause in the previous round of litigation over
 the IFRs, the Agencies 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

1 favor of independent statutory authority to issue the IFRs, and in favor of the Agencies’
2 determination of good cause). But even assuming the IFRs were procedurally improper, the final
3 rules now at issue were issued after receiving and carefully considering public comments (and at a
4 time after the IFRs were enjoined). Therefore, the APA’s notice-and-comment requirements were
5 satisfied with respect to these final rules.

6 The Agencies provided the notice and comment period required under APA § 553 with
7 respect to the final rules. Section 553 requires that an agency provide notice, an opportunity to be
8 heard, and publication of a final rule no less than 30 days before it is to go into effect. 5 U.S.C.
9 § 553. Plaintiffs had that full and timely notice and ample opportunity for comment, and participated
10 in that process. *See* Second PI Mem. at 15 n.17. Indeed, the Agencies received and considered more
11 than 110,000 public comment submissions across both rules, and detailed their consideration of those
12 submissions in the final rulemakings. *See* 83 Fed. Reg. 57,540 (religious rule); 83 Fed. Reg. at
13 57,596 (moral rule). The Agencies also made numerous changes in response to those comments, *see*
14 83 Fed. Reg. 57,556-73; 83 Fed. Reg. 57,613-26 (highlighting comments, responses, and changes).
15 Although Plaintiffs may disagree with those changes, or with the Rules generally, it is not the place
16 of Plaintiffs, nor this Court, to substitute their judgment for that of the Agencies. *See Citizens to*
17 *Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Instead, the Court should consider
18 whether the Agencies examined the relevant data and articulated a satisfactory explanation for their
19 action, including a “rational connection between the facts found and the choice made.” *Motor*
20 *Vehicle Mfrs. Ass’n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

21 The cases Plaintiffs cite all address challenges to interim final rules, not final rules
22 promulgated after notice and comment, and are thus inapposite. In *Paulsen*, the court enjoined an
23 IFR related to an early release incentive program for prisoners—however, the court specifically
24 contrasted that case with others in which “interested parties received some notice that sufficiently
25 enabled them to participate in the rulemaking process before the relevant agency adopted the rule.”

26 _____
27 a court from reassessing its own legal rulings in the same case”); *City of Los Angeles, Harbor Div.*
28 *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).

1 *Paulsen v. Daniels*, 413 F.3d 999, 1007 (9th Cir. 2005). Here, Plaintiffs received full opportunity
2 for notice and comment. In *Levesque*, similarly, the First Circuit voided an interim final rule for
3 failure to provide notice and comment, but let the final rule stand. See *Levesque v. Block*, 723 F.2d
4 175, 188 (1st Cir. 1983). Similarly, in *NRDC*, the Third Circuit upheld a challenge to an interim rule
5 that indefinitely suspended the implementation of certain Clean Water Act Amendments. See *NRDC*
6 *v. EPA*, 683 F.2d 752, 768 (3d Cir. 1982). Although in that case, the court’s remedy included
7 enjoining a later rule to “further suspend” the amendments, which *had* been promulgated with notice
8 and comment, this aspect of the court’s ruling was *not* based on any procedural inadequacy of the
9 “further suspension” rules. See *id.* at 757. Instead, the court enjoined both rules because the question
10 on which the public commented, *i.e.*, whether to “further suspend” the amendments, was not the
11 question that would have been asked had the APA’s procedures been followed. The question “would
12 have been whether the amendments, which had been in effect for some time, should be suspended,
13 and not whether they should be further postponed.” *Id.* at 768.

14 Unlike in *NRDC*, the question posed to the public for comment here was the same question
15 that would have been posed had the IFR been an NPRM. Moreover, the IFRs were enjoined shortly
16 after they went into effect, remedying any procedural defect. Thus, even given this Court’s prior
17 conclusion that the IFRs were procedurally defective, the proper remedy is one that Plaintiffs already
18 received—notice of a proposed rule and an opportunity to comment on that *same* rule. See *Sharon*
19 *Steel Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979). Plaintiffs admit they took advantage of that
20 opportunity by submitting a comment in response to the IFRs. See Second PI Mem. at 15 n.17. They
21 thus have suffered no procedural injury. On the contrary, the final rules amply “present[ed] evidence
22 of a level of public participation and a degree of agency receptivity that demonstrate that a ‘real
23 public reconsideration of the issued rule has taken place.” *Levesque*, 723 F.2d at 188.

