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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STATE OF CALIFORNIA, *et al.*, Plaintiffs, 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 **FEDERAL DEFENDANTS' SUPPLEMENTAL BRIEF**

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INTRODUCTION

Earlier this year in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020), for the second time in six years, the Supreme Court sided with objectors to what is commonly called the contraceptive-coverage mandate. The Court held that Congress's grant of "virtually unbridled discretion" in the Affordable Care Act ("ACA") to determine what counts as preventive care and screenings for purposes of the women's preventive service mandate, as well as possible exemptions to that mandate, authorized the federal agencies responsible for administering the ACA[1] ("the Agencies") to create religious and moral exemptions to any contraceptive-coverage mandate they might impose. 140 S. Ct. at 2379-82. The Supreme Court further counseled that, in crafting the religious exemption, the Agencies were right to consider that the mandate could violate the Religious Freedom Restoration Act ("RFRA"). *Id*. at 2382-84. Accordingly, the Court vacated decisions enjoining the Agencies' 2018 rules (the "Final Rules")[2] providing exemptions accommodating sincere religious and moral objections to the contraceptive-coverage mandate.

Little Sisters further confirms that Plaintiffs' claims under the Administrative Procedure Act ("APA") have no merit, and must be dismissed or resolved in Defendants' favor. The Agencies acted well within their discretion under the APA to make line-drawing decisions by tailoring the Final Rules to address sincere religious objections to the mandate, while simultaneously allowing the optional accommodation to remain in place for religious objectors who wish to use it. The Agencies also appropriately considered the interests of women in promulgating the Final Rules, explained their reasons for their departures from prior policy, responded to significant comments, and justified the creation of an exemption for those with moral objections to contraceptive coverage. Additionally, the Final Rules do not create an unreasonable barrier to the provision of health care or discriminate against women. Finally, Plaintiffs' constitutional claims, which were left unaddressed in their

[1] The Department of Health and Human Services ("HHS"), the Department of Labor, and the Department of the Treasury.

[2] *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").

supplemental brief, fail: The Rules do not violate the Establishment Clause or the Equal Protection Clause. Federal Defendants, therefore, respectfully request the Court to enter summary judgment in their favor.[3]

ARGUMENT

I. The Supreme Court's Decision in *Little Sisters* Supports the Final Rules.

Before the Final Rules were set to go into effect, they were preliminarily enjoined by this Court as well as a district court in the Third Circuit, which found the Final Rules substantively and procedurally invalid. The respective courts of appeals affirmed these injunctions. *See California v. HHS*, 941 F.3d 410 (9th Cir. 2019); *Pennsylvania v. President of United States*, 930 F.3d 543 (3d Cir. 2019). The Supreme Court granted petitions for a writ of certiorari to the Third Circuit filed by the United States and the Little Sisters of the Poor, which had intervened to defend the Rules. The Supreme Court then reversed the court of appeals and remanded the case for further proceedings consistent with its opinion. *Little Sisters*, 140 S. Ct. at 2386.

In its decision, the Court rejected claims (which Plaintiffs have since withdrawn, ECF No. 434) that the Agencies lacked statutory authority to promulgate the exemptions and violated the notice-and-comment requirements of the APA by soliciting comments after issuing the Interim Final Rules ("IFRs"). *See id*. at 2379-86. The Court also addressed three issues that are relevant to the claims Plaintiffs continue to press here.

First, the Court recognized the Agencies' care in responding to comments on the IFRs and the strength of the Agencies' analysis generally, noting that the Final Rules "responded to post-promulgation comments," and "explain[ed] their reasons for neither narrowing nor expanding the exemptions beyond what was provided for in the IFRs." *Id*. at 2378. The Court also observed that the "final rule creating the religious exemption [] contained a lengthy analysis of the [Agencies'] changed position regarding whether the self-certification process violated RFRA" and that the Agencies explained that "in the wake of the numerous lawsuits challenging the self-certification accommodation and the failed attempt to identify alternative accommodations after the 2016 request

[3] This brief supplements, but does not replace, Federal Defendants' summary judgment briefs filed in 2019. Accordingly, Federal Defendants continue to incorporate and rely on those briefs as support for their motion for summary judgment.

for information, 'an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified'" in *Burwell v. Hobby Lobby Stores, Inc*., 573 U.S. 682, 719 (2014). *Little Sisters*, 140 S. Ct. at 2378 (quoting 83 Fed. Reg. at 57,544-45).

Second, the Court held that, "[u]nder a plain reading of [42 U.S.C. § 300gg-13(a)(4)] . . . the ACA gives [the Health Resources & Services Administration ("HRSA")] broad discretion to define preventive care and screenings and to create the religious and moral exemptions." 140 S. Ct. at 2381. The Court found that Congress made a "deliberate choice" to give an "extraordinarily 'broad general directiv[e]' to HRSA to craft the Guidelines, without any qualifications as to the substance of the Guidelines or whether exemptions were permissible." *Id*. at 2382 (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)). Hence, "HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings," and that discretion "leaves [HRSA's] discretion equally unchecked in other areas, including the ability to identify and create exemptions from its own Guidelines." *Id*. at 2380.

