

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

COMMONWEALTH OF PENNSYLVANIA and
STATE OF NEW JERSEY,

Plaintiffs,

v.

No. 2:17-cv-04540-WB

DONALD J. TRUMP, *in his official capacity as President of the United States*; ROBERT F. KENNEDY, JR., *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SCOTT BESSENT, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; LORI CHAVEZ-DeREMÉR, *in her official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA.

Defendants.

**OPPOSITION TO DEFENDANTS' AND INTERVENOR-DEFENDANT'S MOTIONS
FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF STATES' MOTION FOR
SUMMARY JUDGMENT**

MATTHEW J. PLATKIN
Attorney General
State of New Jersey
JOSHUA BOHN
MEGHAN MUSSO
Deputy Attorneys General
New Jersey Attorney General's Office
Richard J. Hughes Justice Complex
25 Market Street
Trenton, NJ 08625
(609) 696-5366
joshua.bohn@law.njoag.gov

JENNIFER C. SELBER
General Counsel
Pennsylvania Office the Governor
MICHAEL J. FISCHER
Executive Deputy General Counsel
AIMEE D. THOMSON
Deputy General Counsel
Governor's Office of General Counsel
30 North Third Street, Suite 200
Harrisburg, PA 17101
(223) 234-4986
aimeethomson@pa.gov

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INTRODUCTION

Both the defendant Agencies and Little Sisters trumpet the Supreme Court’s decision that the Agencies *may* create exemptions from the contraceptive mandate, and *may* account for potential conflicts with the Religious Freedom Restoration Act when doing so, as if the decision is conclusive for the issues that remain in this case. But it is not. No matter the scope of agency discretion, the exercise of that discretion must reflect reasoned decisionmaking. *E.g.*, *Dep’t of Commerce v. New York*, 588 U.S. 752, 773 (2019). The Supreme Court has not assessed the rules at issue in this case against this standard. And held against this basic benchmark, the rules fail.

The Religious Rule, J.A. 1–55, and the Moral Rule, J.A. 56–95, purport to resolve conflicts between the contraceptive mandate and employers’ religious or moral objections to providing that coverage. But the rules sweep far beyond that stated purpose. The Agencies also finalized the two rules without meaningfully engaging with the Agencies’ prior conflicting position on the benefits of contraception, considering reasonable alternatives that permit women to access contraception guaranteed to them by law, or responding to a medical consensus at odds with the Agencies’ medical conclusions. Indeed, entirely absent from the defendants’ briefing is any genuine acknowledgement that the effect of an exemption is to deprive women of access to necessary health care guaranteed to them by law.

The consequence of the Agencies’ unreasoned rules is that 126,400 women—and likely more, given the Agencies’ flawed methodology for estimating the rules’ effects—have lost coverage for care that the Women’s Preventive Services Guidelines recognize as necessary to “address health needs specific to women” and to “prevent unintended pregnancies and improve birth outcomes.” J.A. 3478, 3480. The remedy for these errors is to vacate the Religious Rule and the Moral Rule.

I. The Rules Are Arbitrary and Capricious

A. The Religious Rule Is Not a Reasonable Solution to Any Conflict between the Contraceptive Mandate and the Religious Freedom Restoration Act

Resolving conflicts between the contraceptive mandate and RFRA was ostensibly the impetus for the Religious Rule. J.A. 8–13. But while the Agencies have discretion to devise a solution to that conflict, *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 680–81 (2020), the Religious Rule nevertheless must be reasonably tailored to accomplish that objective, see *Motor Vehicle Mfrs. Ass’n of U.S., Inc., v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)—especially when the consequence of the rule deprives women of access to necessary health care as guaranteed by law, *Little Sisters*, 591 U.S. at 708–09 (Kagan, J., concurring).¹

The Agencies do not—and cannot—dispute that the Religious Rule permits entities, including publicly traded corporations, to avoid compliance with the contraceptive mandate or the Accommodation even if there is no substantial burden on religious exercise. *E.g.*, Fed. Opp’n at 13, 15–16, ECF Nos. 343-1, 344. So even if the Religious Rule resolves *some* RFRA violations, these discrepancies, alone and cumulatively, demonstrate that the Religious Rule is not reasonably tailored for its purpose, making it arbitrary and capricious. And because the Accommodation does not substantially burden religious exercise, the Agencies did not reasonably conclude that the Religious Rule was necessary at all.

¹ The States have never argued that the Agencies could not consider RFRA. *Contra* LS Opp’n at 20–22, ECF No. 342-1; Fed. Opp’n at 1, ECF Nos. 343-1, 344 (citing Am. Compl. ¶ 185). To the contrary, the States’ Amended Complaint alleged exactly what is argued here: the Agencies failed to provide an adequate rationale for concluding that the Accommodation violates RFRA. Am. Compl. ECF No. 89, ¶¶ 185–86.

1. *First*, the Religious Rule allows employers for whom the Accommodation resolved any conflict between the mandate and RFRA to remove contraception from their employees' insurance plans anyway. States' Mem. at 18–19, ECF No. 341-1. This flaw is not about imprecise line drawing, *contra* Fed. Opp'n at 12–13, but instead reveals a disconnect between the problem the Religious Rule identifies and the solution it creates, *Little Sisters*, 591 U.S. at 708–09 (Kagan, J., concurring). The Agencies needed some reasonable explanation why employers for whom the Accommodation resolved any conflict with RFRA may claim the exemption all the same—particularly because the exemption, but not the Accommodation, denies employees coverage for care that the Guidelines recognize as necessary to “address health needs specific to women” and to “prevent unintended pregnancies and improve birth outcomes.” J.A. 3478, 3480. Rather than supplying an explanation, the Agencies express confidence that this problem is inconsequential because no entity satisfied with the Accommodation will invoke the exemption. Fed. Opp'n at 13. But the record belies that assurance: The Religious Rule acknowledges that entities content with the Accommodation might use the exemption. J.A. 41–42.²

Little Sisters—but not the Agencies—denies that the Religious Rule permits an employer to invoke the exemption when the Accommodation would resolve a conflict with RFRA. LS Opp'n at 41–43, ECF No. 342-1.³ That assertion cannot be squared with the rule, which makes the

² Similarly, those with moral objections to covering contraception can claim the exemption even if an alternative, such as the Accommodation, would resolve any objection. *Contra* Fed. Opp'n at 13 n.4.

³ Little Sisters frame their arguments as though they would be subject to the contraceptive mandate in the absence of the Religious Rule. *E.g.*, LS Opp'n at 26, 28, 30. But they neglect to mention that they obtained a permanent injunction against enforcement of “the contraceptive mandate as applied to plans in which the Little Sisters participate.” *Little Sisters*, 591 U.S. at 674 n.6; *see* ECF No. 19-2 (Dec. Mother Superior Marie Vincente ¶ 14) (“Little Sisters Pittsburgh have adopted the Christian Brothers Employee Benefit Trust ... to provide medical benefits coverage for their employees.”); *Little Sisters of the Poor v. Azar*, No. 13-02611, Dkt. 82 (D. Colo. May 29, (continued...))

