

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF)
PENNSYLVANIA and STATE OF)
NEW JERSEY,)
)
Plaintiffs,)
v.)
)
DONALD J. TRUMP, in his official)
capacity as President of the United States;)
et al.,)
)
Defendants.)
_____)

Civil Action No. 2:17-cv-04540 (WB)

**REPLY MEMORANDUM IN SUPPORT OF FEDERAL
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Plaintiffs do not dispute that *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657 (2020), directly controls three of Plaintiffs’ APA claims. Am. Compl. ¶¶ 174-76 (Agencies’ acceptance of comments after the issuance of interim final rules violated the APA), ¶ 182 (Agencies violated the APA by enacting the Final Rules without statutory authority) ¶ 185 (Agencies could not consider RFRA when enacting the religious exemption), ECF No. 89.¹ Plaintiffs have also voluntarily dismissed their constitutional and statutory claims. ECF No. 341-1, at 2 n.1. The rest of Plaintiffs’ claims fare no better.

Plaintiffs make a number of arguments intended to show that the Final Rules are arbitrary and capricious. These arguments fail. The “‘arbitrary and capricious’ standard of the APA is a high bar” for Plaintiffs to cross, *N.J. Bd. of Pub. Utils. v. FERC*, 744 F.3d 74, 102 (3d Cir. 2014), and they do not cross it here. Plaintiffs argue that the Religious Exemption Rule is too broad. But arbitrary and capricious review is not strict scrutiny—there is no narrow tailoring requirement—and the Religious Exemption Rule satisfies the APA by being at least rationally connected to its purpose. Plaintiffs also argue that the Moral Exemption Rule contravenes congressional intent. But as the Supreme Court pointed out in *Little Sisters*, Congress afforded the agencies “broad discretion . . . to create the religious and *moral* exemptions.” 591 U.S. at 677 (emphasis added). Nor is there any defect in the Rules’ explanation of the Agencies’ evolution in thinking: the Rules recognize the Agencies’ changes in position and explain the bases for the changes. Similarly unavailing are Plaintiffs’ attacks on the Rules’ regulatory impact assessments—the Agencies reasonably assessed the impact of the Rules using available information. Finally, although in their

¹ The abbreviations in this brief have the same meaning as in Federal Defendants’ Motion for Summary Judgment.

brief, Little Sisters raise various constitutional challenges to the contraceptive coverage mandate as a whole, the Court need not resolve these arguments if it upholds the Final Rules. Federal Defendants thus respectfully request that the Court enter judgment in their favor.

ARGUMENT

I. The Final Rules Comply With the APA.

A. The Religious Exemption Rule Reasonably Addresses the Problems It Aimed to Resolve, Including the Agencies' Obligation to Consider RFRA.

The religious exemption represents the Agencies' reasonable response to the need to accommodate religious exercise, both as a policy matter and to comply with RFRA. It applies only to entities with sincere religious objections to the contraceptive mandate. The Agencies' decision was both reasoned and reasonable—that Plaintiffs would have crafted a different exemption or accommodation is of no consequence. As Federal Defendants previously noted, Fed. Defs.' SJ Mem. at 37-42, ECF No. 343-1, because RFRA required the Religious Exemption Rule, any error in analyzing or explaining other factors would be harmless. Therefore, the Agencies' decision to consider RFRA's requirements—which has now been upheld by the Supreme Court—was certainly not arbitrary or capricious. Plaintiffs' objections largely rest on their continued resistance to the lenient standard for arbitrary and capricious review. But “[t]he scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Court is to determine only whether the agency’s decision “was the product of reasoned decisionmaking,” *id.* at 52, and whether there was a “rational connection between the facts found and the choice made,” *id.* at 43 (citation omitted).

Contrary to this lenient standard, Plaintiffs appear to assert that the religious exemption must be perfectly tailored to the Agencies' RFRA analysis—and cover no entities except those

that are substantially burdened by the accommodation. But the APA does not require such an exact fit. Plaintiffs offer no response to the cases Federal Defendants have previously cited for the proposition that “[t]he APA does not . . . require agencies to tailor their regulations as narrowly as possible to the specific concerns that generated them.” *Associated Dog Clubs of N.Y., Inc. v. Vilsack*, 75 F. Supp. 3d 83, 92 (D.D.C. 2014). Because the Religious Exemption Rule clearly falls “within a zone of reasonableness,” this Court should decline Plaintiffs’ invitation to require that the Agencies “identify the optimal threshold with pinpoint precision.” *Nat’l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214-15 (D.C. Cir. 2013) (citation omitted).