Third, the Court rejected the argument, espoused by Plaintiffs, that the Agencies "could not even consider RFRA as they formulated the religious exemptions." *Id*. at 2382-83. To the contrary, the Court held that, given "the potential for conflict between the contraceptive mandate and RFRA" and the Court's prior opinions, it was "appropriate for the [Agencies] to consider RFRA" and "unsurprising that RFRA would feature prominently in the [Agencies'] discussion of exemptions." *Id*. at 2383. Indeed, the Court reasoned that, had the Agencies not considered RFRA, they "would certainly be susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem." *Id*. at 2384. Thus, the Court concluded that, "[p]articularly in the context of these cases, it was appropriate for the [Agencies] to consider RFRA." *Id*. at 2383.

II. The Final Rules Are Consistent with the APA's Requirements.

A. The Final Rules Are Not Overbroad.

Plaintiffs assert that the religious exemption is arbitrary and capricious because an entity whose religious objections to contraception could be satisfied through the accommodation may nevertheless employ the religious exemption. Pls.' Supp. Br. at 4-5, ECF No. 433. But "[t]he APA

does not . . . require agencies to tailor their regulations as narrowly as possible to the specific concerns that generated them." *Assoc. Dog Clubs of N.Y., Inc. v. Vilsack*, 75 F. Supp. 3d 83, 92 (D.D.C. 2014). Rather, "[a]n agency has wide discretion in making line-drawing decisions" and "is not required to identify the optimal threshold with pinpoint precision." *Nat'l Shooting Sports Found., Inc.* ("*NSSF*") *v. Jones*, 716 F.3d 200, 214-15 (D.C. Cir. 2013) (quotation marks omitted); *see also Little Sisters*, 140 S. Ct. at 2380 (recognizing broad discretion of agencies to identify and create exemptions).

The line drawn need only be "within a zone of reasonableness." *NSSF*, 716 F.3d at 214. The Religious Exemption Rule easily satisfies this standard. The Rule alleviates the burden on those with religious objections to the mandate, and it does so by exempting such entities from the mandate. *See* 83 Fed. Reg. at 57,556. That some of these religious objections could have been addressed through the "accommodation" does not render the decision to provide a simple exemption for religious objectors unreasonable, and to hold otherwise would be to unduly limit the Agencies' "virtually unbridled discretion . . . to identify and create exemptions from its own guidelines," *Little Sisters*, 140 S. Ct. at 2380, and to demand a pinpoint precision that the APA does not require. And while Plaintiffs suggest that the Agencies erred in characterizing their solution as "straightforward" because they did not eliminate the accommodation, Pls.' Supp. Br. at 5, (an odd position for Plaintiffs to take, given that they generally would prefer more entities use the accommodation), the Agencies' resolution was easier to implement because it did not compel certain objecting entities to use the accommodation while granting others an exemption.

Indeed, because the Agencies retained the accommodation as an option for objecting employers, there is no reason to think that, in practice, the exemption will be utilized by all objecting employers. Providing coverage for contraceptives is cost neutral for an employer or school, *see* Coverage of Certain Preventive Services Under the ACA, 78 Fed. Reg. 39,870, 39,877 (July 2, 2013), and such coverage is a valuable benefit to some employees and students. There is no reason that an employer or school that does not object to providing contraceptive coverage through the accommodation would nevertheless invoke the exemption, since the accommodation would provide its employees or students a benefit that does not cost it anything. The line drawn by the Agencies,

then, is well "within a zone of reasonableness": it is tailored to address sincere religious objections to the contraceptive coverage mandate, while leaving in place the optional accommodation for those religious objectors who elect to use it.

Plaintiffs suggest that the Religious Exemption Rule should have required objecting entities to notify the federal government of their objection, Pls.' Supp. Br. at 4, but the Agencies considered this issue and decided to continue without requiring notices (just as the Agencies had done with respect to the prior exemption). They explained that an additional regulatory mechanism was unnecessary because, among other reasons, "[t]he previous exemption did not require a self-certification or notice" and existing mechanisms are sufficient to allow for effective enforcement. 83 Fed. Reg. at 57,558. To the extent Plaintiffs' real concern is with notice to beneficiaries, the Agencies further noted that ERISA requires entities to provide notices of benefits and changes in benefits, where applicable. *Id.*.

Plaintiffs also object to the Religious Exemption Rule's coverage of publicly traded companies, Pls.' Supp. Br. at 5-6, but this contention similarly lacks merit. For one thing, RFRA applies to publicly traded entities to the extent they exercise religion. *Cf. Hobby Lobby.*, 573 U.S. at 707-08 (discussing the definition of "person" in RFRA). While Federal Defendants are unaware of any publicly traded entity that has a sincere religious objection to providing contraceptive coverage, if one does, then it is not arbitrary or capricious to address that objection. Conversely, if none does, then the mere availability of the exemption harms neither Plaintiffs nor anyone else.