Accommodation only a voluntary alternative to the exemption. 45 C.F.R. § 147.131(c)(2). The Religious Rule’s preamble also contradicts Little Sisters’ position, explaining that the Accommodation is “optional for entities that are otherwise also eligible for the expanded exemptions” and remains “an option that exempt entities can choose.” J.A. 34. Moreover, the exemption is available to an entity that objects to any one of “establishing, maintaining, providing, offering, or arranging” for payment for contraceptive coverage. 45 C.F.R. § 147.132(a)(2). And practically, because no notice is required, States’ Mem. at 10, there is no way to prevent entities who have no objection to the Accommodation—or objection to the contraceptive mandate itself—from “avail[ing] themselves of the exemption,” *cf.* LS Opp’n at 42.

Second, the Religious Rule’s inclusion of publicly traded corporations is a similarly unreasoned expansion. *Little Sisters*, 591 U.S. at 709–10 (Kagan, J., concurring). Whether RFRA applies to publicly traded corporations requires interpreting a statute that the Agencies do not administer. This is the domain of courts, not agencies, *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 519–20 (2018)—and has been since before the Supreme Court instructed courts to independently interpret the statutes agencies do administer, *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024). Agency “discretion” has no place here. *Contra* Fed. Opp’n 15, 41–42. It is not enough that the Religious Rule’s legal conclusions about RFRA’s application to publicly traded companies can

2018) (enjoining the Agencies from enforcing the contraceptive mandate against “all current and future participating employers in the Christian Brothers Employee Benefit Trust Plan, and any-third party administrators acting on behalf of these entities with respect to the Christian Brothers Employee Benefit Trust Plan, including Christian Brothers Services”). Moreover, because Little Sisters administers benefits through a “church plan” that is exempt from ERISA, *see* 26 U.S.C. § 410(d), Little Sisters is not subject to penalties for failing to comply with the mandate, as the government previously conceded, *see* Transcript of Oral Argument at 84:10–24, *Zubik v. Burwell*, 578 U.S. 403 (2016) (Nos. 14-1418 *et al.*).

Given these protections, it is not surprising that during the nearly two years in which the Religious Rule was enjoined, Little Sisters never claimed that they had to take any steps to comply with the contraceptive mandate.

be “discerned.” Fed. Opp’n at 14–15. That may suffice when an agency makes a factually informed policy judgment, but not when an agency interprets a statute. *Loper Bright*, 603 U.S. at 412; *see Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 223–24 (2016).

Viewed *de novo*, the Agencies’ decision to extend the Religious Rule to publicly traded corporations is legally unfounded. The Agencies concluded that RFRA applies to those entities solely because 1 U.S.C. § 1 defines person to include corporations. J.A. 27. Yet that rationale was not sufficient for the Supreme Court to extend RFRA even to closely held companies. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 705–09 (2014); *see also* States’ Mem. at 19. And the Religious Rule made the additional leap from closely held corporations to publicly traded corporations based on 1 U.S.C. § 1 alone, even though *Hobby Lobby* expressed doubt about whether a publicly traded company could have religious beliefs for purposes of RFRA. *Hobby Lobby*, 573 U.S. at 717. Without citing *any* authority, the Religious Rule decided that this uncertain legal question was a “matter of well-established State law.” J.A. 27 & n.61 (citing only the Agencies’ expectations). That the Agencies know of no publicly traded company for which the mandate presents a problem under RFRA, Fed. Opp’n at 15–16, only further signals that the Religious Rule is not addressed to actual RFRA violations.

Third, the Religious Rule is not limited to instances in which compliance with the mandate or the Accommodation imposes a substantial burden, States’ Mem. at 18, which is a predicate for any RFRA violation, 42 U.S.C. § 2000bb-1(a). That requiring coverage of contraception, or imposing monetary penalties for refusing to do so, *can* impose a substantial burden on religious exercise, *see* Fed. Opp’n at 13–14; LS Opp’n at 23, says nothing about whether the Religious Rule reasonably targets those cases. Little Sisters misunderstands this problem as just a failure to require proof of a RFRA violation. LS Opp’n at 23. Omitting the substantial burden requirement, however,

expands the availability of the exemption beyond RFRA violations and so divorces the Religious Rule from its purpose.⁴

Fourth, the Religious Rule does not provide any mechanism to evaluate the sincerity of an objector's religious belief. Omitting such a mechanism will be inconsequential, according to defendants, because employees have existing ways to challenge the sincerity of their employer's religious beliefs if needed. Fed. Opp'n at 16; LS Opp'n at 23–24. But even if employees may rely on the Public Health Service Act, the Internal Revenue Code, or ERISA to recoup wrongfully withheld care, J.A. 22–23, that the Religious Rule outsources the responsibility for ensuring compliance with RFRA further exhibits that the rule itself makes no effort to limit its effect to where the mandate and RFRA collide.

Finally, whether the Religious Rule resolves *some* RFRA violations is immaterial to whether the rule reasonably targets only those violations, and it does not make the rule's over-expansiveness harmless. *Contra* Fed. Opp'n at 37; LS Opp'n at 24–25. Indeed, the Agencies' inattentiveness to actual conflicts is especially unreasonable because unnecessary expansions of the exemption will lead to significant harm. The Guidelines still include contraception as a necessary form of care, J.A. 3480–81, but women working for an employer who claims the exemption will lose coverage. Without that coverage, contraceptive care becomes harder to access. J.A. 434. Each way in which the Religious Rule extends beyond actual RFRA conflicts, then, causes significant harm. That harm demands some justification.

⁴ As if to prove the point, Little Sisters cite a collection of federal regulations that they claim “lift burdens on religious exercise.” LS Opp'n at 22 & nn.10–13. But all cited provisions simply acknowledge that the law *may* yield to accommodate substantial burdens on religious exercise; none provide a categorical exemption from compliance with the law.

2. The Religious Rule is independently arbitrary and capricious because the Agencies failed to adequately justify that it resolves *any* RFRA conflicts. RFRA is a remedial statute, giving courts final say over its meaning. *See Epic*, 584 U.S. at 519–20; *Loper Bright*, 603 U.S. at 412. So a rule promulgated to remedy RFRA conflicts must be guided by judicial decisions about what RFRA prohibits. That the Agencies *may* exercise their rulemaking discretion to resolve RFRA violations as *Little Sisters* held, 591 U.S. at 680, does not free them to decide what violates RFRA without regard to relevant judicial decisions, *contra* LS Opp’n at 20–21.