24 The Ninth Circuit has left in place final rules despite the invalidation of prior interim rules
25 for failure to provide notice and comment. See *Paulsen*, 413 F.3d at 1008 (invalidating an interim
26 rule for failure to comply with notice-and-comment procedures and holding that the rule in effect
27 was the final rule, where the rule previously in force erroneously interpreted a statutory provision);
28

1 *Buschmann v. Schweiker*, 676 F.2d 352 (9th Cir. 1982) (invalidating interim rule and accepting
2 parties' agreement that final rule was valid). Moreover, the Ninth Circuit has also recognized that
3 even where an agency has been found to have improperly dispensed with notice-and-comment
4 procedures, the proper remedy is to offer the lost opportunity to comment rather than enjoining the
5 final rules. *See Western Oil & Gas Ass'n v. EPA*, 633 F.2d 803, 812-13 (9th Cir. 1980) (in a case in
6 which petitioners had not been afforded the opportunity to comment on an EPA rule, "the proper
7 remedy . . . is a reenactment of the deliberative process with correct provision for the petitioners'
8 participation"). That participation has already been afforded to Plaintiffs, who have thus suffered no
9 procedural injury. For these reasons, Plaintiffs are unlikely to succeed on the merits of their claim
10 that the Rules are procedurally invalid.

11 **B. Plaintiffs Are Unlikely to Succeed on Their Substantive APA Claims.**

12 **1. The Rules Are Neither Arbitrary Nor Capricious.**

13 Plaintiffs claim the Rules are arbitrary and capricious because the Agencies "failed to provide
14 an adequate justification for their reversal in policy." *See* Second PI Mem. at 16-19. They allege
15 that the Agencies have not sufficiently justified "such a substantial shift" in policy, have not justified
16 the scope of the Rules, relied on "unfounded" information, and ignored the structure and legislative
17 history of the Women's Health Amendment. *Id.* at 17-19. But Plaintiffs' argument overlooks the
18 actual basis for the decision and substitutes Plaintiffs' judgment for that of the Agencies. The
19 Agencies recognized that the decision whether to expand the religious exemption (and to create a
20 moral exemption) required them to "balance the various policy interests at stake," 83 Fed. Reg. at
21 57,556, *i.e.*, interests in contraceptive coverage on the one hand, and interests in freedom of religion
22 and conscience on the other. They did just that, and decided as a matter of policy to enact "rules
23 [that] will provide tangible protections for religious liberty" and conscience, thereby "impos[ing]
24 fewer governmental burdens on various entities and individuals, some of whom have contended for
25 several years that denying them an exemption from the [Mandate] imposes a substantial burden on
26 their religious exercise." *Id.*; *see also* 83 Fed. Reg. at 57,613 (moral exemption). In so doing, the
27 Agencies reached a different balance than they had previously. But neither that fact, nor Plaintiffs'

1 contrary policy preference—nor anything else—renders the decision arbitrary or capricious.

2 “The scope of review under the ‘arbitrary and capricious’ standard is narrow,” *State Farm*,
3 463 U.S. at 43, and while its requirements can change depending on the circumstances, the Agencies
4 satisfy that standard even as articulated in *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009).
5 The *Fox Television* articulation of the standard is itself not overly demanding; it simply requires an
6 agency to provide a “reasoned explanation” for treating differently “facts and circumstances that
7 underlay or were engendered by the prior policy.” *Id.* at 516. The Agencies did just that. The final
8 rules contain voluminous explanations of the Agencies’ previous positions, their current positions,
9 recognition that their positions changed, discussions of both sides of the issue from public comments,
10 and extensive reasoning why the Agencies support their final conclusion. Over the course of four
11 pages of the Federal Register, 83 Fed. Reg. at 57,552-56; *see also* 83 Fed. Reg. at 57,609-13 (moral
12 rule), the Agencies discuss the efficacy and health effects of contraceptive use as well as the effect,
13 if any, the Mandate had on contraceptive use. Thus, the Agencies did not ignore their prior findings
14 or reliance interests. *See* Second PI Mem. at 17-18. Rather, after reviewing a litany of competing
15 comments and scientific studies regarding the efficacy and health benefits of contraceptives, *see* 83
16 Fed. Reg. at 57,552-55 nn.28-50, the Agencies concluded that an “examination of the record and
17 review of the public comments has reinforced the Departments’ conclusion that significantly more
18 uncertainty and ambiguity exists on these issues than the Departments previously acknowledged
19 when we declined to extend the exemption to certain objecting organizations and individuals.” *Id.*
20 at 57,555. The Agencies’ conclusion was not to eliminate the Mandate altogether, but to expand the
21 exemptions to a number of entities that are dwarfed by those who will still be subject to the Mandate
22 itself. This further demonstrates the Agencies did not ignore factors they had considered in the past.