Plaintiffs also criticize the Moral Exemption Rule on the grounds that it "extends to employers, insurers, and individuals." Pls.' Supp. Br. at 4. Plaintiffs do not explain why this is problematic; the Agencies thoroughly explained why they decided to cover each of those types of entities with sincerely held moral objections to providing coverage for some or all contraceptives. *See, e.g.*, 83 Fed. Reg. at 57,617-19 (explaining the Agencies' reasons for including some for-profit organizations); *id*. at 57,619-20 (same for institutions of higher education); *id.* at 57,620-21 (same for health insurance issuers); *id.* at 57,621-23 (same for individuals).

Finally, Plaintiffs argue that the Agencies did not consider alternatives "that would adequately protect the interests of women." Pls.' Supp. Br. at 7. Despite facilely suggesting that alternatives exist that would satisfy both women who want contraceptive coverage and employers with sincere religious objections to providing it, Plaintiffs identify no such alternatives. Indeed, in 2016, after *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), the Agencies sought public comment on whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while providing a mechanism for contraceptive coverage for their employees. *See* Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies received over 54,000 comments, but, on January 9, 2017, they issued a document entitled "FAQs About Affordable Care Act Implementation Part 36,"[4] concluding that they could not identify a way to amend the accommodation that would both satisfy objecting organizations and ensure that women covered by those organizations' plans receive seamless contraceptive coverage. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventative Services Under the ACA, 82 Fed. Reg. 47,792, at 47,798-47,799, 47,814 (Oct. 13, 2017). Moreover, the Agencies considered a number of alternatives in the Final Rules. *See, e.g.*, 83 Fed. Reg. at 57,542. As the Supreme Court has stated, "[c]ommon sense" teaches that an agency should not be required to address "every alternative device and thought conceivable by the mind of man." *Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.*, 435 U.S. 519, 551 (1978). Indeed, an agency "need not consider every alternative proposed nor respond to every comment made." *NSSF*, 716 F.3d at 215. The agencies' consideration of alternatives readily satisfies the requirements of the APA.

Nor was the Agencies' response to the alternatives they considered "cavalier"—indeed, the multiple pages of the Federal Register Plaintiffs cite in support of this argument demonstrate the opposite. Pls.' Supp. Br. at 7 n.3. And while Plaintiffs criticize as "conclusory" the Agencies' decision that expanding the accommodation process would not resolve all religious objections, *id.*, years of litigation and the Agencies' fruitless solicitation of more than 54,000 public comments in

[4] FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resourcecenter/faqs/aca-part-36.pdf.

2016 have taught that no adjustment to the accommodation would satisfy everyone. 83 Fed. Reg. at 57,544.

B. The Agencies Appropriately Considered the Effect of the Rules on Women.

Plaintiffs contend that Federal Defendants "failed to meaningfully consider women's interests" and"provided inadequate explanations for disregarding prior rules, running afoul of the APA's standard for considering reliance interests, as interpreted by *DHS v. Regents of the University of California*, 140 S. Ct. 1891 (2019). Pls.' Supp. Br. at 8. Plaintiffs' contentions are meritless.

1. The Agencies adequately considered women's interests. *See generally Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (rule is arbitrary and capricious if it "entirely fail[s] to consider an important aspect of the problem"). In the Religious Exemption Rule, across nine pages of the Federal Register, the Agencies considered and discussed "Burdens on Third Parties," "The Health Effects of Contraception and Pregnancy," and the "Health and Equality Effects of the Contraceptive Coverage Mandate." 83 Fed. Reg. at 57,548-56. In the Moral Exemption Rule, the Agencies similarly considered the potential effect of the exemption on women. *See, e.g.*, *id.* at 57,613. In doing so, the Rules evaluated comments regarding, among other things, the potential effects of the exemptions on (i) contraceptive access and costs, (ii) unintended pregnancy, and (iii) economic and social inequality. *Id.* at 57,548. The Agencies also estimated the number of women who would be affected by the religious and moral exemptions. *See, e.g.*, *id.* at 57,574-82. Thus, it is clear that the Agencies did not "entirely fail[]" to consider women's interests. *State Farm*, 463 U.S. at 43.

