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*; 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-DeREMER, *in her official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA. Defendants.	**No. 2:17-cv-04540-WB**

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiffs the Commonwealth of Pennsylvania and the State of New Jersey, by and through their undersigned counsel, file this Motion requesting that this Court grant summary judgment against all Defendants on Count IV of the Amended Complaint, ECF No. 89, filed on December 14, 2018, and vacate the following rules (the "Rules"):

a) Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (82 Fed. Reg. 47,792 & 83 Fed. Reg. 57,536).

b) Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (82 Fed. Reg. 47,838 & 83 Fed. Reg. 57,592).

As set forth in the contemporaneously filed Memorandum of Law, there are no genuine issues of material fact and Movants are entitled to judgment as a matter of law. The Rules are unlawful because they are arbitrary and capricious in violation of the Administrative Procedure Act.

This Motion is supported by the contemporaneously filed Memorandum of Law, the Joint Appendix submitted in this matter at ECF No. 253, and any additional submissions that may be considered by the Court.

March 11, 2025

Respectfully submitted,

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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March 11, 2025

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INTRODUCTION

Under the Women's Health Amendment to the Affordable Care Act, the Health Resources and Services Administration (HRSA), a component of the Department of Health and Human Services (HHS), is charged with creating guidelines that define the preventive services that are necessary for women's health. 42 U.S.C. § 300gg-13(a)(4). Since HRSA released the first version of the Women's Preventive Services Guidelines (Guidelines) in 2011, they have included all "Contraceptive methods and counseling" that have been approved by the Food and Drug Administration. *See* J.A. 311 (2011 Guidelines), 312-A (2019 Guidelines); 87 Fed. Reg. 1763 (Jan. 12, 2022).

Group health plans and health insurance issuers must cover the services identified in the Guidelines without imposing a cost-sharing obligation on the part of the insured. 42 U.S.C. § 300gg-13(a). But, as the Supreme Court held in this case, HHS and the Departments of Labor and Treasury ("the Agencies"), which collectively administer the ACA, have discretion to create exceptions from that obligation. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 675–77 (2020). The Agencies relied on that discretion, as well as the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb *et seq*., in promulgating the regulations at issue in this case. J.A. 1–55 (Religious Rule); J.A. 56–95 (Moral Rule) ("the Rules"). The Rules allow employers, based on their own religious or moral beliefs, to make the Guidelines' contraceptive coverage requirement inapplicable as to their employees.

While the Supreme Court concluded that the Agencies have authority to create exceptions from the contraceptive coverage guarantee, it did not hold that they had exercised that authority lawfully. To the contrary, it reserved the question on whether the Rules were arbitrary and capricious in violation of the Administrative Procedure Act. *See Little Sisters*, 591 U.S. at 688

(Alito, J., concurring) (observing that, on remand, the States "are all but certain to pursue their argument that the current rule is flawed on yet another ground, namely, that it is arbitrary and capricious and thus violates the APA"). Justice Kagan, concurring in the judgment, observed that the Supreme Court's decision "does not mean the Departments should prevail when these cases return to the lower courts." *Id.* at 707 (Kagan, J., concurring). In fact, she made clear that they should not, writing that the Rules "give every appearance of coming up short" when measured against the APA's requirement of "reasoned decisionmaking." *Id.*

Justice Kagan was correct. The Rules are arbitrary and capricious for numerous reasons. Most notably, they sweep well beyond the scope of the problem they purport to address and reflect a failure on the part of the Agencies to consider other, far less burdensome alternatives. They also fail on their own terms, as the justifications offered by the Agencies for certain choices made in promulgating the Rules do not withstand scrutiny. And they demonstrate that the Agencies failed to consider, and adequately respond to, public comments submitted on the Rules—of which 99.96% were critical. For these and other reasons, the Rules violate the APA's requirement of reasoned decisionmaking and must be set aside.[1] This Court should grant the States' motion, enter summary judgment in their favor, and vacate the Rules.