While the Agencies insist that the Religious Rule discussed the relevant legal authority and issues “at length,” Fed. Opp’n at 17, they overstate matters. As to substantial burden, the Agencies made no effort to reconcile their position with the overwhelming contrary case law, including what was then the only post-*Zubik* appellate decision to address the question. *Real Alternatives, Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338, 356–58 & n.18 (3d Cir. 2017) (concluding that the Accommodation does not impose a substantial burden).⁵ Rather, the Agencies cited the only outlier case and moved on. J.A. 11 (citing a pre-*Zubik* Eighth Circuit decision concluding that the Accommodation imposes a substantial burden, but none of the other eight appellate decisions ruling differently). Thus, the problem is not that the Agencies have a different view than that of the States, but instead that the Agencies arrived at their conclusion in contravention of the contrary

⁵ The Supreme Court’s decision in *Fulton v. City of Philadelphia*, 593 U.S. 522 (2021), does not conflict with the Third Circuit’s conclusion in *Real Alternatives* nor its reasoning in *Geneva College v. Sec’y United States Dep’t of Health & Human Servs.*, 778 F.3d 422, 427 (3d Cir. 2015), *vacated and remanded on other grounds sub nom. Zubik*, 578 U.S. 403, 410 (2016). *Contra* LS Opp’n at 26. In *Fulton*, the plaintiff foster agency was asked to “approve” foster family relationships that the agency stated were inconsistent with its religious beliefs. *Fulton*, 593 U.S. at 530 (cleaned up). Here, the Accommodation requires objecting entities to provide notice of their objection—exactly what the Agencies effectively concede must happen for an entity to claim the exemption. Fed. Opp’n at 16.

judicial consensus. Agencies are not at liberty to disregard court decisions in such a way. *See Bastardo-Vale v. Attorney Gen. United States*, 934 F.3d 255, 259 n.1 (3d Cir. 2019) (*en banc*).

Beyond that, the Agencies’ reliance on RFRA as the impetus for the Religious Rule also means that if, in the Court’s view, the rule is not needed to remedy any conflicts, the rationale offered by the Agencies vanishes. That is the case here, and it separately makes the Religious Rule arbitrary and capricious. For reasons this Court has already given, *Pennsylvania v. Trump* (“*Pennsylvania I*”), 351 F. Supp. 3d 791, 821–27 (E.D. Pa. 2019), *rev’d and remanded on other grounds*, 591 U.S. 657 (2020), and which the Third Circuit has affirmed, *Pennsylvania v. President* (“*Pennsylvania II*”), 930 F.3d 543, 572–74 (3d Cir. 2019), *rev’d and remanded on other grounds*, 591 U.S. 657 (2020), the status quo before the Religious Rule did not violate RFRA. The Supreme Court did not reach this issue, *Little Sisters*, 591 U.S. at 680, and thus did not disturb the reasoning in either opinion.

This Court’s earlier analysis was, and remains, correct. *Contra* Fed. Opp’n at 40–42. Indeed, the Agencies now recognize that even with the exemption, “an employer seeking to provide insurance that excludes coverage for contraceptives will in fact need to communicate that direction to their insurer or [third party administrator].” Fed. Opp’n at 16. The Agencies’ point confirms what the States have argued all along: the Accommodation does not “trigger” the provision of contraceptive coverage and so cannot as a factual matter impose a substantial burden on religious exercise, no matter how sincere the objection. *Contra* Fed. Opp’n at 38; LS Opp’n at 30. The obligation to provide coverage lies with the insurer and invoking the Accommodation only removes the employer from the equation.

B. The Agencies Failed to Provide a Reasoned Explanation for Their Reversal on the Safety, Efficacy, and Benefits of Contraception

Although the Agencies had previously acknowledged the well-established safety, efficacy, and benefits of contraception, in the rules they abruptly conclude the evidence is mixed. At the outset, defendants claim that moving from a place of confidence to a place of uncertainty is not actually a changed position. Fed. Opp’n at 22–23; LS Opp’n at 33, 35. Yet moving from consensus to lack of consensus is a change in position, which the Agencies neither acknowledge nor justify. *See Encino Motorcars*, 579 U.S. at 222. Worse, the Agencies attempt to camouflage their changes in position as merely not reaching conclusions about purported scientific debates, Fed. Opp’n at 20–24, while also asking for the deference owed to an agency’s technical expertise, *id.* at 22. The Agencies cannot have it both ways.

First, that some entities object to women using any of the 18 forms of FDA-approved contraception has nothing to do with whether each form of contraception is medically safe and effective for women to use. *Contra* Fed. Opp’n at 20–21. Nor do the Agencies identify any scientific or medical reason to treat all forms of contraception categorically such that the “net benefits” of contraceptive coverage would be “less certain.” *Contra* Fed. Opp’n at 20–21. The Agencies highlight a citation to studies showing side effects of contraceptive use as sufficient evidence to now doubt contraception’s benefits, Fed. Opp’n at 22–23 (citing J.A. 17–18 & nn.28–34), but those studies relate to oral and hormonal contraceptives, which comprise just a few of the FDA-approved methods. The Agencies ignore that contraception, like any medicine, is prescribed individually. If, for a single person, any one of the various forms of contraception can be safely prescribed, the cost of eliminating access to that method cannot be dismissed because the other 17 would not have been prescribed for that individual.

Second, non-medical considerations informed the Agencies’ medical analysis. *Contra* Fed. Opp’n at 21. The Agencies’ review of the “Health Effects of Contraception and Pregnancy” included whether some forms of approved contraception are abortifacients. J.A. 18–19. The Agencies concluded the answer was uncertain because people define pregnancy to begin at different points based on religious beliefs. J.A. 19. The Agencies claim that they did not rely on such beliefs as part of this medical analysis because, in the end, they did not take a position on when pregnancy begins. Fed. Opp’n at 21. Yet using non-medical beliefs to manufacture a medical debate is just as arbitrary as using them to resolve a medical debate. To make matters worse, the Agencies relied on non-medical sources to suggest disagreement about when pregnancy begins despite HHS’s existing definition of pregnancy as beginning at implantation. *See* 45 C.F.R. § 46.202(f).

Third, the Agencies retreated without justification from their earlier position that contraception reduces teen pregnancy. Here, the Agencies do not suggest a new evidentiary basis for the change, but instead insist that they had not previously taken a position. Fed. Opp’n at 21–22. Yet HHS’ Office of Adolescent Health has embraced research showing that contraception reduces teen pregnancy. J.A. 2561–62.⁶ Although the Agencies suggest doing so was not taking a position, the difference between making a definitive pronouncement and embracing research is semantic at best.

Finally, the Agencies changed their position about the efficacy of contraception without discussing that contraceptive equity laws, such as that of Colorado, successfully reduced both unintended pregnancy and abortion. They now deny overlooking that evidence, Fed. Opp’n at 23–24, but the Religious Rule plainly failed to consider that evidence because it stated that no

⁶ Whether agency action is arbitrary and capricious is judged based on information contained in the administrative record. *Camp v. Pitts*, 411 U.S. 138, 142 (1973). HHS’s earlier report on trends in teen pregnancy, however, only documents HHS’s prior position.

comment “point[ed] to studies showing those state mandates reduced unintended pregnancies,” J.A. 20.