Plaintiffs' arguments to the contrary are unpersuasive. Plaintiffs argue that "[d]espite [] findings and admissions [from earlier briefs and regulatory actions contending that there is a compelling interest in contraceptive coverage], Defendants failed to explain why it was rational to so strongly prioritize employers' interests, at the expense of the millions of women who have benefitted from the Women's Health Amendment." Pls.' Supp. Br. at 9. There are numerous defects with this statement. First, the Rules clearly explain that the Agencies have now concluded that there is no compelling interest in requiring entities with religious and moral objections to providing

contraceptive coverage to do so. 83 Fed. Reg. at 57,547. Second, the Agencies did not irrationally "prioritize employers' interests;"[5] rather, they concluded, in their judgment, that the policy interests in favor of expanding the religious exemption and creating the moral exemption, to protect the interests of those with sincere conscience objections, outweighed the interests in leaving the contraceptive-coverage mandate unchanged. *Id*. at 57,555-56. *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038 (D.C. Cir. 2012) (noting that a "[policy] reevaluation is well within an agency's discretion," even without new facts). Finally, there is no evidence that "millions of women" have been affected by these exemptions. This is hyperbole with no basis in the record. Rather, the Agencies concluded, based on the record, that the Final Rules would likely affect, at most, 126,400 women, 83 Fed. Reg. at 57,581.

Plaintiffs' claims that the Agencies improperly "prioritize[d]" the interests of religious and moral objectors are little more than policy objections that afford no basis for relief. To start, Plaintiffs claim that the Agencies should have required notice or self-certification from entities invoking the exemption to enable the Agencies to track how many women have been affected by the exemptions. Pls.' Supp. Br. at 9. But the Agencies considered whether to impose a notice or self-certification process and decided that an additional regulatory mechanism was unnecessary because, among other reasons, "[t]he previous exemption did not require a self-certification or notice" and existing mechanisms are sufficient to allow for effective enforcement. 83 Fed. Reg. at 57,558. In short, the Agencies weighed the benefits and burdens of a notice or self-certification process, and made a reasoned policy judgment not to create an additional regulatory hurdle. Plaintiffs would prefer a different outcome and want the Court to substitute their judgment for that of the Agencies, but under the APA, it cannot do so. *State Farm*, 463 U.S. at 43.

[5] Plaintiffs repeatedly refer to those with sincere religious and moral objections simply as "employers." *See* Pls.' Supp. Br. at 7-13. But contrary to the impression Plaintiffs intend to create through the repeated use of the word "employer," the Agencies were not weighing the interests of women in contraceptive coverage against the economic interests of employers. Rather, they were balancing the interest in contraceptive coverage against sincere religious and moral objections to the provision of that coverage. *See, e.g.*, 83 Fed. Reg. at 57,556. Plaintiffs' use of the word "employer" should not obscure this fact.

None of Plaintiffs' other examples demonstrates that the Agencies acted in an arbitrary or capricious fashion. Plaintiffs assert that "Defendants also fail to explain their rationale for allowing all [religious and moral objectors] the ability to access the Exemption as quickly as possible, despite the fact that Defendants did not identify employers in need of immediate relief." Pls.' Supp. Br. at 9. The Final Rules, in fact, explain their rationale for the timing of the availability of the expanded exemptions. To start, the Agencies noted that some commenters asked the Agencies "to add language indicating that an exemption cannot be invoked in the middle of a plan year." 83 Fed. Reg. at 57,559. But the Agencies explained that "[n]one of the previous iterations of the exemption regulations included such provisions," *id.*, and they laid out in detail limits on the ability of objectors to switch from the accommodation to the expanded exemptions. They further explained that "[b]ased on the objections of various litigants and public commenters, we believe that some entities [were] [] using the accommodation . . . only because previous regulations denied them an exemption"—*i.e.*, are in immediate need of relief—and they may invoke one of the exemptions using a "transitional 60-day[] notice procedure (if applicable)." *Id.* at 57,571. The Agencies concluded that those who choose to remain in or enter into the accommodation in a future plan year, notwithstanding the availability of the exemption, will have to "wait until the first day of the following plan year to change [from the accommodation] to exempt status." *Id.* The Agencies, then, weighed various considerations and made a reasonable policy determination, which has been entrusted to them by Congress, *Little Sisters*, 140 S. Ct. at 2380, and the Court must decline Plaintiffs' invitation to substitute its judgment for that of the Agencies. *State Farm*, 463 U.S. at 43.

Plaintiffs' arguments challenging the applicability of the Religious Exemption Rule to publicly traded companies and the applicability of both rules to closely held for-profit entities are similarly flawed. We have already explained the flaws in this argument as to publicly traded companies. *See supra* § II.A. As for closely held for-profit entities, applying the exemptions to them flows naturally from *Hobby Lobby*, which held that RFRA applies to such entities. 573 U.S. at 708. Thus, applying the exemptions to for-profit entities demonstrates an effort to reach rational

conclusions that align with RFRA, the APA, and precedent, not an arbitrary and capricious prioritization of the interests of objectors.

2. Plaintiffs insist that the Agencies' "explanations fall short of the reasoned decisionmaking that would be necessary to justify such a dramatic departure from the Departments' prior policies, at the expense of the fundamental policy interests underlying the Women's Health Amendment," Pls.' Supp. Br. at 10-11, but their insistence does not make it so. The Agencies adequately explained their changed positions, as Defendants have already discussed. Defs.' Mot. to Dismiss, or in the Alternative, Mot. for Summ. J., & Defs.' Opp'n to Pls.' Mot. for Summ. J. ("Fed. Defs.' MSJ") at 32-37, ECF No. 366. Plaintiffs' arguments do not actually focus on whether the Agencies sufficiently explained matters on which they changed position, in the vein of *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009). Rather, Plaintiffs' arguments amount to little more than their request for the Court to substitute its policy judgment for that of the Agencies.