BACKGROUND

I. Women's Health Guidelines

The Women's Health Amendment to the ACA requires that group health plans and health insurance issuers cover for women, without cost-sharing, "preventive care and screenings … as

[1] Plaintiffs' amended complaint alleged that the Rules violated the Equal Protection Clause (Count I), Title VII of the Civil Rights Act and the Pregnancy Discrimination Act (Count II), and the Establishment Clause (Count V). Because Plaintiffs believe that the arbitrary and capricious arguments are conclusive here, and to allow this matter to be fully resolved without further delay, Plaintiffs voluntarily dismiss these other counts under Rule 41.

provided for in comprehensive guidelines supported by" HRSA. 42 U.S.C. § 300gg-13(a)(4). After the ACA passed, HRSA commissioned the Institute of Medicine (IOM), a widely respected organization of medical professionals, to recommend what preventive services should be covered for women. *See* J.A. 326–27. The IOM, in turn, convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. *See* J.A. 317–18. After conducting an extensive study, the IOM committee issued a comprehensive report identifying eight evidence-based preventive health services it recommended be covered. J.A. 313–561.

One of the eight preventive services was "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education." J.A. 335. That recommendation was based on evidence that "contraception and contraceptive counseling are effective at reducing unintended pregnancies." *Id.* The committee noted that "[n]umerous health professional associations and other organizations recommend [the use of] family planning services as part of preventive care for women." *Id.* And the report discussed in detail the health and other risks associated with unintended pregnancies, described studies showing that contraception was effective when used correctly, and explained that cost was a significant barrier to the effective use of contraception. J.A. 427–34.

Two weeks after the IOM committee released its report, HRSA adopted it and issued its first "Women's Preventive Services Guidelines." J.A. 310–12. Consistent with the committee's report, that 2011 version of the Guidelines required health plans to cover "[a]ll Food and Drug

Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." J.A. 311.[2]

II. The Agencies Work to Accommodate Religious Objections to Contraception

Shortly after HRSA adopted the IOM report, the Agencies issued an interim final regulation that "provide[d] HRSA with the discretion" to make the Guidelines' contraceptive coverage requirement inapplicable to any insurance plan maintained by "churches, their integrated auxiliaries, and conventions or associations of churches" and "the exclusively religious activities of any religious order." J.A. 271; J.A. 306; 26 U.S.C. § 6033(a)(3)(A)(i) & (iii).

Alongside the exemption for churches and related entities, the Agencies announced, in 2012, that they would further consider how to accommodate organizations that did not qualify for the church exemption but nonetheless objected to providing contraception. Specifically, the Agencies said that they "plan[ned] to develop and propose changes … that would meet two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit organizations' religious objections to covering contraceptive services." J.A. 300. During this process, the Agencies created a "safe harbor" for certain organizations that did not comply with the Women's Health Amendment's direction to cover the contraceptive methods and services defined in the Guidelines. *Id.*

The Agencies subsequently issued an Advanced Notice of Proposed Rulemaking, a Notice of Proposed Rulemaking, and ultimately a final rule. J.A. 290–97; 269–89; 238–68. The final rule

[2] HRSA has updated the Guidelines several times since 2011. *See* J.A. 96–97, 180–82, 312-A; 87 Fed. Reg. 1763 (Jan. 12, 2022); 88 Fed. Reg. 876 (Jan. 5, 2023); 89 Fed. Reg. 472 (Jan. 4, 2024); 89 Fed. Reg. 106,522 (Dec. 30, 2024). The Guidelines continue to include contraception as a service that "address[es] health needs specific to women." HRSA, *Women's Preventive Services Guidelines*, https://www.hrsa.gov/womens-guidelines (last visited Mar. 11, 2025) (attached as Exhibit 177, J.A. 3410–3417).

created the "Accommodation," an alternative available to any nonprofit entity that held "itself out as a religious organization" and that had religious objections to "providing coverage for some or all of any contraceptive services required" by the Guidelines. J.A. 243. The Accommodation allowed an employer not to provide contraceptive coverage for its employees if the employer submitted a standardized form to its insurance company (if the employer was fully insured), or third-party administrator (if the employer was self-insured) that informed the insurer or administrator of the religious objection. *See* J.A. 243–44; *see also id.* 1971–72.