The reasonableness of the Agencies’ choice is demonstrated because as a practical matter, entities that do not object to having their participants and beneficiaries obtain contraceptive services through the accommodation are unlikely to stop utilizing the accommodation, given that the accommodation is cost-neutral and that contraception is valuable to some employees and students. Plaintiffs’ suggestion that the Agencies may not go further than the bare minimum required by RFRA would require the Agencies to err on the side of impinging on religious liberty or, at the very least, to hit a bullseye that the past fourteen years of litigation have shown is easy to miss. It would also impose a significant substantive constraint on the Agencies’ “broad [statutory] discretion . . . to create the religious . . . exemption[.]”—a constraint nowhere recognized by the Supreme Court. *Little Sisters*, 591 U.S. at 676-77 (describing the discretion as “virtually unbridled”). That is not what the APA requires. Regarding the religious exemption’s application to publicly traded companies, Plaintiffs erroneously try to impose a standard higher than arbitrary and capricious review for agency decisions involving application of a statute that the agency does not administer. Pls.’ SJ Reply at 4, ECF No. 345. The authority Plaintiffs cite for this remarkable proposition, *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), held that “courts . . .

may not defer to an agency interpretation of the law simply because a statute is ambiguous.” *Id.* at 413. But the Agencies are not asking the Court to defer to their interpretation of RFRA on the grounds that that statute is ambiguous; instead, they have shown that their application of RFRA in the Rules is not arbitrary and capricious. Plaintiffs’ theory that some higher standard applies would vitiate arbitrary and capricious review, since agencies frequently must consider a variety of factors and statutes in their reasoning. The Agencies’ analysis is sensible under RFRA, particularly after *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), recognized that RFRA protected certain for-profit companies. It was therefore not arbitrary for the Agencies to act to protect any publicly traded objectors. Indeed, to conclude that the Agencies were required to wait until the Supreme Court ruled on such an objection would require the Agencies to *under*-protect religious exercise.

While Plaintiffs still object that the religious exemption lacks a “mechanism to evaluate the sincerity of an objector’s religious belief,” they acknowledge that the Agencies considered this issue and identified at least three avenues to address any insincere objection (the Public Health Service Act, the Internal Revenue Code, and ERISA, *see* Religious Exemptions & Accommodations for Coverage, 83 Fed. Reg. 57,558 (Nov. 15, 2018); Pls.’ SJ Reply at 6. Plaintiffs’ labelling of these avenues as “outsourc[ing],” *id.*, misses the point—the entire discussion of these avenues in the Final Rules formed part of the Agencies’ analysis of what would be required to protect only sincere objections. Plaintiffs’ mere disagreement with the Agencies’ conclusions is not cognizable under arbitrary and capricious review. Even if Plaintiffs’ second-guessing of the Agencies’ policy decisions were appropriate under the APA, Plaintiffs provide no reason to believe that insincere objections to the mandate are likely, given that contraceptive coverage is cost neutral and is considered to be a valuable benefit by some employees and students.

Plaintiffs argue that potential harm to women who may lose contraceptive coverage requires “some justification.” *Id.* at 6. But the Agencies provided such justification: they considered the potential effects on women at length and ultimately concluded that the Rules represented the best balancing of the various interests. *See infra* I.B. That Plaintiffs disagree does not mean that the Agencies acted arbitrarily or capriciously.

Turning to RFRA, Plaintiffs raise the implausible argument that it is unclear whether “the Religious Rule resolves any actual RFRA conflicts.” Pls.’ SJ Reply at 7. This argument is directly contrary to the Supreme Court’s explanation in *Little Sisters* that *Hobby Lobby* established that the contraceptive mandate was “unlawful as applied to religious entities with complicity-based objections.” 591 U.S. at 682. That is the RFRA conflict the Agencies sought to resolve—relieving the substantial burden imposed by the mandate on those with complicity-based objections. The Supreme Court held that the Agencies properly considered “RFRA concerns raised in ‘public comments and . . . court filings in dozens of cases—encompassing hundreds of organizations.’” *Id.* (quoting 82 Fed. Reg. 47,792, 47,802 (Oct. 13, 2017)). Indeed, it would likely have been arbitrary and capricious if the Agencies “did not look to RFRA’s requirements.” *Id.*