Plaintiffs first argue that the Rules "ignore[] that the Women's Health Amendment was designed to ensure women receive full and equal coverage." But the ACA does not obligate the Agencies to require employers and schools to provide contraceptive coverage. Rather, Congress afforded HRSA the authority to determine whether, and to what extent, to require private entities to offer contraceptive coverage. *Little Sisters*, 140 S. Ct. at 2380 (noting that, under the ACA, "HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings" and "to identify and create exemptions from its own Guidelines"). And the Agencies have not treated women unequally: it is the relevant provision of the ACA that obligates employers and schools to offer coverage without cost sharing only for preventive services for women. *See* Fed. Defs.' MSJ at 49.

Plaintiffs next argue that the Rules "fail to explain how women would 'challenge' their employer's claim when HHS has not set forth any type of process for employees to assert such challenges." Pls.' Supp, Br. at 11. But the Rules identify the existing processes for challenging improper invocations of the exemptions. *See* 83 Fed. Reg at 57,558 ("The Mandate is enforceable through various mechanisms in the [Public Health Services] Act, the [Internal Revenue] Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so

at the risk of enforcement under such mechanisms."); *see also* 26 U.S.C. § 4980D; 29 U.S.C. § 1132(a); 42 U.S.C. § 300gg-22; 45 C.F.R. part 150. The Rules are not arbitrary and capricious for relying on such existing processes.

Plaintiffs also argue that the Final Rules incorrectly "assume that women are able to both identify and select a potential future employer [or school] based on whether that employer or [school] will cover their contraceptive care." Pls.' Supp. Br. at 11. The Final Rules make no such assumption. The Final Rules recognize that some women may lose contraceptive coverage that they desire based on the Final Rules, although they note that some women who lose coverage may not desire it, because they may share the beliefs of their employers. 83 Fed. Reg. at 57,561. The Final Rules also recognize that women may be able to determine in advance whether an employer offers contraceptive coverage and make their employment choices accordingly, just as they do with respect to other benefits. *See id.* As to colleges and universities, the Religious Exemption Rule simply points out that many students who attend institutions with religious missions "do so because of the institutions' religious tenets," but that "[a]t a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans they arrange." *Id.* at 57,564. These are commonsense statements, which Plaintiffs cannot, and do not, challenge.

As the Final Rules explained, the Agencies could not accommodate the interests of all women who might want contraceptive coverage and all employers and schools with sincere religious or moral objections to providing it. *See, e.g.*, *id*. at 57,556. The Final Rules thus adopted the expanded exemption with optional accommodation as the best approach to resolving the competing interests. Plaintiffs' strawman argument reflects nothing more than a dispute with the policy decision that the Agencies made, but a mere policy disagreement does nothing to demonstrate that the Final Rules are arbitrary and capricious—they are not.

3. Plaintiffs also argue that the Agencies inadequately considered reliance interests, contrary to the holding of *Department of Homeland Security v. Regents of the University of California*, 140 S. Ct. 1891 (2019). Pls.' Supp. Br. at 12-13. Not so. *Regents* requires that an agency

evaluate any reliance interests that may have built up and weigh them against competing policy concerns. *Regents*, 140 S. Ct. at 1915. The Agencies did just that. As noted at the outset of this section, the Agencies considered the effect of the Rules on women, including any reliance interests that had built up. *See, e.g.*, 83 Fed. Reg. at 57,556 (considering whether the contraceptive coverage mandate has "led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive, contraceptive methods"). And they weighed these interests against competing policy concerns: "[W]e conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions." *Id. Regents* requires nothing more.

C. The Agencies Sufficiently Justified Their New Policy.

Plaintiffs argue that the Agencies insufficiently explained their reasoning in departing from their prior policy. Pls.' Supp. Br. at 14-15. These arguments fail. "The scope of review under the 'arbitrary and capricious' standard is narrow." *State Farm*, 463 U.S. at 43. An agency generally 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." *Fox Television Stations*, 556 U.S. at 515. The Agencies plainly meet this standard.

Plaintiffs are wrong to suggest that the Agencies were required to disavow all of their prior factual findings to justify promulgating a new rule. The Ninth Circuit has recognized that changed factual circumstances are not a prerequisite to policy change. *Village of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc). Here, the Agencies considered the record and rebalanced "the various policy interests at stake." 83 Fed. Reg. at 57,556. That does not mean that they rejected all of their prior factual conclusions—there is nothing inconsistent, for example, in the Agencies promulgating the Final Rules while at the same time recognizing that contraceptives can be beneficial. The Final Rules simply address the proper balance between conscience objections and

the contraceptive coverage requirement. *Id*. Plaintiffs therefore miss the mark in arguing that the Rules wrongly "do not reject," for example, that contraceptives have benefits for women. Pls.' Supp. Br. at 14.