C. The Agencies Provided No Reasoned Justification for the Moral Rule

The Agencies’ justification for the Moral Rule is similarly lacking. *See Little Sisters*, 591 U.S. at 709–10 (Kagan, J., concurring). Congress may not have included anything in the Women’s Health Amendment specifically precluding the Agencies from creating moral exemptions to the Guidelines, *Little Sisters*, 591 U.S. at 677, but Congress’s expectations matter all the same because the Agencies discussed them in justifying the Moral Rule, J.A. 64. Specifically, in creating the Moral Rule, the Agencies stated, “It is not clear to the [Agencies] that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar [moral] exemptions. Therefore, the [Agencies] consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases.” J.A. 67; *see also id.* (calling the Moral Rule “consistent with the scope of exemptions that Congress has established in similar contexts”). But because the Agencies unreasonably judged Congress’s expectations, the Moral Rule is arbitrary and capricious. Standard methods of statutory interpretation, the legislative record, and subsequent legislative history all unavoidably demonstrate that Congress did not anticipate a moral exemption would be included if contraception was included in the Guidelines. States’ Mem. at 29–32.

D. The Agencies’ Failure to Consider or Explain the Denial of Reasonable Alternatives is Arbitrary and Capricious

Despite several alternatives that would reasonably accommodate both religious objections and satisfy the mandate to ensure women’s access to contraceptive coverage, *see* States’ Mem. at 32–37, the Agencies vastly broadened exemptions without providing a process that ensured women otherwise received contraceptive coverage, to the detriment of tens of thousands of women

the Agencies acknowledged would likely lose coverage. J.A. 43. Vacatur is appropriate here because the Agencies “ignore[ed] ostensibly reasonable alternatives” despite admitting the expanded exemptions and optional accommodation it chose “suffer[] from noteworthy flaws,” including the loss of contraceptive coverage for tens of thousands of women. *See City of Brookings Mun. Tel. Co. v. F.C.C.*, 822 F.2d 1153, 1169 (D.C. Cir. 1987) (noting “the failure of an agency to consider obvious alternatives has led uniformly to reversal”). The counterpoints defendants offer prove wanting.⁷

First, the Agencies claim that the “scope of the present exemptions is necessary ‘to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage,’” and to “treat like cases alike.” Fed. Opp’n at 27 (quoting 83 Fed. Reg. at 57,542). But not all religious objections *to the contraceptive mandate itself* are alike. Some take issue with the Accommodation on complicity grounds, while others do not. The religious exemptions could have been extended only to the former—for instance, to employers that provide notice of or otherwise

⁷ While Defendants assert this “contention is absent” from the States’ filings earlier in the litigation, Fed. Opp’n at 25, that elides how this point fits into the States’ APA challenges on the whole. For one, the Agencies’ obligation to meaningfully consider, and explain their rejection of, alternatives that would result in less loss of insurance coverage for contraceptive services is part and parcel of their obligation to explain how these sweeping exemptions can be reconciled with the Mandate itself. And risk of coverage loss created by these exemptions has been part of the case throughout. *See, e.g.*, Am. Compl., ECF No. 89, ¶¶ 112-115, 182, 184, 188; J.A. 1389 (multistate comment letter highlighting that the proposed rules failed to provide a “reasoned and evidence-based explanation” for the “evisceration of the relied-upon accommodation requirements, which balanced religious exercise and full and equal health coverage for women,” and create “unreasonable barriers” to care in “preventing women from accessing” contraceptive care); J.A. 1314 (arguing the “alternative options identified by the [Agencies] for women to access birth control coverage are completely deficient”); J.A. 1352 (objecting that Agencies “jettisoned the careful balance” between contraceptive coverage and religious objections); J.A. 1369 (same); J.A. 1380-81 (arguing that despite exemptions, the Agencies still must “provide[] contraception at no additional cost to employees”); J.A. 1426 (same); J.A. 1395 (demanding plans cover no-cost contraception coverage). And doctrinally, failure to consider and/or address reasonable alternatives flows from the *State Farm* requirements that have, likewise, always been part of this case. *See* States’ PI Brief, ECF No. 91-2 at 30–35.

assert a complicity-based objection—while the Accommodation could remain the default option for all other employers. The Agencies offer no rebuttal for why this would not be practicable. Nor do they explain what possible interest there is in treating an employer that does *not* have a complicity-based religious objection to the Accommodation—and therefore experiences no burden on the exercise of their religion—as though it does.

Second, the Individualized Contraceptive Arrangement reflects the *kind of analysis* that could, and should, have been performed by the Agencies: a process that is more responsive to complicity-based objections while ensuring women have access to contraception guaranteed by law.⁸ *See* States’ Mem. at 35–36. Indeed, the administrative record here shows the Agencies at times downplayed their obligation under the Mandate altogether. *See, e.g.*, J.A. 14 (noting that if some individuals “do not receive contraceptive coverage from” employers “who the government chose not to coerce, that result ... is not a result the government has imposed,” and “[b]urdens that may affect third parties as a result of revisiting the exercise of agency discretion may be relevant to the RFRA analysis, but they cannot be dispositive”). Even if such a process arguably “require[d] some additional action” by employees of exempt employers, Fed. Opp’n at 29, the Agencies effectively concede that the exemptions also require additional action by employers, *id.* at 16.

Third, the impact of the broad religious and moral exemptions the Agencies adopted is not theoretical. As noted, the Agencies received numerous comments, including from Pennsylvania, highlighting that many women—potentially tens of thousands—would lose access to covered

⁸ Contrary to defendants’ assertion, the withdrawal of the 2023 Proposed Rules did not reflect a “considered” rejection of the substance of the proposals. *Contra* Fed. Opp’n at 29–30. Rather, the withdrawal reserved the ability to make “new proposals that may be substantially identical or similar to” the 2023 Proposed Rules, and expressly held it “does not affect the [Agencies’] ongoing application of existing statutory and regulatory requirements or its responsibility to faithfully administer the statutory requirements the proposed rules would have implemented if finalized.” 89 Fed. Reg. 106,393 (Dec. 30, 2024).

contraceptive services. *E.g.*, J.A. 778, 812, 814, 845, 1384–92. And by maintaining the mandate, the Agencies “committed” themselves “to minimizing the impact on contraceptive coverage, even as they sought to protect employers with continuing religious objections.” *Little Sisters*, 591 U.S. at 709 (Kagan, J., concurring); *see also* *Zubik v. Burwell*, 578 U.S. 403, 408 (2016) (tasking Agencies with “accommodat[ing] [objecting employers’] religious exercise while at the same time ensuring that women covered by [objecting employers’] health plans receive full and equal health coverage, including contraceptive coverage” (cleaned up)); 42 U.S.C. § 18114 (barring issuance of any rule that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care” or “impedes timely access to health care services”).⁹

Finally, *Little Sisters*’ argument that the Agencies did not have to consider reasonable alternatives because contraceptive coverage may be available under other laws, such as Title X and Medicaid, rings hollow. *Contra* LS Opp’n at 37–38. As multiple commenters noted in 2017, many employees enrolled in employer-sponsored coverage are ineligible for such programs; the administration was contemporaneously reducing coverage and availability of those programs; and state laws largely did not provide uniform coverage. *See, e.g.*, J.A. 1316–17, 1337–41, 1355–59, 1372–76, 1382, 1406, 1455–59, 1463–67, 1482–86, 1497–1501. Those concerns remain today, particularly since the current Administration has withheld all or some Title X funding which could