Plaintiffs’ apparent basis for arguing that the Religious Exemption Rule would not resolve any RFRA conflicts is decisions of various circuit courts that were vacated by the Supreme Court in light of *Zubik v. Burwell*, 578 U.S. 403 (2016) (per curiam), or substantially undermined by *Little Sisters*. Plaintiffs also cite *Real Alternatives, Inc. v. Secretary*, 867 F.3d 338 (3d Cir. 2017), but that case presented only the question of whether the accommodation substantially burdened employees—not objecting employers or schools. *See id.* at 355 & n.17. In any event, as previously noted, there is no requirement that Agencies survey a particular number of legal cases, or adopt the view of a particular case, especially in an area of the law that (prior to *Little Sisters*) was

unsettled. Plaintiffs’ citation to a case in which an agency acted ultra vires by rejecting a binding interpretation of law, Pls.’ SJ Reply at 8 (citing *Bastardo-Vale v. Att’y Gen. United States*, 934 F.3d 255, 259 n.1 (3d Cir. 2019) (en banc)), is inapposite because there is no binding interpretation of law that precludes the Agencies’ actions. And concluding that the Agencies were arbitrary and capricious in resolving RFRA conflicts would be particularly senseless here, where the Supreme Court has already held that the Agencies were correct to identify RFRA concerns and to work to resolve them. If the Supreme Court had agreed with Plaintiffs that the accommodation had resolved any RFRA conflicts with the mandate, it would not have “directed the parties on remand [in *Zubik*] to ‘accommodat[e]’ the free exercise rights of those with complicity-based objections to the self-certification accommodation,” nor held that RFRA was “an important aspect of the problem” that the Agencies needed to consider. *Little Sisters*, 591 U.S. at 681-82 (second alteration in original) (citations omitted). This Court should not rely on a Third Circuit decision in this case that has been reversed and remanded by *Little Sisters*, Pls.’ SJ Reply at 8, but should instead consider the issues in light of the Supreme Court’s guidance in *Little Sisters*.

Finally, Plaintiffs argue that the fact that even under the Rules, an objecting employer will need to take some action to use the exemption suggests that no entities are substantially burdened by the accommodation. *Id.* Respectfully, however, neither Plaintiffs nor this Court may “tell [objecting entities] that their beliefs are flawed.” *Little Sisters*, 591 U.S. at 681. In any event, some entities’ objection to the accommodation stems from their belief that the accommodation forces them to provide contraceptives through their plan, *id.* at 668, not cease to provide them. And *Hobby Lobby* and *Little Sisters* make clear that, for those with religious objections to the mandate or accommodation, the penalty inflicted for noncompliance imposes a substantial burden. *Hobby Lobby*, 573 U.S. at 724-26; *Little Sisters*, 591 U.S. at 691-92 (Alito, J., concurring).

B. The Agencies Provided a Reasoned Explanation for Their Position on the Safety, Efficacy, and Benefits of Contraception.

Plaintiffs contend that the Agencies inadequately explained changes in their views on the safety, efficacy, and benefits of contraception. Pls.’ SJ Reply at 9. That contention is incorrect: as an initial matter, contrary to the statement of Plaintiffs, Federal Defendants have not “revers[ed]” their positions on the safety, efficacy, and benefits of contraceptives. *Id.* Instead, they adopted only the more nuanced conclusion that the benefits of contraception and the mandate are less certain than previously recognized and do not justify obligating those with sincere religious and moral objections to provide contraceptive coverage. *See, e.g.*, 83 Fed. Reg. at 57,555-56. The Final Rules contain voluminous explanations of the Agencies’ previous position on that issue, the Agencies’ recognition that their position had changed, discussions of public comments on the issue, and extensive reasoning for the Agencies’ change. *See, e.g., id.* at 57,546-56.²

Plaintiffs take issue with the fact that the Agencies did not weigh the costs and benefits of the Final Rules separately for each of the 18 FDA-approved contraceptive methods. Pls.’ SJ Reply at 9. That Plaintiffs would have preferred for the Agencies to write the Rules differently does not establish that the Rules are arbitrary and capricious. *See, e.g., Am. Paper Inst., Inc. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 422 (1983). To the contrary, the Agencies’ approach was rational. Under the Rules, depending on the scope of its religious beliefs, an objecting entity could be exempt from providing coverage for all recommended contraceptive methods listed in comprehensive guidelines supported by HRSA. *See* 83 Fed. Reg. at 57,575. It was thus reasonable for the Agencies to collectively assess the benefits and burdens of the exemptions with regard to

² Plaintiffs insist that “defendants claim that moving from a place of confidence to a place of uncertainty is not actually a changed position.” Pls.’ SJ. Reply at 9. But Federal Defendants made no such claim: rather, Federal Defendants acknowledged in their opening brief that, in the Final Rules, the Agencies changed certain positions. Fed. Defs.’ SJ Mem. at 18-19.

all such recommended methods of contraception. Plaintiffs relatedly argue that the studies cited by the Rules as support for the proposition that some contraceptives have negative health effects relate only to oral and hormonal contraceptives. Pls.’ SJ Reply at 9. That is irrelevant. That some contraceptives may have more mixed health effects than previously thought is relevant to the consideration of the benefits and burdens of the Rules, even if the Agencies’ assessment of the health effects of other forms of contraception did not change.