An insurance provider receiving an objection from a fully insured employer was required to "[e]xpressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan," and instead "[p]rovide separate payments for any contraceptive services required to be covered … for plan participants and beneficiaries for so long as they remain enrolled in the plan." J.A. 265. The insurer further had to "segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services." *Id.* Finally, the insurer was required to provide written notice to plan participants and beneficiaries of the fact that "the eligible organization does not administer or fund contraceptive benefits," but that such benefits were available directly from the insurer. J.A. 266.

Under this system, a fully insured objecting employer could opt out of providing contraception, but its plan participants and beneficiaries would still receive the benefits they were entitled to under the Guidelines. Shifting the burden to the insurer to provide the services directly was not expected to impose additional costs on the insurer, because "[c]overing contraceptives … yields significant cost savings," in the form of lower "direct medical costs of pregnancy." J.A. 241. Thus, as a result of providing contraceptive coverage, the insurer would expect to see lower expenses from other services provided to the organization's participants and beneficiaries.

Unlike fully insured employers, self-insured employers directly pay for the health expenses they elect to cover, typically with the administrative assistance of an outside organization known as a third-party administrator (TPA). Under the Accommodation, self-insured objecting employers could submit the standardized objection to their TPA. J.A. 263–64. The TPA then assumed the obligation to provide contraceptive coverage to plan participants and beneficiaries, either by paying for contraceptive services directly or by contracting with another entity to do so. J.A. 264. And the TPA was obligated to provide the same notice that insurers were required to provide, stating that the employer did not provide contraceptive benefits, but that such benefits were available from the TPA. *Id.*

In these respects, the Accommodation functioned in precisely the same manner for self-insured and fully insured employers. But because TPAs for self-insured plans do not bear the costs for other benefits provided to plan participants and beneficiaries, they would not be expected to save money by providing contraceptive coverage. As a result, the regulations created a mechanism for HHS to reimburse TPAs for the cost of providing contraceptive coverage, and to offer an allowance for administrative expenses and profit. J.A. 251–52. The payments operated through an adjustment to the Federally-Facilitated Exchange user fee paid by companies participating in federally administered healthcare exchanges. J.A. 251.

III. Litigation over Contraceptive Coverage

Despite the Agencies' efforts, several employers and colleges filed lawsuits challenging their obligation to cover contraceptive care in existing health plans, or, for those eligible for the Accommodation, their obligation to notify their insurer or TPA that they would not be doing so.

In one set of cases, closely held, for-profit corporations that were not eligible for the Accommodation challenged their obligation to cover contraceptive care, arguing that being required to do so violated their rights under the Religious Freedom Restoration Act (RFRA), 42

U.S.C. § 2000bb *et seq*. Two of these challenges were consolidated before the Supreme Court in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). The Court held in *Hobby Lobby* that requiring closely held, for-profit corporations with religious beliefs that were substantially burdened by covering contraceptive care to do so violates RFRA because the government could promote access to contraceptive care without requiring an objecting employer to cover that care by utilizing the Accommodation mechanism. *Id.* at 728–32.

Three days after its decision in *Hobby Lobby*, the Court ruled that an employer that qualified for the Accommodation could, instead of sending its objection notice to its insurer or TPA, directly notify HHS of its objection. *Wheaton College v. Burwell*, 573 U.S. 958 (2014). The Court stressed, however, that its order should not affect the ability of covered individuals "to obtain, without cost, the full range of FDA approved contraceptives" as HHS could rely on the notice to "facilitate the provision of full contraceptive coverage under the Act." *Id.* at 959.