23 The Agencies’ view of the medical evidence is accorded deference because it falls within
24 HHS’s expertise. *Nat’l Wildlife Fed. v. Nat’l Marine Fisheries Serv.*, 422 F.3d 782, 798-99 (9th Cir.
25 2005). It cannot be deemed arbitrary and capricious given the highly deferential character of that
26 standard. Similarly, the Agencies addressed any reliance interests that may have arisen, concluding,
27 after reviewing applicable studies and comments, that “it is not clear that merely expanding
28

1 exemptions as done in these rules will have a significant effect on contraceptive use,” given that
2 “there is conflicting evidence regarding whether the Mandate alone, as distinct from birth control
3 access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or
4 eliminated workplace disparities, where all other women’s preventive services were covered without
5 cost sharing.” 83 Fed. Reg. at 57,556.

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

14 Plaintiffs’ more specific objections fare no better. They contend that the Agencies provided
15 no justification for the scope of the Rules. *See* Second PI Mem. at 18. But this is simply untrue—
16 the Rules provide multiple pages of discussion regarding the scope of the Rules, comments that the
17 Agencies received regarding the scope of the Rules, and the Agencies’ response to those comments.
18 *See* 83 Fed. Reg. at 57,542-44. Plaintiffs further point out that the Agencies are not aware of
19 particular publicly traded entities that have objected to providing contraceptive coverage on the basis
20 of religion. *See* Second PI Mem. at 18. But the Agencies discuss this objection specifically: they
21 note that “in a country as large as the U.S., comprised of a supermajority of religious persons, some
22 publicly traded entities might claim a religious character for their company, or the majority shares
23 (or voting shares) of some publicly traded companies might be controlled by a small group of
24 religiously devout persons so as to set forth such a religious character.” 83 Fed. Reg. at 57,562. For
25 this reason, the Agencies determined that they should equalize the availability of religious
26 exemptions for for-profit entities that are not closely held. *See id.* at 57,562-63. It is clear that
27 Plaintiffs’ real issue is that they disagree with the Agencies’ conclusion, not that the Rules lack a
28

1 rational justification in violation of the APA. Disagreement is not an injury for which the APA can
2 provide relief. Moreover, even if (contrary to fact) the Agencies had not provided sufficient
3 justification for extending the exemption to publicly traded companies, that could be a basis only for
4 enjoining the portion of the Rules that applies to such companies, not the Rules in their entirety.

5 Second, Plaintiffs claim that the Rules “rely on information about women’s health that is
6 ‘unfounded’” according to their declarants. But Plaintiffs have not argued that the decision runs
7 counter to the conclusions of the record, simply that it runs counter to evidence provided by their
8 declarants. Second PI Mem. at 18. This is irrelevant. The Agencies’ decision is consistent with the
9 record evidence, as is evident from a review of the studies cited by the Agencies. 83 Fed. Reg. at
10 57,552-55 nn.28-50. The Agencies made clear they were not taking a “definitive position” on
11 “evidentiary issues” concerning contraception broadly—they were only considering whether
12 expanding the religious and moral exemptions is appropriate in light of numerous competing public
13 comments citing various studies on those issues. *Id.* at 57,556. Under the APA, the Agencies’
14 decision should be reviewed on the basis of the administrative record. *See Fla. Power & Light Co.*
15 *v. Lorion*, 470 U.S. 729, 743-44 (1985) (“The task of the reviewing court is to apply the appropriate
16 APA standard of review to the agency decision based on the record the agency presents to the
17 reviewing court.”) (internal citation omitted). Although there are “limited exceptions” that “operate
18 to identify and plug holes in the administrative record,” *Lands Council v. Powell*, 395 F.3d 1019,
19 1030 (9th Cir. 2005), they do not apply here. *See id.* (extra-record admissions are necessary only (1)
20 “to determine ‘whether the agency has considered all relevant factors and has explained its decision,
21 (2) if the agency has relied on documents not in the record, (3) when supplementing the record is
22 necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a
23 showing of agency bad faith.’”) (internal citation and quotation marks omitted). Plaintiffs’ use of
24 the declarations goes far beyond that. Plaintiffs rely on the declarations to attempt to show that the
25 Agencies erred in the exercise of their judgment about the efficacy and health benefits of
26 contraceptives and number of women affected. This is improper. As the Ninth Circuit has explained,
27 “[c]onsideration of the [extra-record] evidence to determine the correctness or wisdom of the
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1 agency's decision is not permitted, even if the court has also examined the administrative record."
2 *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980).