But in any event, the Agencies did address each of the issues identified by Plaintiffs. That Plaintiffs disagree with the Agencies' conclusions is not a reason to find the Agencies' action arbitrary and capricious. On pages 14 to 15 of their brief, Plaintiffs list (in single-spaced, bullet-point form) a series of statements from previous regulations, which Plaintiffs allege both have not been withdrawn and are inconsistent with the Final Rules. *See* Pls.' Supp. Br. at 14-15. Plaintiffs are wrong, as the point-by-point rebuttal below demonstrates.

(1) The Agencies thoroughly explained their conclusion that applying the mandate to objecting entities did not serve a compelling interest. 83 Fed. Reg. at 57,546-48.

(2) – (4) Each of these statements deals with the benefits of contraception. While the Agencies acknowledged benefits of contraception for women, they cited ample medical evidence—including more than twenty studies from well-established, peer-reviewed medical journals—for their conclusion that the benefits of contraceptives and the contraceptive mandate are more uncertain than previously recognized. *See, e.g., id*. at 57,552-53 nn.28-34, 57,555. And, the health benefits of contraceptives and the contraceptive mandate are medical and health policy issues, which lie well within the ambit of HHS's scientific and technical expertise. *See, e.g., Styrene Info. & Research Ctr., Inc. v. Sebelius*, 944 F. Supp. 2d 71, 87 (D.D.C. 2013).

(5) While the Agencies had previously sought to provide contraceptive coverage to women "seamless[ly]," the Agencies determined that the government did not have a compelling interest in such seamlessness as reflected in the prior rule's multiple exceptions, including exemptions for grandfathered plans, churches, and churches' integrated auxiliaries, as well as the application of the accommodation to self-insured church plans. 83 Fed. Reg. at 57,548.

(6) – (7) The Agencies did not need to reverse their prior recognition of the disadvantages faced by women in the workplace or of the possibility that the expanded exemption would lead to some women losing coverage for contraception in order to conclude that, on balance, the Agencies should provide a more fulsome exemption for religious and moral objectors while recognizing that women would still have access to contraception from a number of sources. *Id*. at 57,551.

Plaintiffs' final two examples are not the Agencies' past conclusions in rulemakings, but characterizations of those conclusions in litigation briefs. Plaintiffs offer no authority suggesting that agencies act arbitrarily or capriciously if they do not specifically address such litigation statements in promulgating rules. In any event, the Agencies did in fact comprehensively consider the potential effect of the Religious Exemption Rule on women's health and equality. *Id*. at 57,555-56. The Agencies noted "conflicting evidence" and stated that they did not take a "definitive position on those evidentiary issues" but "conclude[d] that the Religious IFC and these final rules . . . are not likely to have negative effects on the health or equality of women nationwide." *Id*. at 57,556. Plaintiffs offer no basis to dispute those conclusions, which is appropriate because a court in arbitrary and capricious review is to ensure only that an agency's reasoning may be reasonably discerned.

D. Federal Defendants Adequately Responded to Comments.

Plaintiffs cross-reference their earlier briefing to argue that Federal Defendants did not sufficiently respond to comments. *See* Pls.' Supp. Br. at 15-16. For the reasons addressed in Federal Defendants' earlier briefing, this argument falls short. *See* Fed. Defs' MSJ at 42-43; Defs.' Reply Br. in Supp. of Mot. to Dismiss, or in the Alternative, Mot. for Summ. J. ("Fed. Defs.' Reply MSJ") at 21, ECF No. 388. Indeed, all the APA requires is that an agency "*respond* to significant comments, *i.e.*, those which raise relevant points and which, if adopted, would require a change in the agency's proposed rule." *Am. Mining Congress v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992) (quoting *Home Box Office v. FCC*, 567 F.2d 9, 35 & n.58 (D.C. Cir. 1977) (per curiam)) (emphasis added). The Agencies here did so, and *Little Sisters* further bolsters this conclusion by approvingly noting that the Agencies "responded to post-promulgation comments, explaining their reasons for neither narrowing nor

expanding the exemptions beyond what was provided for in the IFRs." *See Little Sisters*, 140 S. Ct. at 2378. Plaintiffs here make no new arguments to the contrary, and the claim must be rejected.