After these decisions, the Agencies initiated a formal rulemaking process to amend the eligibility criteria for the Accommodation consistent with *Hobby Lobby*, J.A. 218–27, and issued interim final rules to address the Court's order in *Wheaton College*, J.A. 228–37. The interim rules allowed objecting entities to establish eligibility for the Accommodation by notifying HHS of their objection to covering contraception. J.A. 228–37. Both sets of rules were finalized one year later. J.A. 118–217.

In another set of cases, employers already eligible for the Accommodation alleged that that option violated their rights under RFRA. Many of these cases, including one from the Third Circuit rejecting this challenge, *see Geneva College v. Sec'y of HHS*, 778 F.3d 422 (3d Cir. 2015), were ultimately consolidated before the Supreme Court in *Zubik v. Burwell*, 578 U.S. 403 (2016). Six days after argument in *Zubik*, the Court directed the parties to submit supplemental briefing to

"address whether and how contraceptive coverage may be obtained by petitioners' employees through petitioners' insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees." *Zubik v. Burwell*, 578 U.S. 901 (2016). The order proposed one such arrangement, but added that "[t]he parties may address other proposals along similar lines." *Id.* After the parties submitted supplemental briefing, the Court decided that the parties should be "afforded an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'" *Zubik*, 578 U.S. at 408 (cleaned up). The Court vacated all lower court decisions in the consolidated cases. *Id.* at 410.

Several months after the Court's order in *Zubik*, the Agencies announced that "no feasible approach has been identified … that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage," J.A. 172. Because the Accommodation best reconciled access to contraceptive coverage and religious objections to providing that coverage, the Agencies left that process in place. J.A. 172–73. A few months later, the Third Circuit again ruled that the Accommodation does not violate RFRA. *Real Alts., Inc. v. Sec'y of HHS*, 867 F.3d 338, 359–66 (3d Cir. 2017).

IV. The Agencies' Rules

In May 2017, President Trump issued an executive order directing the Agencies to "consider issuing amended regulations" to address "conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of Title 42, United States Code." J.A. 167. The order did not acknowledge the Court's instruction in *Zubik* that the Agencies ensure that women covered by health plans offered by objecting entities "receive full and equal health coverage, including contraceptive coverage." 578 U.S. at 408 (cleaned up). The Agencies

thereafter issued two interim final rules—one addressing religious objections to contraception and the other on moral objections—which became effective a week before they were published in the Federal Register. J.A. 98–141 (interim Religious Rule); J.A. 141–166 (interim Moral Rule). The two interim rules made several sweeping changes to the availability of contraceptive coverage.

Following the acceptance of comments, in November 2018, the Agencies issued final versions of the Rules, which maintained the substantive changes first promulgated through the interim versions. J.A. 1–55; 56–95. Among those changes, the Rules:

***Create a Greatly Expanded Religious Exemption for Employers*:** The Religious Rule directs that an employer may make the Guidelines' contraceptive coverage requirement inapplicable to its employees if the employer has a religious objection to covering or arranging payments for contraceptive care, or objects to having an insurer or TPA do so. 45 C.F.R. § 147.132(a); *see also* J.A. 55. According to the Agencies, a complete exemption of this sort is needed because the Accommodation itself violates RFRA in many cases. J.A. 11–12.

Other than for churches and affiliated entities, the Agencies have never before directed that certain health insurance plans be altogether removed from the otherwise general requirement to cover contraceptive care without cost sharing. The consequence for any woman covered by such a plan is the loss of coverage, without cost sharing, for contraceptive services and counseling. The Religious Rule does not create any mechanism for women who will lose coverage to obtain it from other sources, and it does not suggest that the Agencies will work to ensure that any such women have coverage.

***Create a Moral Exemption for Employers*:** The Agencies created a moral exemption that functions much like the religious exemption. 45 C.F.R. § 147.133(a); *see also* J.A. 94–95. The Moral Rule does not define what beliefs qualify as a "sincerely held moral conviction" sufficient

to claim the exemption. Not only have the Agencies never before created a moral exemption, the Agencies have never before permitted a moral objector to use the Accommodation.