Plaintiffs also argue that the Agencies erred by using “non-medical beliefs [about whether certain forms of contraception function as abortifacients] to manufacture a medical debate” and to suggest disagreement about when pregnancy begins. *Id.* at 10. Tellingly, Plaintiffs do not cite to any page in the Federal Register to support this argument. The Agencies did not rely on the fact that some commenters view certain contraceptives as abortifacients to assess the health effects of contraception (or to redefine pregnancy), but instead as evidence that some entities have conscience objections to contraceptives that may interfere with implantation. 83 Fed. Reg. at 57,554. Indeed, contrary to Plaintiffs’ argument, the Agencies “d[id] not take a position on the scientific . . . debate[]” regarding whether some contraceptives are abortifacients. *Id.*

Plaintiffs close with unpersuasive arguments regarding teenage pregnancy rates and Colorado’s contraceptive equity law. Their argument related to teen pregnancy rates rehashes the argument made in their opening brief, which Federal Defendants have already refuted. Fed. Defs.’ SJ Mem. at 21-22. With respect to Colorado’s contraceptive equity law, Plaintiffs contend that the Agencies “plainly failed to consider [comments regarding that law] because [they] stated that no comment ‘point[ed] to studies showing those state mandates reduced unintended pregnancies.’” Pls.’ SJ Reply at 10-11 (quoting 83 Fed. Reg. at 57,555). But the Agencies’ statement that “public commenters did not point to studies showing those state mandates reduced unintended

pregnancies” does not show that the Agencies failed to consider state contraceptive laws. Rather, it demonstrates that the Agencies did not agree that the studies “show[ed]” that the state mandates were the cause of a reduction in unintended pregnancies. Under the APA, the Court should defer to the Agencies’ conclusions—not Plaintiffs’—regarding scientific matters, like this one, within HHS’s area of expertise. *See Kleissler v. U.S. Forest Serv.*, 183 F.3d 196, 198 (3d Cir. 1999).

C. The Moral Exemption Rule Comports With Congressional Intent.

Plaintiffs contend that the Moral Exemption Rule is arbitrary because Congress would not have wanted the Agencies to promulgate a moral exemption. Pls.’ SJ Reply at 11. But the Supreme Court reached the opposite conclusion about congressional intent. “Congress could have limited HRSA’s discretion in any number of ways, but it chose not to do so.” *Little Sisters*, 591 U.S. at 677. Instead, through the ACA, Congress gave “HRSA broad discretion . . . to create the religious and *moral* exemptions.” *Id.* (emphasis added). This holding resolves the matter.

D. The Agencies Adequately Considered Regulatory Alternatives.

As detailed in Federal Defendants’ opening brief, the Agencies rationally explained why they rejected regulatory alternatives that would not accomplish their policy objectives and instead adopted the Final Rules. Fed. Defs.’ SJ Mem. at 25-31. Though Plaintiffs respond with two main counterarguments, neither is persuasive.³

³ Preliminarily, as Federal Defendants have explained, Plaintiffs’ claim that the Agencies did not adequately explain their reasons for rejecting certain regulatory alternatives favored by Plaintiffs is nowhere to be found in either Plaintiffs’ complaint or in their initial summary judgment briefing. Fed. Defs.’ SJ Mem. at 25-26. Plaintiffs’ response that this claim “fits into” their challenges “on [the] whole,” SJ Reply at 12 n.7, misses the mark. It is axiomatic that a party “may not amend his complaint through arguments in his brief in opposition to a motion for summary judgment.” *Jones v. Treece*, 774 F. App’x 65, 67 (3d Cir. 2019) (citation omitted). Because Plaintiffs never raised this claim in their complaint, they should not be heard to raise it for the first time during renewed merits briefing.