3 Finally, Plaintiffs claim that the Agencies' extension of exemptions ignored the legislative
4 history of the Women's Health Amendment and the conclusions of the IOM report. *See* Second PI
5 Mem. at 8-19. For the reasons discussed in section IV.B.2, the Agencies' action does not violate the
6 Women's Health Amendment, § 300gg-13(a)(4). Plaintiffs apparently assume that imposing
7 anything less than a categorical, exemption-free contraceptive-coverage requirement is irrational—
8 yet Plaintiffs do not argue that the exemption for churches is improper and, indeed, several plaintiffs
9 confer broad religious exemptions to their own state contraceptive-coverage laws. *See* "State Laws
10 and Policies: Insurance Coverage of Contraceptives," available at [https://www.gutmacher.org/state-](https://www.gutmacher.org/state-policy/explore/insurance-coverage-contraceptives)
11 [policy/explore/insurance-coverage-contraceptives](https://www.gutmacher.org/state-policy/explore/insurance-coverage-contraceptives) (stating that Connecticut, Delaware, Hawaii, and
12 Maryland have "expansive" religious exemptions; California and New York have "limited" religious
13 exemptions; and Illinois has an "almost unlimited" religious exemption). Plaintiffs are not irrational
14 to provide such exemptions, and neither are the Agencies.

15 2. The Rules Are Not Contrary to the Women's Health Amendment.

16 Plaintiffs' argument that the Rules violate the Women's Health Amendment, 42 U.S.C. §
17 300gg-13(a)(4), fails because the ACA grants HRSA, and in turn the Agencies, significant discretion
18 to shape the content and scope of any preventive-services guidelines adopted pursuant to § 300gg-
19 13(a)(4). The ACA does not specify the types of preventive services that must be included in such
20 guidelines. Instead, as relevant here, it provides only that, "with respect to women," coverage must
21 include "such additional preventive care and screenings . . . as provided for in comprehensive
22 guidelines supported by [HRSA]." *Id.* § 300gg-13(a)(4). Several textual features of § 300gg-13(a)
23 demonstrate that this provision grants HRSA broad discretionary authority.

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

5 Second, nothing in the statute mandates that the guidelines include contraception at all, let
6 alone include all types of contraception for all types of employers with covered plans. On the
7 contrary, the statute provides only for coverage of preventive services “as provided for in
8 comprehensive guidelines supported by [HRSA] for purposes of this paragraph.” *Id.* § 300gg-
9 13(a)(4). The use of the phrase “for purposes of this paragraph” makes clear that HRSA should
10 consider the particular context of the directive in shaping the guidelines, and the use of the phrase
11 “as provided for” indicates that HRSA has discretion to define not only the services to be covered
12 under that directive, but also the manner or reach of that coverage. *See also* 83 Fed. Reg. at 57,540
13 n.10; 57,541 (discussing the Agencies’ interpretation of the word “as” to confer discretion to the
14 Agencies). That suggestion is further reinforced by the absence of the words “evidence-based” or
15 “evidence-informed” in this subsection, as compared with § 300gg-13(a)(1), (3), which confirms that
16 Congress authorized HRSA to consider factors beyond the scientific evidence in deciding whether
17 to support a coverage mandate for particular preventive services.

18 Accordingly, § 300gg-13(a)(4) must be understood as a positive grant of authority for HRSA
19 to develop the women’s preventive-services guidelines and for the Agencies, as the administering
20 Agencies of the applicable statutes, to shape that development. *See* 26 U.S.C. § 9833; 29 U.S.C. §
21 1191c; 42 U.S.C. § 300gg-92. That is especially true for HHS, as HRSA is a component of HHS
22 that HHS created and is subject to the HHS Secretary’s general supervision. *See* 47 Fed. Reg. 38,409
23 (Aug. 31, 1982). The text of § 300gg-13(a)(4) thus authorized HRSA to adopt guidelines for
24 coverage that include an exemption for certain employers, and nothing in the ACA prevents HHS
25 from supervising HRSA in the development of those guidelines. Indeed, since their first rulemaking
26 on this subject in 2011, the Agencies have consistently interpreted the broad delegation to HRSA in
27 § 300gg-13(a)(4) to include the authority to reconcile the ACA’s preventive-services requirement
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1 with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely,
2 by exempting churches and their integrated auxiliaries from the contraceptive-coverage mandate.
3 *See* 76 Fed. Reg. at 46,623.