***Create an Individual Exemption*:** The Rules also create, for the first time, a process for individuals to make the Guidelines' contraceptive coverage requirement optional as to the insured's plan, if the insured has a religious or moral objection to contraception. 45 C.F.R. §§ 147.132(b), 147.133(b); *see also* J.A. 55, 95.

***Make the Accommodation Optional*:** The Rules make the Accommodation optional in all cases. 45 C.F.R. § 147.131; *see also* J.A. 54. As a result, no objecting employer is required to use it, even if the Accommodation would fully satisfy any religious or moral objection to covering contraceptive care.

***Allow Publicly Traded Corporations to Use Exemption or Accommodation*:** The Religious Rule, but not the Moral Rule, makes the newly created exemption available to publicly traded corporations. 45 C.F.R. § 147.132(a)(1)(i)(D); *see also* J.A. 27. The Agencies justify this expansion by claiming "in a country as large as the U.S., comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character." J.A. 27.

***Fail to Require Notice*:** The Rules provide that "exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them." J.A. 23; *accord* J.A. 78. Rather, the only notice that exempted plans are required to provide participants is that which ERISA already mandates. So long as plans that do not provide contraception indicate that fact somewhere in their plan documents, they fully comply with the Rules. J.A. 23, 78–79.

V. This Action

Pennsylvania filed this action shortly after the agencies issued the interim rules. *See* Compl., ECF No. 1. The complaint alleged, among other things, that the Rules violated the APA's substantive and procedural limitations on agency rulemaking. *Id.* Pennsylvania moved for a nationwide preliminary injunction, *see* Mot. Prelim. Inj., ECF No. 9, which this Court granted in December 2017, *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017). The Court concluded that the Agencies had improperly failed to take comment before issuing the interim rules, in violation of the procedural requirements of the APA, that the agencies lacked statutory authority under the ACA to create exemptions from the requirements of the Women's Health Amendment, and that those exemptions could not be separately justified by RFRA. *Id.* at 570–81.

While the first preliminary injunction was on appeal, the Agencies finalized the Rules. Pennsylvania—joined by New Jersey—filed an amended complaint challenging the final versions of the Rules on the same grounds as the interim versions. *See* Am. Compl., ECF No. 89. Three days later, the States filed a second motion for a preliminary injunction. *See* Mot. Prelim. Inj., ECF No. 90. This Court again entered a nationwide preliminary injunction. *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019). The Court concluded that the Agencies' acceptance of comments following the issuance of the interim rules did not cure their violation of the APA's procedural requirements, and that the Agencies lacked authority, under either the Women's Health Amendment or RFRA, to create exemptions from the Guidelines. *Id.* at 812–27.

On appeal, the Third Circuit affirmed this Court's decision in all respects. *Pennsylvania v. President*, 930 F.3d 543 (3d Cir. 2019). That court agreed that the Agencies lacked good cause to forgo the need for public comment on a proposal. *Id.* at 565–69. And that court further held that the Women's Health Amendment did not give the Agencies the discretion to create exemptions from the Guidelines, and that RFRA neither required nor authorized the Religious Rule

independent of the Women's Health Amendment. *Id.* at 570–74. Finally, it upheld the scope of the nationwide injunction entered by this Court. *Id.* at 575–76.

The Supreme Court reversed the Third Circuit. The Court first held the Women's Health Amendment provides the Agencies with discretion to define both what services must be covered, and who must cover them. *Little Sisters*, 591 U.S. at 676. The Court then briefly discussed RFRA, rejecting the argument "that the Departments could not even consider RFRA as they formulated the religious exemption from the contraceptive mandate." *Id.* at 680.[3] The Court made clear, however, that it "need not reach" whether RFRA required or authorized the Rules. *Id.* The Court next held that the Agencies' acceptance of comments following the issuance of the interim rules satisfied the APA requirements, effectively overruling the Third Circuit's decision in *NRDC v. EPA*, 683 F.2d 752 (3d Cir. 1982), as well as similar decisions from other courts of appeals. *Little Sisters*, 591 U.S. at 683–86.