First, contrary to Plaintiffs' contentions, the Agencies have explained why the scope of the present exemptions is necessary. A more limited exemption to the contraceptive mandate would result in some religious objections by plan sponsors and individuals that are eligible for the current exemption, some objectors not being subjected to the contraceptive coverage mandate if they fall under the indirect exemption for certain self-insured church plans, and other objectors having to choose between the mandate and the accommodation even though they objected to both. *See* 83 Fed. Reg. at 57,542. Thus, "to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage," and to honor the "background rule" established by Congress "against substantially burdening sincere religious beliefs except where consistent with [RFRA's] stringent requirements," the Agencies decided not to limit the exemptions' scope to employers with complicity-based objections to the accommodation. *Id.*

Although Plaintiffs now argue that the religious exemption could have been extended only to "employers that provide notice of or otherwise assert a complicity-based objection," Pls.' SJ Reply at 13, the Agencies explained that requiring exempt entities to submit a particular self-certification or notice "would impose an additional paperwork burden" on these entities "and would also involve additional public costs if those certifications or notices were to be reviewed or kept on file by the government." 83 Fed. Reg. at 57,558. And importantly, the Agencies "are not aware of instances where the lack of a self-certification . . . led to abuses or to an inability to engage in enforcement." *Id.* Nor have Plaintiffs identified any instances in which an entity without a sincere complicity-based religious objection to the accommodation has relied on the religious exemption. Indeed, it would be manifestly irrational for an employer with no complicity-based objections to the mandate to choose the exemption over the accommodation because including contraception as a seamless part of an employer's insurance plan costs an employer nothing and

would deprive its employees of a valuable benefit to which the employer has no objection. “A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.” *Id.* at 57,576. The Agencies thus reasonably concluded that it is likely that this large number of entities will continue to use the accommodation. *Id.* at 57,578. Plaintiffs have provided no evidence to believe that any entity—much less a significant number—without a complicity-based objection has opted for the religious exemption rather than the accommodation.

Second, Plaintiffs rely on the Agencies’ 2023 notice of proposed rulemaking as evidence of the kind of additional analysis that Plaintiffs believe the Agencies should have performed when issuing the Final Rules. *See* Pls.’ SJ Reply at 13. But, as Federal Defendants explained in their opening brief (and Plaintiffs do not refute), Plaintiffs did not present this proposed alternative to the Agencies during the challenged rulemaking. In any event, as explained previously, adopting a separate process for women of exempt employers to separately enroll in, in order to obtain contraceptive coverage would not necessarily be viable, as suggested by the Agencies’ failure to finalize the 2023 NPRM after considering comments for several years. Nor would such a separate process accomplish the Agencies’ policy objectives. As the Agencies have stated, creating such a process “would not achieve the Women’s Health Amendment’s goal of ensuring that women have seamless cost-free coverage of contraceptives” because it would “require some additional action by the affected women and could require them to obtain contraceptive care from providers other than those from whom they typically receive women’s health care.” Coverage of Certain Preventive Services Under the Affordable Care Act, 88 Fed. Reg. 7,236, 7,254 (Feb. 2, 2023). Moreover, even if the Court were to conclude that the Agencies had not provided a sufficient

explanation for not adopting such a separate process, then the appropriate remedy would be to remand without vacatur for the Agencies to provide such explanation. Fed. Defs.’ SJ Br. at 30.

E. The Agencies Engaged in Reasoned Decisionmaking.

The Rules comply with the APA’s undemanding requirement of reasoned decisionmaking. *See Nat’l Ass’n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 658 (2007). The Agencies concluded that applying the contraceptive mandate to employers with conscience objections is not the least restrictive means of furthering a compelling governmental interest as applied to those objectors. *See, e.g.*, 83 Fed. Reg. at 57,556. Moreover, they clearly explained the multiple independent reasons for reaching this conclusion, including that the Rules already do not apply to churches or integrated auxiliaries, *see, e.g., id.* at 57,547-48. These rationales are reasonable. *See Little Sisters*, 591 U.S. at 696 (Alito, J., concurring). Plaintiffs’ four counterarguments thus fail.

First, Plaintiffs state that substantial adverse comments “may signal” an error in judgment, Pls.’ SJ Reply at 15 (citation omitted), but even if that were correct (which it is not, *see* Fed. Defs.’ SJ Mem. at 31-32), the adverse comments received by the Agencies do not signal any error here, as discussed herein and in Federal Defendants’ opening brief. Second, Plaintiffs claim that the Rules are arbitrary because they fail to “confront a contrary consensus from medical experts.” *Id.* at 16. But the administrative record does not reflect a “contrary consensus,” *see, e.g.*, 83 Fed. Reg. 57,552-55, and, in any event, courts are to defer to the scientific judgments of expert agencies, *Kleissler*, 183 F.3d at 198. Moreover, the Rules address medical judgments as part of a broader balancing of the benefits of the contraceptive coverage mandate and the interests of those with conscience objections to providing coverage, and such balancing is beyond the purview of medical experts who are only considering one aspect of the equation. *See* 83 Fed. Reg. at 57,556. Third, Plaintiffs argue that the Agencies purportedly failed to consider “whether Title X clinics have