E. The Moral Exemption Is Not Arbitrary or Capricious.

Plaintiffs contend that the Moral Exemption Rule was arbitrary and capricious because it was not supported by RFRA, and thus Congress did not "intend[] the agency to consider [moral] objections." *See* Pls.' Supp. Br. at 16. But the fact that RFRA does not justify the Moral Exemption Rule does not render it arbitrary or capricious. The Moral Exemption Rule was not intended to alleviate religious conflicts, but instead to provide relief to entities with a *non-religious*, moral objection to the mandate. *See, e.g.*, 83 Fed. Reg. at 57,573. Indeed, Congress did not prohibit the Agencies from creating an exemption for those with moral objections to contraceptive coverage. The Supreme Court itself concluded just the opposite in *Little Sisters*, holding: "Under a plain reading of the statute, then, we conclude that the ACA gives HRSA broad discretion to define preventive care and screenings and to create the religious and *moral* exemptions." *Little Sisters*, 140 S. Ct. at 2381 (emphasis added). That holding is binding on this Court, and refutes Plaintiffs' contention that the Agencies acted impermissibly by creating moral exemptions.

In fact, the Moral Exemption Rule demonstrates rational decisionmaking. Litigation by those with moral objections to the mandate illustrates the usefulness of a moral exemption for addressing non-religious conscience objections in the context of contraceptive coverage, *see* 83 Fed. Reg. at 57,602-03, and the existence of conscience protections in other federal and state statutes reflects the "tradition of protecting moral convictions in certain health contexts." *Id*. at 57,601. These are reasonable rationales for the Agencies' decision, which is all the APA requires.

F. The Majority of Plaintiffs' Arguments with Respect to the Religious Exemption Rule Fail Under the Harmless Error Provision of the APA.

The majority of Plaintiffs' arguments under the APA's arbitrary and capricious clause assail the Rules for inadequately considering or explaining certain issues. *See* Pls.' Supp. Br. at 3-16. These arguments lack merit. *See supra* I.B-E. But even if they were meritorious, they would fail with respect to the Religious Exemption Rule under the APA's harmless error clause. Under that clause, "due account shall be taken of the rule of prejudicial error." 5 U.S.C. § 706. Any error here would

be harmless. The arbitrary and capricious clause exists to ensure that agencies engage in reasoned decisionmaking. *See, e.g.*, *Fox v. Clinton*, 684 F.3d 67, 74-75 (D.C. Cir. 2012). But the Agencies had no decision to make with regard to the Religious Exemption Rule: RFRA obligated the Agencies to issue it. *See* Fed. Defs.' MSJ at 21-22. To be sure, the Agencies nevertheless considered all the factors Plaintiffs identify and thoroughly explained that they would have issued the same Rule even if the matter were a discretionary one. But because RFRA required the religious exemption, it ultimately does not matter what the Agencies considered or did not consider, or how they explained their decision-making process.

III. The Final Rules Are Consistent With Sections 1554 and 1557 of the ACA.

A. The Rules Do Not Create an Unreasonable Barrier to Obtaining Health Care.

Section 1554 of the APA prohibits regulations that "*create*[] any *unreasonable* barriers to the ability of individuals to obtain appropriate medical care" or "*impede*[] timely access to health care services." 42 U.S.C. § 18114(1), (2) (emphasis added).[6] Contrary to Plaintiffs' strained reading of the statute, Pls.' Supp. Br. at 16-18, "creating" or "impeding" something requires an affirmative act. The Supreme Court has long recognized this common-sense "distinction between regulations that impose burdens on health care providers and their clients and those that merely reflect Congress's choice not to subsidize certain activities." *California v. Azar*, 950 F.3d 1067, 1092 (9th Cir. 2020) (en banc) (citations omitted); *see, e.g.*, *Rust v. Sullivan*, 500 U.S. 173, 200-01 (1991); *Harris v. McRae*, 448 U.S. 297, 316 (1980).

Plaintiffs' supplemental brief reviews the out-of-pocket costs of obtaining a variety of forms of contraceptives, and notes that certain women may be required to absorb these costs or switch to a less expensive (and effective) form of contraception as a result of price pressure. Pls.' Supp. Br. at 16-17. But the Agencies did not "create" through regulation the costs of contraceptives, and the Final

[6] Plaintiffs' complaint fails even to mention 42 U.S.C. § 18114(6), which generally prohibits regulations that "limit[] the availability of health care treatment for the full durations of a patient's medical needs." *See* Second Am. Compl. ¶ 52, ECF No. 170 (relying solely on 42 U.S.C. § 18114(1), (2)). Nor do Plaintiffs' merits briefs mention this provision. *See* ECF Nos. 311, 385, 392. A litigant may not amend its complaint by presenting a new theory for the first time in a supplemental brief after summary judgment briefing has already concluded. In any event, such a theory would fail for the same reasons that Plaintiffs' theories under subsections (1) and (2) fail, as explained below.

Rules impose no barriers, cost or otherwise, on any woman who wishes to obtain contraceptives. Rather, the Final Rules create exemptions that narrow the scope of employers subject to the contraceptive-coverage requirement, which was not required by the preventive-services mandate in the first place. These Rules accordingly do not thwart the purposes of the preventive-services mandate. No legislative scheme "pursues its purposes at all costs," *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987), and the exemptions reflected in the Final Rules apply to only a small subset of employers. Even if the Court were to conclude that these Rules impose "barriers" to coverage, as explained above, those barriers are not "unreasonable" ones in light of the substantial burden on religious exercise that the contraceptive-coverage requirement creates and the numerous exemptions to the requirement that already exist in law.