Justices Alito and Gorsuch concurred with the majority's opinion but would have ruled that RFRA compelled the Religious Rule. *See id.* at 688 (Alito, J., concurring) ("RFRA compels an exemption for the Little Sisters and any other employer with a similar objection to what has been called the accommodation to the contraceptive mandate.").

Concurring in the judgment only, Justice Kagan, joined by Justice Breyer, concluded that the language of the Women's Health Amendment was ambiguous and the Agencies' interpretation was entitled to *Chevron* deference. *Id.* at 704 (Kagan, J., concurring). Justice Kagan stressed, however, that the Court's conclusion on the scope of the Women's Health Amendment "does not

[3] Although the Court characterized this as "respondents' argument," the States had, in fact, argued to the contrary. *See, e.g.*, Transcript of Oral Argument at 79:13–15, *Little Sisters of the Poor Saints Peter and Paul Home*, 591 U.S. 657 (2020) (Nos. 19-431 & 19-454) ("We don't dispute that agencies should take RFRA into account.").

mean the Departments should prevail when these cases return to the lower courts." *Id.* at 707. She emphasized that "[a]n agency acting within its sphere of delegated authority can of course flunk the test of 'reasoned decisionmaking.'" *Id.* at 707 (cleaned up). She then described several ways in which the Agencies had done so here, ranging from the decision to "exempt[] all employers with objections to the mandate, even if the accommodation met their religious needs," to the inclusion of publicly traded companies within the scope of the Religious Rule and the issuance of the Moral Rule, which could not be justified by RFRA. *Id.* at 708–10.

Justice Ginsburg, joined by Justice Sotomayor, dissented and criticized the majority for "cast[ing] totally aside countervailing rights and interests in its zeal to secure religious rights to the *nth* degree." *Id.* at 710 (Ginsburg, J., dissenting). She read the Women's Health Amendment to grant HRSA the authority to identify *what* preventive services were to be covered, but not *who* was to cover them. *Id.* at 718–21. Justice Ginsburg then rejected the government's alternative argument that RFRA justified the Religious Rule, noting that the Rule "imposes significant burdens on women employees," *id.* at 725, and that the Accommodation "does not substantially burden objectors' religious exercise," *id.* at 727.

VI. Other Challenges to the Rules

In addition to Pennsylvania and New Jersey, several other states challenged the Interim and Final Rules.

California, joined by fifteen other states, filed suit in the Northern District of California. *See California v. HHS*, No. 17-5783 (N.D. Cal. filed Oct. 6, 2017). The district court found that the rules likely violated the APA and entered a preliminary injunction, applicable to the plaintiff states only. *See California v. HHS*, 351 F. Supp. 3d 1267, 1284–85, 1301 (N.D. Cal. 2019). That decision was subsequently affirmed by the Ninth Circuit. *See California v. HHS*, 941 F.3d 410, 418 (9th Cir. 2019). The Supreme Court, following its decision in this case, vacated the Ninth

Circuit's decision and remanded the case. *See HHS v. California*, 141 S. Ct. 192 (2020). The parties filed cross-motions for summary judgment, which were argued on December 16, 2020. *See* ECF No. 445, No. 17-5783 (N.D. Cal.). The matter was stayed pending the Biden Administration's Notice of Proposed Rulemaking, *see infra* Background Part VII. After that NPRM was withdrawn, the district court lifted the stay and indicated that it would rule on the pending summary judgment motion that had been stayed. *See* Order, ECF No. 521, No. 17-5783 (N.D. Cal. Jan. 8, 2025).