4 In light of this statutory and regulatory backdrop, the Agencies’ exercise of authority to
5 expand the exemption is, at the very least, a reasonable construction of the statute entitled to
6 deference. *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

7 **3. The Rules Otherwise Comply With the ACA.**

8 The Final Rules do not violate the ACA’s nondiscrimination requirement, 42 U.S.C. § 18116,
9 or its prohibition on unreasonable barriers to healthcare, *id.* § 18114. *See* Second PI Mem. at 11-12.
10 With respect to § 18116, the Rules do not discriminate on the basis of sex, facially or otherwise. The
11 Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing
12 an exemption for those with religious and conscience objections. But the Rules and Guidelines do
13 not require any coverage of male contraceptives. *See* 78 Fed. Reg. at 8,456, 8,458 n.3 (Feb. 6, 2013).
14 Nor could they: the statutory provision requiring coverage for additional preventive services
15 supported by HRSA pertains only to such services for “women.” 42 U.S.C. § 300gg-13(a)(4). Thus,
16 the Rules do not treat men more favorably, and any sex-based distinctions flow from the statute
17 requiring coverage of additional preventive services for women only. Moreover, any distinctions in
18 coverage among women are not premised on sex, but on the existence of a religious or moral
19 objection by an individual’s employer to facilitating contraceptive coverage.

20 No other factor reflects any invidious intent to discriminate on the basis of sex. Nor does
21 the Agencies’ conclusion regarding the lack of a compelling interest in these circumstances
22 demonstrate an intention to discriminate against women: the Rules explain the non-discriminatory
23 reasons for the conclusion and address medical evidence in the course of doing so, *see, e.g.*, 83 Fed.
24 Reg. at 57,546-48, and the conclusion is not inconsistent with applicable precedent, *Hobby Lobby*,
25 134 S. Ct. at 2766, 2780 (noting that the Tenth Circuit held that enforcing the contraceptive mandate
26 against objecting employers did not serve a compelling interest but “find[ing] it unnecessary to
27 adjudicate this issue”). The final religious exemption rule accommodates religion by “expand[ing]

1 exemptions to protect religious beliefs for certain entities and individuals with religious objections
2 to contraception whose health plans are subject to a mandate of contraceptive coverage.” 83 Fed.
3 Reg. at 57,540. The final moral exemption rule is designed to protect sincerely-held “moral
4 convictions” by exempting those with such convictions from facilitating the provision of
5 contraceptive services. *Id.* at 57,596. The government may permissibly accommodate deeply-held
6 moral convictions and has furthered this important interest in a variety of contexts since the founding.
7 *See Welsh v. United States*, 398 U.S. 333 (1970); *United States v. Seeger*, 380 U.S. 163 (1965); *Doe*
8 *v. Bolton*, 410 U.S. 179 (1973); 83 Fed. Reg. at 57,594 n.1. Indeed, some of the plaintiffs protect
9 moral beliefs in healthcare. *See, e.g.*, Cal. Health & Safety Code § 123420; Md. Code Ann., Health
10 – Gen. § 20-214.

11 With respect to § 18114, Plaintiffs argue—also without legal authority—that the Rules create
12 an unreasonable barrier to medical care. Second PI Mem. at 11-12. However, the Rules merely
13 narrow the scope of the Mandate rather than impose affirmative barriers on access to contraception.
14 *Cf. Harris v. McRae*, 448 U.S. 297, 316 (1980) (“[A]lthough government may not place obstacles in
15 the path of a woman’s exercise of her freedom of choice, it need not remove those not of its own
16 creation[, such as indigency].”). Worse, under Plaintiffs’ interpretation, § 18114 would mandate the
17 provision of all “appropriate medical care,” rendering the ACA’s extensive discussion of Essential
18 Health Benefits surplusage. *See generally* 42 U.S.C. §§ 18021, 18022.