funding to absorb any increased demand” from the Rules, contending that this issue is “different . . . and broader” than eligibility limits to Title X. Pls.’ SJ Reply at 16. However, the Rules are not premised on the idea that Title X has the capacity to assist all women affected by the Rules, and thus cannot be arbitrary or capricious on this basis. *See* 83 Fed. Reg. at 57,551. Finally, Plaintiffs argue that Defendants’ response to comments regarding contraceptive counseling was somehow only “tangentially relevant” to those comments. Pls.’ SJ Reply at 16. But the Rules themselves belie such an assertion. *See* 83 Fed. Reg. at 57,556 (responding to comment by noting that “it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health”).

F. Plaintiffs’ Challenges to the Regulatory Impact Analysis Are Meritless.

Plaintiffs’ arguments that the Agencies’ regulatory impact analysis is arbitrary and capricious remain meritless. *See* Fed. Defs.’ SJ Mem. at 34-37. The most basic flaw is that Plaintiffs largely ignore the deferential standard applicable to such analyses. *See* Pls.’ SJ Reply at 17; *cf. Consumer Elecs. Ass’n v. FCC*, 347 F.3d 291, 303 (D.C. Cir. 2003). Moreover, they incorrectly argue that the Agencies improperly “excluded” dependents of people who claim the individual exemption. Pls.’ SJ Reply at 17. As with their opening brief, however, Pls.’ SJ Mem. at 30-31, Plaintiffs identify no comment suggesting that such individuals were improperly excluded. *See id.*; *see also* 83 Fed. Reg. at 57,568. In any event, any such exclusion would have minimal relevance, since, as a matter of common sense, most dependents likely share the policyholder’s faith. *See* 83 Fed. Reg. at 57,568-69 (objecting individuals “would not use the objectionable items even if they were covered”).

Furthermore, in an attempt to make the Agencies’ estimates appear outlandish, Plaintiffs again conflate the Agencies’ estimation of the number of entities using the accommodation with

their alternative method of using user-fee adjustments. *See* Pls.’ SJ Reply at 18. Their opening brief attacked the use of the 209-entity estimate in the context of one of two methods used by the Agencies to estimate the number of women affected, which relied on information related to the user-fee adjustment. As explained previously, however, the 209-entity estimate was not a factor in calculating the estimates based on user-fee adjustments. *See* Fed. Defs.’ SJ Mem. at 35. The Agencies were careful to describe how they arrived at both numbers separately, as well as why they were inherently imperfect estimates. *See, e.g.*, 83 Fed. Reg. at 57,576. In response, Plaintiffs contend that the purported disconnect between the two renders the 209-entity estimate a “meaningless, unexplained number[.]” Pls.’ SJ Reply at 19. But just because the Agencies arrived at different estimates using different methodologies does not render one or the other “meaningless;” it simply means that there were “multiple levels of uncertainty involved in measuring the effect of the expanded exemption.” 83 Fed. Reg. at 57,574. Both methodologies are rationally supported and explained in the Rules, which is all the APA requires.

Next, Plaintiffs contend that the Agencies’ decision to rely on statements of hospitals to determine how many would continue to use the accommodation was irrational. Pls.’ SJ Reply at 19. But it is reasonable for an agency to rely on the statements of regulated entities about their future intentions, while acknowledging that some entities may change course, which is exactly what the Agencies did here. 83 Fed. Reg. at 57,576-77. The APA requires only reasoned decisionmaking, not clairvoyance.

Finally, Plaintiffs continue to press their argument that the Agencies improperly used “the same assumption twice,” *i.e.*, that they purportedly first estimated that 379,000 women of childbearing age “receive insurance coverage from an entity reasonably likely to use the exemption,” but then improperly cut that estimate again by two thirds. Pls.’ SJ Reply at 19. This

argument misunderstands the significance of the 379,000 number. It does not represent the number of employees of entities “reasonably likely to use the exemption,” but rather the number of employees of entities that had not covered contraceptives prior to the coverage mandate and, thus, whose employers could conceivably qualify for the new exemption. *See* 83 Fed. Reg. at 57,580. As described in Federal Defendants’ opening brief, the Agencies then reasonably estimated that one-third of those individuals receive coverage from an employer or school that in fact would likely qualify for the new exemptions. The first number was derived from the number of “private, non-publicly traded, third party employers that did not cover contraception pre-Affordable Care Act, and whose plans were neither exempt nor omitted from mandatory contraceptive coverage under the previous regulations,” but crucially, no information or comments suggested that “all or most entities that omitted coverage of contraception pre-[ACA] did so on the basis of sincerely held conscientious objections . . . or . . . religious beliefs.” *Id.* at 57,580-81. The Agencies thus appropriately reduced the number of potentially affected employees; they did not mistakenly double-count their reduction as Plaintiffs contend.