Massachusetts also challenged the rules. *See Massachusetts v. HHS*, No. 17-11930 (D. Mass. filed Oct. 6, 2017). The district court in that case ultimately entered final judgment in favor of the Agencies, *see Massachusetts v. HHS*, 513 F. Supp. 3d 215, 219 (D. Mass. 2021), which was subsequently appealed. No. 21-1076 (1st Cir. Jan. 27, 2021). After the Biden Administration indicated that it would attempt to draft new rules, *see infra* Background Part VII, the First Circuit held the appeal in abeyance. *See* Order, No. 21-2076 (1st Cir. Mar. 12, 2021). In February 2025, the parties informed the court that they agreed that the matter should be taken out of abeyance and the appeal resolved. *See* Status Report, No. 21-2076 (1st Cir. Feb. 3, 2025).

VII. Subsequent Developments In This Action

After President Biden took office in 2021, and while dispositive motions were pending in this matter, the Court stayed this case in August 2021 at the request of the Federal Defendants. ECF No. 281. On August 16, 2021, the Agencies announced an intention to initiate rulemaking to amend the Rules. ECF No. 282. After delays due to resource limitations and competing demands for resources caused in part by the COVID-19 pandemic, *see* ECF No. 285, the Agencies submitted a draft proposed rule to the Office of Management and Budget for review by its Office of Information and Regulatory Affairs on July 8, 2022, with the intention to publish proposed rulemaking upon completion of that review, ECF No. 288.

On February 2, 2023, the Agencies published a Notice of Proposed Rulemaking, "Coverage of Certain Preventive Services Under the Affordable Care Act," 88 Fed. Reg. 7236 (Feb. 2, 2023) ("2023 Proposed Rule"). *See* ECF No. 299. The States, as part of a coalition of 21 state attorneys general, submitted a comment letter dated April 3, 2023 that: (1) supported the 2023 Proposed Rule to the extent it sought to rescind the moral exemption and improve access through a new individual contraceptive arrangement (ICA); (2) opposed retention of the expanded religious exemption; and (3) proposed improvement to the proposed ICA, including (i) expanding the number of individuals eligible to participate in the ICA, (ii) publicizing the ICA to increase use by eligible individuals, providers, and issuers, (iii) increasing protections for eligible individuals who use the ICA, and (iv) improving the ICA's appeal for providers. *See* Attorney Generals of 21 States, Commonwealths and Districts, Comment Letter on Proposed Rule for Coverage of Certain Preventive Services Under the Affordable Care Act (April 3, 2023).[4] The States urged the Agencies to "swiftly adopt our recommendations in the Final Rule." *Id.* at 28.

After the comment period closed on April 3, 2023, the Federal Defendants requested further time for the Agencies to evaluate the more than 44,000 comments received. ECF Nos. 299, 302. The Court held a status conference on January 9, 2024, and thereafter issued an Order the same day denying all pending summary judgment motions without prejudice and continuing the stay. *See* ECF No. 311. In status reports filed January 22, 2024, and April 22, 2024, the Federal Defendants advised the Court and the parties that the Agencies expected to publish a final rule in August 2024. *See* ECF No. 312, 322. By status reports dated July 22, 2024, and October 21, 2024, the Federal Defendants advised the Court and parties that the final rule was expected to be published in December 2024. *See* ECF No. 323. On December 23, 2024, the Federal Defendants

[4] https://www.regulations.gov/comment/CMS-2023-0016-10768.

notified the Court and parties that the Agencies were withdrawing the 2023 Proposed Rule in its entirety, effective upon publication on December 30, 2024. *See* ECF No. 326. No reason for the withdrawal was provided. *Id.*

The States now file this motion for summary judgment in accordance with the January 17, 2025, Order, which was issued after the January 15, 2025,[5] status conference in this matter. ECF No. 335.

ARGUMENT

The Rules do not comply with the APA's demand of reasoned decisionmaking. The Religious Rule sweeps well beyond what is necessary to address the RFRA violation the Agencies purport to remedy, and, based on the Agencies' own analysis, denies contraceptive coverage to tens of thousands of women unnecessarily. Making matters worse, the Agencies failed to adequately justify their conclusion that a RFRA violation exists in the first place. They also did not offer anything close to a reasonable explanation of their stark reversal on the question whether contraception is safe and effective, nor did they adequately explain the need for a separate "Moral Rule." And they failed to consider several reasonable, less burdensome alternatives—a particularly glaring failure in light of the real harm caused by the unnecessarily broad sweep of the Rules. Finally, the Agencies did not consider several significant comments that identified flaws in the Rules, and the regulatory impact analysis they prepared was inadequate. As a result of these many flaws, the Rules should be vacated.