Additionally, Plaintiffs err in attempting to distinguish the Ninth Circuit's *en banc* decision in *California v. Azar*, which rejected a challenge under Section 1554 for similar reasons. *California*, 950 F.3d at 1091-95; *see* Pls.' Supp. Br. at 18-19. While it is correct that *California* itself concerned restrictions on a federally-funded program, the Ninth Circuit's analysis was not limited to such restrictions. Rather, in declaring that "[t]he Supreme Court has long made a distinction between regulations that impose burdens on health care providers and their clients and those that merely reflect Congress's choice not to subsidize certain activities," 950 F.3d at 1092, the Ninth Circuit cited, *inter alia*, *Regan v. Taxation With Representation of Washington*, 461 U.S. 540 (1983), which did not involve a federally-funded program. *See id*. at 541-44, 549-50 (rejecting contention that Congress could not condition tax-exempt status for non-profit corporations on prohibiting such corporations from engaging in lobbying, and explaining that "[w]e have held in several contexts that a legislature's decision not to subsidize the exercise of a fundamental right does not infringe the right" (citing, *inter alia*, *Buckley v. Valeo*, 424 U.S. 1 (1976))). Plaintiffs' attempt to cabin the Ninth Circuit's decision in *California* thus runs contrary to that decision's plain language. For the same reasons that a governmental decision not to subsidize the provision of abortion services did not run afoul of Section 1554, the decision not to require private entities with conscience objections to provide contraceptive coverage is similarly permissible.

B. The Final Rules Do Not Discriminate Against Women.

Federal Defendants' summary judgment briefs explain that because the Rules do not discriminate on the basis of sex, they do not violate Section 1557 of the ACA, which prohibits the government from excluding, denying, or discriminating against individuals "on the grounds" prohibited by Title VI of the Civil Rights Act, Title IX of the Education Amendments of 1972, and the Age Discrimination Act of 1975. 42 U.S.C. § 18116; *see* Fed. Defs.' MSJ at 48-51, Fed. Defs.' Reply MSJ at 23-24. Nor does *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), cited by Plaintiffs, suggest otherwise. That case held that under Title VII, "[a]n employer who fires an individual for being homosexual or transgender fires that person for traits or actions it would not have questioned in members of a different sex." *Id*. at 1737. Such a holding is far afield from this case. Here, the Final Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing an exemption for those with religious and moral objections. Any distinctions in coverage among women are thus not premised on sex, but on the existence of a religious or moral objection on the part of an employer to facilitating the provision of contraceptives. Although it is true that neither the Final Rules nor the Guidelines require any coverage of male contraceptives, *see* Coverage of Certain Preventative Services Under the ACA, 78 Fed. Reg. 8456, 8458 n.3 (Feb. 6, 2013), that is because 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). Consequently, the Rules do not treat men more favorably, and any sex-based distinctions flow from the statute. The Final Rules are therefore consistent with Section 1557 of the ACA.

IV. Plaintiffs' Constitutional Claims Remain Flawed.

Plaintiffs do not address their Establishment Clause or Equal Protection claims in their supplemental brief. There is a good reason for this reticence: the claims lack merit. Take first the Establishment Clause claim. "[T]here is no basis for an argument . . . that the [Final Rules] violate[] that Clause." *Little Sisters*, 140 S. Ct. at 2396 n.13 (Alito, J., with Gorsuch, J., concurring). The Moral Exemption Rule does not pertain to religious beliefs at all. With respect to the Religious Exemption Rule, the majority in *Little Sisters* held not only that the Agencies could consider

religious-based objections to the contraceptive-coverage mandate and accommodation, but that they were obliged to do so, and that the ACA grants "broad discretion to define preventive care and screenings and to create the religious and moral exemptions." *Id.* at 2381. When the Agencies considered religious-based objections as they were required to, and exercised the broad discretion afforded to them to create the religious exemption, they did not run afoul of the Establishment Clause. As the Supreme Court has repeatedly held, "there is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause." *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005) (quotation marks omitted).

Plaintiffs' equal protection claim fares no better. *See* Fed. Defs.' MSJ at 48-51. The Final Rules do not discriminate on the basis of sex, as explained above. The Final Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing an exemption for those with religious and conscience objections. The Rules do not require any coverage of male contraceptives. *See* 78 Fed. Reg. at 8458 n.3. Nor could they: the statutory provision requiring coverage for additional preventive services pertains only to such services for "women," 42 U.S.C. § 300gg-13(a)(4), so any distinction between men and women flows from the statute, not the Rules. Finally, any distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection to facilitating the provision of contraceptives.

CONCLUSION

For the reasons stated above and in Federal Defendants' merits briefs, the Court should enter summary judgment for Defendants.

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Respectfully submitted,

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