⁹ The Agencies’ assertion that the Final Rules do not implicate 42 U.S.C. § 18114 because the statute only applies to “direct government interference with health care” misunderstands the States’ arguments. *Contra* Fed. Opp’n at 31. The States do not assert that the Agencies have violated the statute, but rather, that they acted arbitrarily and capriciously by failing to consider reasonable alternatives that eliminate and/or reduce barriers to healthcare. States’ Mem. at 37. This failure to consider, and to reasonably explain the unavailability of such alternatives, “strayed from their obligation under [§ 18114]” and “violated the APA.” *Id.*

impact up to 30 percent of patients served annually by the Title X program,¹⁰ and the White House has requested significant cuts to the Department of Health and Human Services in the fiscal year 2026 budget.¹¹

E. The Agencies Failed to Consider Significant Comments

Ninety-nine percent of public comments opposed the rules. States' Mem. at 38. While rulemaking is not simply about counting comments, Fed. Opp'n at 31, the "[p]resence in the record of substantial quantities of adverse comment may signal clear error of agency judgment," *Telocator Network of Am. v. FCC*, 691 F.2d 525, 538 n.106 (D.C. Cir. 1982). The Agencies, relying on *NRDC v. EPA*, 822 F.2d 104 (D.C. Cir. 1987), suggest that the volume of comments against the rules is immaterial, Fed. Opp'n at 31–32, but that case addressed whether the weight of comments, "without more," could demonstrate that an agency's on the record fact finding was not supported by substantial evidence, *NRDC* at 122 n.17. That is not the posture here. Plus, there is far "more."

The imbalance of comments is relevant, first, because the Agencies justified the rules as responsive to comments. *See, e.g.*, J.A. 11 (explaining that the Religious Rule was needed to respond to concerns raised in comments about the religious burden caused by complying with either the mandate or Accommodation); J.A. 59 & n.5 (noting that commenters had supported a moral exemption prior to 2017). Presenting the rules as responsive to commenters' interests without addressing that the overwhelming weight of comments opposed the rules is a clear error of judgment. The error is particularly stark for the Moral Rule because the Agencies have not

¹⁰ Megan L. Kavanaugh, *Trump Administration's Withholding of Funds Could Impact 30% of Title X Patients*, Guttmacher Institute (Apr. 8, 2025), <https://tinyurl.com/r89vkpsk> (last accessed May 19, 2025).

¹¹ Office of Management & Budget, Letter to Senate Committee on Appropriations (May 2, 2025), <https://tinyurl.com/5fvszeb6> (last accessed May 19, 2025).

identified any part of the ten supportive comments that expressed a non-religious moral objection to contraception.

Moreover, the Agencies did not respond to comments from the medical community that voiced concerns with many of the Agencies' medical judgments. While a comment's significance may typically depend on its content rather than its author, Fed. Opp'n at 32 (citing *City of Portland v. EPA*, 507 F.3d 706 (D.C. Cir. 2007)), here the content and author are not so easily separated. Medical comments are relevant because they come from medical experts, and a rule that espouses medical judgments, as here, is arbitrary if it fails to confront a contrary consensus from medical experts. *See Mayor of Baltimore v. Azar*, 973 F.3d 258, 276–79 (4th Cir. 2020) (*en banc*).

Further, the Agencies claim to have responded to comments expressing a concern about the Religious Rule's effect on access to contraceptive *counseling*, Fed. Opp'n at 33–34, but they do so by pointing to the Religious Rule's estimation that contraceptive *methods* are available outside employer-provided insurance plans, J.A. 21. And even that tangentially relevant answer is belied by comments about the limited capacity of state- and federally-funded programs—an issue raised in yet another set of comments that the Agencies did not answer. Several commenters identified funding shortages for Title X clinics as reason to doubt that those clinics could meet any increased need caused by the rules. *See States' Mem.* at 39 (collecting comments). The Agencies claim to have discussed those comments, Fed. Opp'n at 32–33 (citing J.A. 16), but in fact discussed limits on patient eligibility for Title X clinics. Whether Title X clinics have funding to absorb any increased demand has different—and broader—implications than whether only some of those who lose coverage will be eligible to go to a Title X clinic.

In this way, *Ohio v. EPA*, 603 U.S. 279 (2024), is apt. *Contra* Fed. Opp'n at 34 n.7. There, commenters explained that details in the EPA's uniform ozone emissions-control plan were

premised on the faulty assumption that it would apply to a fixed group of states. 603 U.S. at 287. The Supreme Court held that the EPA’s severability provision, which functioned to retain the plan regardless of the number of states participating, had “not address[ed] the applicants’ concern so much as sidestep[ped] it.” *Id.* at 295. So too here, commenters explained that the Agencies’ rules were premised on erroneous medical and scientific conclusions and faulty assumptions about access to contraceptive care. But rather than addressing these concerns, the Agencies merely “sidestep[ped]” them.

Finally, this Court has not definitively ruled on the adequacy of the Agencies’ response to significant comments. *Contra* Fed. Opp’n at 33; LS Opp’n at 39. This Court’s earlier decision reached only the few comments submitted with the States’ preliminary injunction motion, which was filed before the administrative record was available. *See Pennsylvania I*, 351 F. Supp. 3d at 811–12. The Supreme Court has not reached this question either. *Contra* LS Opp’n at 39. The Supreme Court said only as a descriptive matter that the Agencies responded to comments between the interim and final rules. *Little Sisters*, 591 U.S. at 672–73.

F. The Agencies’ Regulatory Impact Analysis Is Arbitrary and Capricious

In the end, the Agencies concluded that the benefits of the rules outweigh their costs. While the Agencies’ balancing of the costs and benefits may be owed some deference, Fed. Opp’n at 34, the Agencies may not calculate the costs and the benefits in an arbitrary manner. Instead, an agency’s estimate of the costs of its rule must be based on “figures that make at least some modicum of sense” instead of those “pulled from thin air.” *Baltimore*, 973 F.3d at 282 (cleaned up). That did not happen here.

First, the rules omitted the dependents of policyholders that use the individual exemption in the estimate of people who will lose coverage. Both defendants incorrectly claim that group was excluded because the Agencies assumed that dependents of people who claim the individual

exemption will share the faith of the policyholder, Fed. Opp'n at 34–35; LS Opp'n at 40, but defendants cite nothing in the rules reflecting that assumption.