19 **4. The Religious Exemption Rule Is a Permissible Response to a Substantial**
20 **Burden on Religious Exercise.**

21 Even if the ACA did not permit the Agencies to establish religious exemptions to the
22 Mandate, RFRA *authorized* the Agencies to adopt the Religious Exemption Rule. The Supreme
23 Court held in *Hobby Lobby* that, absent some form of exemption or accommodation, the Mandate
24 imposes a substantial burden on objecting employers. 134 S. Ct. at 2775. And the Court further held
25 that application of the Mandate to objecting employers was not the least restrictive means of
26 furthering any compelling governmental interest because the accommodation would have satisfied
27 the objecting employers’ religious concerns in that case. *See id.* at 2780-83. But the Court did not
28 decide whether the accommodation would satisfy RFRA for all religious claimants, nor did it suggest

1 that the accommodation is the only permissible way to alleviate the substantial burden imposed by
2 the Mandate. *See id.* at 2782. Thus, after “further consideration” and “review of the public comments
3 [t]he Departments have determined that, in light of RFRA, an expanded exemption rather than
4 the existing accommodation is the most appropriate administrative response to the substantial burden
5 identified by the Supreme Court in *Hobby Lobby*.” 83 Fed. Reg. at 57,544-45.

6 Previously, the Agencies had “attempted to develop an accommodation that would either
7 alleviate the substantial burden imposed on religious exercise or satisfy RFRA’s requirements for
8 imposing that burden.” 82 Fed. Reg. at 47,806. But those attempts were unsuccessful and instead
9 led to half a decade of RFRA litigation and serial regulatory amendments, *id.* at 47,814, imposing
10 significant costs on the Agencies, the courts, and regulated entities and plan participants, who were
11 left uncertain about their rights and obligations. Nothing in RFRA compelled the Agencies’ novel
12 (but ultimately unsuccessful) efforts at accommodation. Similarly, nothing in RFRA prohibits the
13 Agencies from now employing the more straightforward choice of an exemption—much like the
14 existing and unchallenged exemption for churches. Indeed, if the Agencies had simply adopted an
15 exemption from the outset—as they did for churches—no one could reasonably have argued that
16 doing so was improper because the Agencies were required to invent the accommodation instead.
17 Neither RFRA nor the ACA compels a different result here based merely on path dependence.

18 A contrary approach would place agencies in an impossible position. Agencies are often
19 presented with claims that their requirements substantially burden the exercise of religion. If
20 agencies were legally prohibited from offering an exemption unless they concluded that no other
21 possible accommodation would be consistent with RFRA, the result would be protracted and
22 unnecessary litigation. This approach is consistent with the Supreme Court’s recognition in
23 analogous contexts that an entity faced with potentially conflicting legal obligations should be
24 afforded some leeway. For example, the Supreme Court has held that, under Title VII, an employer
25 may “engage in intentional discrimination for the asserted purpose of avoiding or remedying an
26 unintentional disparate impact” if the employer has “a strong basis in evidence to believe it will be
27 subject to disparate-impact liability if it fails to take the race-conscious, discriminatory action.” *Ricci*

1 *v. DeStefano*, 557 U.S. 557, 585 (2009). Critically, the Supreme Court did not require the employer
 2 to prove that it *actually would* “be subject to disparate-impact liability.” Instead, it adopted a more
 3 flexible standard that “appropriately constrains employers’ discretion in making race-based
 4 decisions” but was not “so restrictive that it allows employers to act only when there is a provable,
 5 actual violation”—a standard that would have left employers in an untenable position. *Id.* at 583.
 6 So too here.⁶

7 **5. RFRA Requires the Religious Exemption Rule.**

8 In any case, the Religious Exemption Rule is required by RFRA: the Mandate as applied to
 9 those who object on sincere religious grounds to providing or arranging for contraceptive coverage
 10 imposes a substantial burden on religion, and it is not justified by a compelling government interest.

11 The Religious Exemption Rule reasonably concludes that the Mandate, even as modified by
 12 the accommodation, imposes a substantial burden on the exercise of religion, 83 Fed. Reg. at 57,546,
 13 and Plaintiffs do not seriously contend to the contrary.⁷ In *Hobby Lobby*, the Supreme Court held
 14 that the forced choice between complying with the Mandate or paying potentially stiff financial
 15 penalties constitutes a substantial burden for entities with religious objections. 134 S. Ct. at 2779.
 16 The accommodation, like the Mandate, imposes a substantial burden because it requires some
 17 religious objectors to “act in a manner that they sincerely believe would make them complicit in a
 18 grave moral wrong as the price of avoiding a ruinous financial penalty.” *Sharpe Holdings*, 801 F.3d
 19 at 941; *see also* 83 Fed. Reg. at 57,546 (noting comments from entities substantially burdened by the
 20 Mandate and accommodation).