II. The Court Need Not Resolve the Remaining Contentions by Plaintiffs and Little Sisters.

A. The Court Need Not Resolve Little Sisters’ Constitutional Challenges If It Upholds the Final Rules.

In its summary judgment brief, Little Sisters raises two constitutional challenges to the contraceptive coverage mandate as a whole.⁴ Little Sisters argues that the Court can provide no redress to Plaintiffs because the mandate was void *ab initio* for two reasons: (1) it was authorized

⁴ Little Sisters also argues that the contraceptive coverage mandate would violate the First Amendment if it required them to provide contraceptive coverage in violation of their religious beliefs. Little Sisters’ SJ. Br. at 16-20. But the Final Rules eliminate any such obligation, and those rules should be upheld. The Court need not address Little Sisters’ argument.

by an unconstitutional delegation of authority, and (2) it was approved by an officer, the Administrator of HRSA, who was appointed in violation of the Appointments Clause. Little Sisters’ SJ Br. at 12-16, ECF No. 342-1. The Court need not address these arguments if it upholds the Final Rules. The Little Sisters have not brought these arguments as claims against the Federal Defendants, and the Court should consider them only if doing so were necessary to resolve the existing claims in this case (which it is not).

To the extent this Court believes it must address them, these arguments fail. First, Little Sisters’ nondelegation argument fails because Congress provided HRSA with criteria to guide its delegation of authority: HRSA-supported comprehensive guidelines, “with respect to women, [for] such additional preventive care and screenings not described in paragraph (1).” 42 U.S.C. § 300gg-13(a)(4). These criteria constitute a sufficient intelligible principle under governing precedent. *See, e.g., FCC v. Consumers’ Rsch.*, No. 24-354, 2025 WL 1773630, at *8, 12 (U.S. June 27, 2025); *Whitman v. Am. Trucking Assocs.*, 531 U.S. 457, 474 (2001). *Little Sisters* does not hold to the contrary—the Court expressly disavowed reaching any conclusion on nondelegation. 591 U.S. at 679. *See also Braidwood Mgmt. Inc. v. Becerra*, 627 F. Supp. 3d 624, 648-52 (N.D. Tex. 2022) (rejecting nondelegation challenge to, *inter alia*, 42 U.S.C. § 300gg-13), *aff’d on other grounds*, 104 F.4th 930 (5th Cir. 2024).⁵

Second, Little Sisters’ Appointments Clause argument also fails. Indeed, the Supreme Court recently rejected a similar Appointments Clause challenge to another subpart of the ACA’s Preventive Services’ Provision—42 U.S.C. § 300gg-13(a)(1), which requires no-cost coverage of

⁵ The plaintiffs in *Braidwood* conceded their nondelegation claim before the Fifth Circuit in light of binding circuit precedent, *see* 104 F.4th at 939 n.23, and the Supreme Court denied the plaintiffs’ cross-petition for certiorari that included this nondelegation claim, *see Braidwood Mgmt., Inc. v. Becerra*, 145 S. Ct. 1053 (2025).

“‘evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations’ of the [United States Preventive Services] Task Force.” *Kennedy v. Braidwood Mgmt., Inc.*, No. 24-316, 2025 WL 1773628, at *5 (U.S. June 27, 2025).

As with the Task Force at issue in *Braidwood*, the HRSA Administrator is properly appointed as an inferior officer by the Secretary of HHS because the Administrator’s “work is directed and supervised by the Secretary of HHS, a principal officer.” *Id.* at *8 (citation omitted) (relying on sources of Secretarial control that apply equally to the HRSA Administrator). Little Sisters contends that “Congress has *never* vested the appointment of the HRSA Administrator” in the Secretary of HHS. Little Sisters’ SJ Br. at 16, ECF No. 342-1. But Reorganization Plan No. 3 of 1966, which was “ratified and affirmed” by Congress “as law” in 1984, authorizes the Secretary to appoint the HRSA Administrator. *Braidwood*, 2025 WL 1773628, at *20 (quoting Pub. L. No. 98-532, 98 Stat. 2705 (1984)); *see* Reorganization Plan. No. 3 of 1966, 5 U.S.C. app. 1, § 1(a) (transferring to the Secretary “all functions of the Public Health Service, . . . and of all . . . officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service”). *Willy v. Administrative Review Board*, 423 F.3d 483 (5th Cir. 2005), held that a substantively identical Reorganization Plan, coupled with 5 U.S.C. § 301, “vests the Secretary with ample authority to . . . appoint [inferior officers] and delegate final decision-making authority to them.” *Id.* at 491-492. In any event, the Secretary has ratified the HRSA-supported guidelines describing the contraceptive items and services that must be covered pursuant to 42 U.S.C. § 300gg-13. *See Braidwood Mgmt.*, 627 F. Supp. 3d at 640 (concluding that “[t]he Secretary ratified the HRSA guidelines that Plaintiffs challenge, which remedies any appointment