Second, in the interim Religious Rule, the Agencies had assumed that 1,027,000 people received insurance from an entity that had been using the Accommodation before the Religious Rule, and that 75% of them, or about 770,000, received insurance through one of 100 religious hospitals or health systems the Agencies believed would continue using the Accommodation despite the new rule. J.A. 127. The Agencies assumed the remaining 25%, or roughly 257,000 people, worked for one of 109 entities that the Agencies expected would take advantage of the exemption. *Id.* In the final Religious Rule, the Agencies assumed that in fact 2,907,000 people received insurance from an entity that previously used the Accommodation. J.A. 42. Despite the almost threefold increase from the interim rule, the Agencies still assumed that those 2.9 million people all received insurance through the same 209 entities identified in the interim Religious Rule and that 75% of them—or 2,180,000 people—received coverage from one of the 100 religious hospital or health systems that would stick with the Accommodation. *Id.*

By the Agencies' logic, these 100 hospitals and health systems added, on average, 7,000 policyholders each in just two years. The more plausible explanation is that the Agencies initially underestimated the total number of entities that had used the Accommodation, and that the correct number was far greater than 209. But by clinging to the 209 figure, the Agencies could continue to assert that 75% of all people employed by entities that invoked the Accommodation worked for the 100 hospitals and health systems they identified and (according to the Agencies) would not lose coverage. J.A. 42. In this way, the number of entities assumed to have used the Accommodation prior to the rules affected the Agencies' impact analysis. But even if that number

was meaningless, as the Agencies propose, Fed. Opp’n at 35, it is unclear why using meaningless, unexplained numbers makes the impact analysis *less* arbitrary.

Third, the Agencies assumed that the 100 religious hospitals and health systems that previously used the Accommodation would continue to do so based on public statements made *before* an exemption was available to any of them. J.A. 41 & n.87. And immediately after citing those public statements, the Agencies conceded that some of the hospitals and health systems may make use of the exemption. J.A. 42. The context of these statements, rather than the forum in which they were made, undermines their value. *Contra* Fed. Opp’n at 35–36; LS Opp’n at 40.

Finally, after estimating that 379,000 women receive insurance coverage from an entity reasonably likely to use the exemption, the Agencies cut that estimate by two thirds because they assumed the majority of the employers that started covering contraception because of the mandate were not employers with religious objections to covering contraception. J.A. 45–46; *see also* States’ Mem. at 42–43. That very same assumption, however, was part of the Agencies’ initial estimate that only 379,000 women received insurance coverage through an entity likely to use the exemption. J.A. 45–46. Indeed, the Agencies decided in the first place that only 6% of employers that did not cover contraception before the mandate had not done so for religious reasons. J.A. 44 & n.103. The unreasonable course here was using the same assumption twice: once on the front end to lower the number of women who receive insurance from an entity likely to use the exemption, and once more on the back end to cut that figure down to a third.

II. The States Have Standing

While the Agencies do not dispute the States’ Article III standing, Little Sisters attempts to resurrect a standing challenge that has already been rejected by both this Court and the Third Circuit. *Pennsylvania II*, 930 F.3d at 562; *Pennsylvania I*, 351 F. Supp. 3d at 807–08. Both courts found that the States had established Article III injuries that were traceable to the challenged rules

and were redressable by this court. *Id.* Third Circuit precedent instructs that “once the plaintiff shows standing at the outset, she need not keep doing so throughout the lawsuit.” *Hartnett v. Pennsylvania State Educ. Ass’n*, 963 F.3d 301, 305 (3d Cir. 2020). “Instead, the burden shifts” to the defendant, who bears a “heavy burden” of proving that “there is no longer a live controversy.” *Id.* at 305–06 (quoting *Friends of the Earth, Inc. v. Laidlaw Env’t. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000)). Little Sisters, pressing the same challenges to standing that have already been rejected, cannot meet that heavy burden. *Contra* LS Opp’n at 8–12.

The record shows that the States have Article III injury because the rules “inflict a direct injury upon the States by” creating serious risk that many women will lose contraceptive coverage and thus “impos[e] substantial financial burdens on [state] coffers.” *Pennsylvania I*, 351 F. Supp. 3d at 807; *Pennsylvania II*, 930 F.3d at 563 (“the State-funded programs will be tapped to provide coverage for financially eligible women whose employers invoke the Exemptions”); *see also* States’ Mem. at 39–40 (noting Final Rules comments raising issue of “higher costs to State and local government in providing birth control to women”); *see also* J.A. 2371–72 at ¶¶ 15, 18 (anticipating that women losing coverage would seek coverage from state-funded programs); ECF No. 90-22 at ¶ 18 (same).

Little Sisters and the Agencies concede as much, acknowledging that women whose employers claim the exemptions can turn to state-funded programs to obtain contraception. Fed. Opp’n at 40; LS Opp’n at 37–38. In fact, Little Sisters asserts that women denied coverage will utilize Title X clinics, LS Opp’n at 37–38, ignoring the fact that Title X clinics in Pennsylvania rely on state as well as federal funding. *See, e.g.*, Comments of Governor Tom Wolf and Attorney

General Josh Shapiro on Proposed Rule, Compliance With Statutory Program Integrity Requirements, Docket No. HHS-OS-2018-0008, 83 Fed. Reg. 25,502, at 3 (July 31, 2018).¹²

Little Sisters nonetheless argues that the States' claims must now be dismissed because they have not identified specific employers who have declined contraceptive coverage. LS Opp'n at 8. But the "States need not define injury with such a demanding level of particularity" as Little Sisters demand. *Pennsylvania II*, 930 F.3d at 564. As the Third Circuit held, the record confirms that the effect of the rules is to deprive women of insurance coverage, causing them to rely on state programs. *Id.* at 562–63 (noting that the Agencies' own analyses showed that "between 70,500 and 126,400 women nationwide will lose contraceptive coverage as a result of their employers' invocation of the [Religious Rule]" alone). That harm is as real now as it was before.¹³ The cases cited by Little Sisters, LS Opp'n at 9–10 (citing *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 385–86 (2024); *Greenberg v. Lehocky*, 81 F.4th 376, 385 (3d Cir. 2023)), are inapposite because at no point had the plaintiffs there established standing as a matter of law.

Little Sisters' redressability arguments are likewise unavailing. Little Sisters suggests that no matter what happens to the rules, the Guidelines themselves now contain the rules' exemptions and will live on independent of the rules. LS Opp'n at 10–11. But the Guidelines do not independently create exemptions from their otherwise generally applicable requirements. They

¹² Available at <https://www.regulations.gov/comment/HHS-OS-2018-0008-200551>.