21 The Religious Exemption Rule also reasonably concludes that there is no compelling interest

22 ⁶ To be sure, if providing an exemption for an objecting religious employer would prevent
 23 the contraceptive-coverage mandate from achieving a compelling governmental interest as to that
 24 employer, then RFRA would not authorize that exemption. *See Hobby Lobby*, 134 S. Ct. at 2779-
 25 80. But, as explained below, 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.

26 ⁷ Plaintiffs assert that “‘person,’ as defined in RFRA, does not extend to for-profit publicly-
 27 traded corporations.” Second PI Mem. at 14. But *Hobby Lobby*, relying in part on the Dictionary
 28 Act, 1 U.S.C. § 1, interpreted the term “person” in RFRA to include closely held for-profit
 corporations, *Hobby Lobby*, 134 S. Ct. at 2768-69, and it added that “[n]o known understanding of
 the term ‘person’ includes *some* but not all corporations.” *Id.* at 2769.

1 in imposing the Mandate on the small percentage of employers with sincere religious objections. *Id.*
2 at 57,546-48. The Agencies explained, among other things, that the lack of a compelling interest is
3 evidenced by: (i) Congress’s history of flexibility regarding contraceptive coverage, *id.* at 57,546-
4 47; (ii) the underinclusiveness of the ACA, as evidenced by the exemption of grandfathered plans
5 and church plans from the Mandate, *id.* at 57,547; *cf. Advocate Health Care Network*, 137 S. Ct. at
6 1658-59; (iii) the Agencies’ expert determination that the administrative record does not contain
7 adequate evidence to meet the high standard of demonstrating a compelling interest, 83 Fed. Reg. at
8 57,547; and (iv) the availability of contraceptives from other sources, *id.* at 57,548.

9 Plaintiffs assert that, regardless of RFRA’s mandates, “[t]o the extent that an employer has a
10 religious objection, Defendants must still ensure that their female employees are not deprived of their
11 entitlement to equal access to medical care and coerced to participate in the religious beliefs of their
12 employer.” Second PI Mem. at 14-15. But the ACA contains no such guarantee, *see supra* II.B.2-
13 3, and neither does RFRA, which contains no substantive standards for government provision of
14 medical care or limitations on the religious expression or conduct of private employers. Plaintiffs’
15 reasoning—that an employer’s declining to provide a benefit to an employee for religious reasons
16 amounts to coerced participation in religion—would doom the longstanding exemption for churches
17 and their integrated auxiliaries. The Agencies considered these issues and concluded that the final
18 rules do not impermissibly burden third parties because they merely relieve the government burden
19 on certain regulated entities—the government has no obligation to benefit third parties by requiring
20 that all employers provide contraceptive coverage without cost sharing. 83 Fed. Reg. at 57,549. To
21 the extent that Plaintiffs’ argument echoes their earlier Establishment Clause argument concerning
22 burdens on third parties, the Agencies previously rebutted it. *See* Defs.’ PI Opp’n at 29-32, ECF No.
23 51. In the end, nothing in the Rules requires women who work for objecting employers to change
24 their beliefs or to participate in the religion of their employer.

25 **III. Plaintiffs Have Not Shown Irreparable Harm From Implementation of the Rules**

26 The Ninth Circuit has held that “the states are likely to suffer irreparable harm absent an
27 injunction” in the event the IFRs are implemented because “it is reasonably probable that the states
28

1 will suffer economic harm from the IFRs” and “will not be able to recover monetary damages
 2 connected to the IFRs,” despite the speculative nature of these allegations. *California*, 2018 WL
 3 6566752, at *14. That conclusion was in error, and it would be equally erroneous as applied to the
 4 Rules. The Agencies maintain that no irreparable harm will befall Plaintiffs if the Rules are allowed
 5 to go into effect, making entry of a preliminary injunction on this factual record inappropriate.