defects of HRSA regarding those guidelines”), *aff’d in relevant part*, 104 F.4th 930 (5th Cir. 2024); *Guedes v. ATF*, 920 F.3d 1, 13 (D.C. Cir. 2019).⁶

B. Any Relief Should Be Limited to Remand Without Vacatur.

As set forth above, Plaintiffs are not entitled to relief. However, in the event that the Court were to conclude that the Agencies had failed to provide an adequate explanation for their action or had committed other error, remand without vacatur would be the appropriate remedy. Fed. Defs.’ SJ Mem. at 43.

“Vacatur typically is inappropriate where it is ‘conceivable’ that [an agency] can, if given the opportunity, create a supportable rule.” *Prometheus Radio Project v. FCC*, 824 F.3d 33, 52 (3d Cir. 2016) (citation omitted); *see also Comite de Apoyo a Los Trabajadores Agricolas v. Solis*, No. 09-240, 2010 WL 3431761, at *25 (E.D. Pa. Aug. 30, 2010) (“An inadequately supported rule need not necessarily be vacated.”) (citation omitted). Here, it is “reasonably likely” that remand without vacatur would allow the Agencies to “redress [any] failure of explanation[.]” *Vecinos para el Bienestar de la Comunidad Costera v. FERC*, 6 F.4th 1321, 1332 (D.C. Cir. 2021). A significant number of errors alleged by Plaintiffs would simply reflect a deficiency in the Agencies’ explanation underlying their decision: for example, Plaintiffs’ contention that the Moral Rule is not adequately explained or that the Agencies did not provide an adequate response to certain comments. If these contentions were credited and the Court were to conclude that the administrative record “does not provide [the] kind of reasoned explanation” required by the APA, then the appropriate remedy would be to “remand to the [Agencies] for a sufficiently reasoned” explanation without vacatur. *Coinbase, Inc. v. SEC*, 126 F.4th 175, 203-04 (3d Cir. 2025); *see*

⁶ If the Court is inclined to adopt Little Sisters’ arguments, Federal Defendants respectfully request that the Court permit separate briefing to allow them to more fully address those arguments.

also, e.g., *U.S. Postal Serv. v. Postal Regul. Comm’n*, 785 F.3d 740, 756 (D.C. Cir. 2015) (remanding agency decision for clarification and reconsideration).⁷

In deciding whether vacatur is appropriate, a court “must also consider the ‘disruptive consequences of vacating.’” *Prometheus Radio Project*, 824 F.3d at 52 (citation omitted). Here, vacatur would “invite chaos” and “presumably would lead to [the resumption of] drawn-out litigation” by entities objecting to the contraceptive-coverage mandate on religious grounds. *Id.* Remand without vacatur would thus be the appropriate remedy if the Court were to conclude that the Agencies had failed to adequately explain their reasoning or had committed similar error. Indeed, the Agencies have been applying the challenged rules for more than six years without encountering any significant difficulties.⁸

CONCLUSION

For the reasons stated above and in their opening brief, Federal Defendants respectfully request that the Court enter judgment in their favor.

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Respectfully submitted,

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⁷ The single-Justice concurring opinion in *Corner Post, Inc. v. Board of Governors*, 603 U.S. 799 (2024), cited by Plaintiffs, is not to the contrary. *See id.* at 837 n.6 (“In some circumstances, usually when a court rules that an agency must provide additional explanation for the challenged agency action or must regulate some entity or activity *more* extensively, some courts have remanded to the agency without vacatur.” (Kavanaugh, J., concurring)).

⁸ In any event, even if the Court were to determine that vacatur is appropriate—and it should not, for the reasons stated above—any order should apply only to Plaintiffs and only to the portions of the Final Rules deemed unlawful, for the reasons explained in Federal Defendants’ opening brief. *See Fed. Defs.’ SJ Br.* at 43-45.

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