¹³ Little Sisters' assertion that the States' "sat on their heels for the last four years," LS Opp'n at 8, does not accurately characterize the intervening developments since the rules were promulgated. As the court is aware, the parties had filed summary judgment motions and were prepared to bring this matter to resolution when the Agencies requested a stay on March 5, 2021, to evaluate the rules given the change in Administration. ECF Nos. 269, 271, 275. While the States "remain[ed] concerned about the ongoing harms," ECF No. 280 at ¶ 11, and the motions remained pending, the Agencies took appropriate steps toward amending the rules. *See* ECF No. 299 (notice of proposed rulemaking); ECF Nos. 312, 322, 323 (Agencies representing final rule would be published in 2024). The withdrawal of the rulemaking on December 23, 2024, marked a sudden course reversal. ECF No. 326.

merely reflect the rules’ direction that certain employers are exempt. The rules themselves “delineat[e] what exemptions and accommodations apply if [the Health Resources and Services Administration] lists contraceptives in its Guidelines.” J.A. 8; *see also* J.A. 88–89. Indeed, the rules’ legal conclusion was that the Agencies “are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.” J.A. 6; *accord* J.A. 61. Exemptions from the Guidelines always have been the work of the Agencies, not HRSA; prior exemptions resulted from regulations the Agencies promulgated to “guide HRSA in exercising its discretion.” J.A. 100; *see also* J.A. 6 (“The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter”). Little Sisters incorrectly cites the Supreme Court for the conclusion that the Agencies’ regulations and HRSA’s guidelines each “may limit the other’s effect,” LS Opp’n at 11, when in fact the Supreme Court observed only that the Guidelines are subject to any lawfully-created agency exemption, *Little Sisters*, 591 U.S. at 665-66. The exemptions now contained in the Guidelines reflect the Agencies’ having limited the Guidelines’ effect.

Separately, no injunction obtained against the mandate is an obstacle to relief. *Contra* LS Opp’n at 11–12. Women insured by an entity covered by an injunction at the time the rules were promulgated were excluded from the Agencies’ estimate of the rules’ impact. J.A. 40–41. And existing injunctions do not resolve the Rules’ application to entities that need not show a right to relief under RFRA.

III. Little Sisters' Other Arguments Should Be Rejected

Little Sisters also attacks the contraceptive mandate on several grounds that it argues deprive the States of any redressable injury. LS Opp'n at 12–20. These arguments are well beyond the scope of this case, which is not about any challenge to the mandate.

As a threshold matter, this Court need not reach Little Sisters' constitutional challenges because they are not properly presented. As the Supreme Court and the Third Circuit already observed earlier in this litigation, Little Sisters intervened in this suit to “defend[] the portions of the religious exemption [interim final rule] that apply to religious nonprofit entities” and “*to seek the same relief as the federal government.*” *Commonwealth of Pennsylvania v. President United States of Am.*, 888 F.3d 52, 57 n.2, 62 (3d Cir. 2018) (emphasis added); *Little Sisters*, 591 U.S. at 674 n.6 (holding that Little Sisters did not need to demonstrate appellate standing separate from the Agencies because the Little Sisters did not “pursue[] relief that is broader than or different from” the Agencies). The relief sought by the federal government (and so by Little Sisters as well) is summary judgment rejecting the States' challenges to the Religious Rule and the Moral Rule—not prospective relief running against the validity or enforcement of the mandate itself.

Compounding their problems, Little Sisters ask the Court to “reach the question of whether the Mandate violates” various constitutional principles and hold that the mandate “may not be enforced.” LS Opp'n at 13–14, 16. But this relief would run against the Federal Government or its officers, not the States. Because Little Sisters is an Intervenor-*Defendant*, they could only obtain this relief through pleaded crossclaims, *see* Fed. R. Civ. P. 13(g)—which they did not bring. Little Sisters' affirmative defenses in their proposed answer, ECF No. 20 at 22, apply only to the relief requested by the States, which is vacatur of the rules. And in any event, these affirmative defenses do *not* include the non-delegation doctrine or the Appointments Clause, which Little Sisters now

invoke. *Id.* In short, any such argument against the mandate is waived or beyond the scope of this case, and the Court should not reach it.

Furthermore, each argument founders on the merits. *First*, Little Sisters invokes the non-delegation doctrine, which stops Congress from assigning responsibility to an agency without also providing an intelligible principle to guide the agency’s exercise of its responsibility. *Gundy v. United States*, 588 U.S. 128, 135-36 (2019) (plurality). The standard is “not demanding.” *Id.* at 146. Only *two* statutes have *ever* failed that standard, and only then because “Congress had failed to articulate *any* policy or standard” as to discretion. *Id.* (emphasis added). There is no basis for the Women’s Health Amendment to be the third.¹⁴ The Guidelines are to include services that are: (1) for women, (2) preventive, and (3) exclusive of services that the United States Preventive Task Force recommends. 42 U.S.C. § 300gg-13(a)(4). That is an intelligible principle.

Second, Little Sisters get no further with the Appointments Clause, which requires that “Officers of the United States” be appointed by the President and confirmed by the Senate. U.S. Const. art. II, § 2 cl. 2. Little Sisters wrongly suggests that the HRSA Administrator is akin to the SEC administrative law judges who were found to be inferior officers under the Appointments Clause due to the significant judicial authority they wielded in *Lucia v. SEC*, 585 U.S. 237, 247–49 (2018). Unlike the decisions of SEC ALJs, who have “extensive powers” over parties appearing before them, *id.* at 241–42, the Guidelines have no independent force. Congress has directed insurers to comply with the Guidelines, and compliance is defined by the Agencies, not HRSA or its Administrator. 42 U.S.C. § 300gg-13(a)(4); 45 C.F.R. Part 147; *see Lofstad v. Raimondo*, 117 F.4th 493, 499–500 (3d Cir. 2024) (management council’s ability to pocket-veto Secretary of

¹⁴ The Supreme Court recently denied certiorari on an identical non-delegation claim against the HRSA Guidelines. *Braidwood Mgmt., Inc. v. Becerra*, 145 S. Ct. 1053 (Jan. 13, 2025).

Commerce decisions without any method of override rendered them officers, but authority to make recommendations of plans and amendments did not).

Even if the HRSA Administrator were an “Officer of the United States,” there is no Appointments Clause violation. The Administrator has been properly appointed because Congress has vested in the HHS Secretary broad authority and discretion to authorize other officers, agencies or employees of HHS to perform any of the functions of the Secretary. *See* Reorganization Plan No. 3 of 1966, 80 Stat. 1610 at §§ 2–3; 5 U.S.C. § 301. As a sub-agency of the Public Health Service within the Department of Health and Human Services, HRSA is expressly “under the supervision and direction of the Secretary,” 42 U.S.C. § 202, and its Administrator is answerable to the HHS Secretary, *see* 47 Fed. Reg. 38,409, 38,410 (Aug. 31, 1982).

Further, as one district court has already held, the HHS Secretary’s ratification of all HRSA Guidelines and Recommendations by Jan 1, 2022, Memo, *see Braidwood Mgmt., Inc. v. Becerra*, 627 F. Supp. 3d 624, 639–41 (N.D. Tex. 2022),¹⁵ effectively cures any purported Appointments Clause defect, *see Kajmowicz v. Whitaker*, 42 F.4th 138, 153 (3d Cir. 2022) (“properly appointed official’s ratification of an allegedly improper official’s prior action ... resolves the claim on the merits by remedy[ing] the defect (if any) from the initial appointment”) (quoting *Guedes v. Bur. of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 13 (D.C. Cir. 2019)); *see also NLRB v. Newark Elec. Corp.*, 14 F.4th 152, 160–63 (2d Cir. 2021); *CFPB v. Gordon*, 819 F.3d 1179, 1191–92 (9th Cir. 2016). So, the Appointments Clause contention is wrong three times over. *Cf.*

¹⁵ In the subsequent appeal, the Fifth Circuit asked the district court to resolve certain claims raised by plaintiffs as to ratification in the first instance, *see Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 956 (5th Cir. 2024), but Little Sisters has not made any such arguments here.