6 **IV. The Balance of Equities And Public Interest Make Injunctive Relief Inappropriate**

7 Plaintiffs claim that the balance of equities and public interest factors favor the requested
 8 preliminary injunction. Where the federal government is a party, these two inquiries merge. *Nken*
 9 *v. Holder*, 556 U.S. 418, 435 (2009). As discussed, Plaintiffs have not alleged sufficient harm to
 10 establish irreparable harm. On the other side of the ledger, the government suffers irreparable
 11 institutional injury whenever its laws are set aside by a court. *See Maryland v. King*, 133 S. Ct. 1, 3
 12 (2012) (Roberts, C.J., in chambers). Moreover, the government and the public at large have a
 13 substantial interest in protecting religious liberty and conscience. *See Kikumura v. Hurley*, 242 F.3d
 14 950, 963 (10th Cir. 2001) (allegation of RFRA violation satisfies irreparable-harm requirement);
 15 *Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996) (same).

16 Plaintiffs claim that the Rules upend the status quo. *See* Second PI Mem. at 24. But churches
 17 have long been able to claim an exemption to the Mandate—the Rules simply equalize the
 18 availability of the exemptions for others with similar sincerely held religious beliefs or moral
 19 convictions. “RFRA is inconsistent with the insistence of an agency such as HHS on distinguishing
 20 between different religious believers . . . when it may treat both equally by offering both of them the
 21 same accommodation.” *Hobby Lobby*, 134 S. Ct. at 2786. The government, the public, and
 22 employers with burdened beliefs have a strong interest in having the Rules implemented.

23 **V. Even If Plaintiffs Prevail, a Limited Injunction Is the Appropriate Remedy**

24 If the Court rules in Plaintiffs’ favor, any injunction should be no broader than necessary to
 25 provide Plaintiffs complete relief, and should therefore be limited to the parties before this Court.⁸

26
 27 ⁸ For that reason, no injunction should run against the portion of the Rules that permits issuers
 28 and plan sponsors to offer plans to individuals that account for sincerely-held objections the
 individual may have; Plaintiffs do not demonstrate any harm from that aspect of the Rules. Any

1 See *Lewis v. Casey*, 518 U.S. 343, 357 (1996). On appeal, the Ninth Circuit vacated the nationwide
 2 scope of the prior injunction, *California*, 2018 WL 6566752, at *16, and a nationwide injunction is
 3 no more appropriate now. Such injunctions are proper only when “*necessary* to give prevailing
 4 parties the relief to which they are entitled.” *Id.* at *15 (internal quotation marks and citations
 5 omitted). They are suspect under the APA, which allows preliminary injunctions only “to the extent
 6 necessary to prevent irreparable injury,” 5 U.S.C. § 705; undercut the class action process; and can
 7 create “substantial interference with another court’s sovereignty,” *California*, 2018 WL 6566752, at
 8 *15 n.9. For example, a nationwide injunction would run directly counter to an earlier district court
 9 ruling denying the relief Plaintiffs seek here to another state that challenged the Mandate on a similar
 10 legal theory. *Massachusetts v. HHS*, No. 17-cv-11930, 2018 WL 1257762 (D. Mass. Mar. 12, 2018).

11 Plaintiffs fail to show that a nationwide injunction is necessary to redress any injury to them.
 12 See *California*, 2018 WL 6566752, at *16 (“The scope of the remedy must be no broader and no
 13 narrower than necessary to redress the injury shown by the plaintiff states.”).⁹ As an afterthought, a
 14 few of Plaintiffs’ declarants note concerns about regulating patients from other jurisdictions, as well
 15 as out-of-state students and employers. Second PI Mem. at 25. But Plaintiffs have failed to offer
 16 anything more than speculation about the likelihood and scope of these problems, much less prove
 17 which states, regions, or institutions would need to be covered by an injunction to prevent them. The
 18 evidence presented is not enough to justify all of the drawbacks of a nationwide injunction.

19 CONCLUSION

20 For these reasons, the Court should deny Plaintiffs’ motion for a preliminary injunction.

21 Dated: January 3, 2019

Respectfully submitted,

22 JOSEPH H. HUNT
 23 Assistant Attorney General

24 _____
 24 injunction also should not interfere with the Agencies’ ability to resolve other existing litigation
 25 challenging the prior accommodation rules. See ECF No. 105.

26 ⁹ Plaintiffs assert that a nationwide injunction is appropriate on a showing of “nationwide
 27 impact or sufficient similarity to plaintiff states,” Second PI Mot. at 25 (quoting *California*, 2018
 28 WL 6566752, at *17), even if that impact is in non-plaintiff states. That characterization of the law
 contradicts the holding in *California*, as well as the language that any injunction must be “necessary
 to give prevailing parties” relief. Plaintiffs’ view of *California* should be rejected; it wrests a dictum
 out of context to undermine the case’s central holding.

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