Kajmowicz, 42 F.4th at 154 (courts should “avoid deciding issues, especially constitutional ones, when they need not do so in order to resolve cases”).

Third, Little Sisters’ Free Exercise arguments cannot prevail on the merits. Little Sisters’ reliance on *Fulton v. City of Philadelphia* is unavailing. *Contra* LS Opp’n at 17. There, municipal policy violated the Free Exercise Clause largely because, by establishing a “formal system of entirely *discretionary* exceptions” that religious objectors could pursue, the policy was “not generally applicable” but instead “‘invite[d]’ the government to decide which reasons for not complying with the policy are worthy of solicitude.” *Fulton*, 593 U.S. at 537 (emphasis added). But if the States prevail and the Religious and Moral Rules are vacated, there would be no system of discretionary exceptions. *See* States’ Mem. 7–8 (citing to J.A. 118-217 and the post-*Zubik* rules which maintained the mandatory Accommodation while “allow[ing] objecting entities to establish eligibility for the Accommodation by notifying HHS of their objection to covering contraception”). Instead, entities seeking the Accommodation who meet the eligibility and procedural requirements would be excused from compliance with the mandate. *See* J.A. 192–93; *contra Fulton*, 593 U.S. at 523 (challenged policy permitted exceptions “at the sole discretion of the Commissioner”) (cleaned up).

Nor would vacating the rules create any constitutionally defective categorical exceptions. *Contra* LS Opp’n at 17–18. The ACA categorically exempts, or “grandfather[s],” certain health plans from preventive-service coverage requirements based on how long they had been in existence at the time of the law’s enactment—that is, for reasons wholly unrelated to religious status. *See* 42 U.S.C. § 18011; 45 C.F.R. § 147.140. That exemption is generally applicable; plans provided by religious and secular employers alike may qualify. It therefore does not “prohibit[] religious conduct while permitting secular conduct that undermines the government’s asserted

interests *in a similar way*.” *Fulton*, 593 U.S. at 534 (emphasis added, citation omitted); *see Spivack v. City of Philadelphia*, 109 F.4th 158, 177 (3d Cir. 2024) (“[W]hen a religious exemption would affect the government’s interests in a different way or to a greater extent than another type of exemption,” courts “draw no ... inference” supporting a Free Exercise violation). Vacating the Rules would restore a generally applicable set of regulations that are legal and constitutional.¹⁶

IV. The Rules Must Be Vacated

Finally, the appropriate remedy here is to “hold unlawful and set aside” the rules and vacate them nationwide. 5 U.S.C. § 706(2). Contrary to the Agencies’ assertions, Fed. Opp’n at 43–45, such relief is not party-specific.¹⁷ *See Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 827 (2024) (Kavanaugh, J., concurring) (quoting Mila Sohoni, *The Past and Future of Universal Vacatur*, 133 Yale L.J. 2304, 2311 (2024)) (describing the position that “the APA does not allow vacatur” as “both novel and wrong,” and one that “disregards a lot of history and a lot of law”); *id.* at 829–37 (surveying text, history, and precedent supporting view that § 706 provides for vacatur).

As courts have long held, nationwide vacatur is the usual remedy in an APA action because when a court “determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *accord Braidwood Mgmt.*, 104 F.4th at 951; *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019); *Nat’l Mining*

¹⁶ Little Sisters’ theory premised on church autonomy principles is likewise belated and beyond the scope of this case. To the extent the Court is inclined to reach it, it should reserve judgment and allow for supplemental briefing after the Supreme Court’s resolution of *Catholic Charities Bureau, Inc. v. Wisconsin Labor & Industry Review Commission*, No. 24-154 (U.S.).

¹⁷ The Agencies also critique nationwide injunctions as a general equitable remedy, outside the context of the APA. Fed. Opp’n at 44. While the States pleaded both vacatur and injunctive relief in their Amended Complaint, ECF 89, at present the States seek only the former.

Ass’n v. U.S. Army Corps. Of Eng’rs, 145 F.3d 1399, 1409 (D.C. Cir. 1998). This remedy “is not party-restricted,” has “nationwide effect,” “affects persons in all judicial districts equally,” and “is the default remedy for unlawful agency action.” *Braidwood Mgmt.*, 104 F.4th at 951 (citations omitted and cleaned up). In short, nationwide vacatur of the rules is the appropriate remedy under the APA in this case.

The Agencies also assert that remand without vacatur would be appropriate, at least as to one particular defect in the rules’ reasoning. Fed. Opp’n at 30. But the case they cite for that proposition, *Coinbase, Inc. v. SEC*, did not actually award such a remedy. *See* 126 F.4th 175, 203–04 (3d Cir. 2025) (opting to remand to agency to explain denial of petition for rulemaking rather than mandate rulemaking). While the Third Circuit has remanded without vacatur for procedural defects in the administrative process, *see, e.g., Prometheus Radio Project v. FCC*, 824 F.3d 33, 59–60 (3d Cir. 2016) (remanding due to unreasonable delay in agency’s review of certain rules, while “vacat[ing]” a separate “procedural invalid” rule “and remand[ing] the matter”), the Agencies cite no Third Circuit case squarely holding that remand without vacatur was warranted for defects of the kind present here, namely, *substantively* unreasonable decisionmaking. *Cf. Council Tree Commc’ns, Inc. v. F.C.C.*, 619 F.3d 235, 258 n.13 (3d Cir. 2010) (court “express[ing] no view,” in case implicating reasoned-decisionmaking challenge, as to whether courts “are authorized to order” remand without vacatur).

Finally, severance is an inappropriate remedy for the same reasons asserted in the States’ opening brief, States’ Mem. at 44, and this Court should vacate the Rules in their entirety for the foregoing reasons.

CONCLUSION

For the reasons above, the States' Motion for Summary Judgment should be granted, defendants' motions for summary judgment should be denied, and the rules should be vacated.

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Respectfully submitted,

MATTHEW J. PLATKIN
Attorney General
State of New Jersey

JENNIFER C. SELBER
General Counsel
Pennsylvania Office the Governor

s/ Joshua Bohn

s/ Aimee D. Thomson

JOSHUA BOHN
MEGHAN K. MUSSO
Deputy Attorneys General
New Jersey Attorney General's Office
Richard J. Hughes Justice Complex
25 Market Street
Trenton, NJ 08625
(609) 696-5366
joshua.bohn@law.njoag.gov

MICHAEL J. FISCHER
Executive Deputy General Counsel
AIMEE D. THOMSON
Deputy General Counsel
Governor's Office of General Counsel
30 North Third Street, Suite 200
Harrisburg, PA 17101
(223) 234-4986
aimeethomson@pa.gov

Attorneys for New Jersey

Attorneys for Pennsylvania