[5] At the January 15 status conference, the parties agreed to proceed with dispositive motions on the Rules, that the administrative record as to the Rules was set, and that no factual changes would impact summary judgment. To the extent any party argues to the contrary, the States reserve the right to submit factual evidence as necessary to respond to those arguments.

I. The Rules Are Arbitrary and Capricious

Agency action that is "arbitrary, capricious, [or] an abuse of discretion" must be set aside. 5 U.S.C. § 706(2)(A). This analysis requires a court to "ensure, among other things, that the agency has offered 'a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made.'" *Ohio v. EPA*, 603 U.S. 279, 292 (2024) (quoting *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Failure on the part of the agency renders the agency action unlawful. *See id.*

Similarly, agency action should be vacated if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. In conducting this review, "it is well established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Id.* at 50. Finally, when agency action constitutes a change to existing policy, the agency must provide a "reasoned explanation" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

Here, several aspects of the Rules fail these standards.

A. The Religious Rule Does Not Reasonably Address the Problem it Purports to Resolve

The Religious Rule's purpose is to "expand the protections for the sincerely held religious objections of certain entities and individuals." J.A. 2. The Agencies' discretion under the Women's Health Amendment permits them to protect religious objections to contraception because "the potential for conflict between the contraceptive mandate and RFRA is well settled." *Little Sisters*, 591 U.S. at 681. Still, the APA demands a "rational connection" between any conflicts that exist and the Agencies' chosen solution. *State Farm*, 463 U.S. at 43; *see also Little Sisters*, 591 U.S. at

707 (Kagan, J., concurring). So here, the Religious Rule must reasonably target whatever conflicts exist between RFRA and either the requirement that group health plans cover contraceptive care or the Accommodation. "Assessed against that standard of reasonableness, the exemptions HRSA and the Departments issued give every appearance of coming up short." *Id*.

First, a RFRA violation exists only when the government "substantially burden[s]" the exercise of religion. 42 U.S.C. § 2000bb-1(a). The Religious Rule, however, makes the Guidelines' inclusion of contraceptive coverage inapplicable to any employer that merely *objects* to contraception based on a sincerely held belief. 45 C.F.R. § 147.132(a)(2). The objecting employer need not even claim that directly covering contraception, or complying with the Accommodation, would cause a substantial burden. *See id.*

Second, the Religious Rule allows an employer satisfied with the Accommodation to nonetheless make the Guidelines' contraceptive coverage requirement inapplicable to that employer's employees.[6] Conflicts with RFRA cannot justify empowering employers to erase the Guidelines' contraceptive coverage requirement when, under the existing options, there was no RFRA conflict to begin with. And in the Religious Rule, the Agencies concede that some employers for whom the Accommodation relieves any RFRA violation may elect to use the exemption. J.A. 26, 41–42. This over-inclusiveness is problematic because only the Accommodation preserves access to contraceptive coverage, and contraceptive methods and counseling are among the Guidelines' list of services that are "necessary for women's health and well-being"—a conclusion that the Rules do not disturb. *See supra* Background Parts II & IV; J.A. 8, 68, 312-A, 3411–13. A reasonable solution to any RFRA violation would do as little damage as

[6] The Moral Rule shares this flaw, as the Accommodation process is just an optional alternative to the exemption. J.A. 87.

possible to women's access to contraception, but the Agencies have not been guided by that priority. Instead, they have extended the exemption even when it is not needed to serve the Rules' purported objectives. And in every instance in which the Accommodation fully resolves an entity's religious or moral objection, but the entity elects the exemption instead, the Rules "yield[] all costs and no benefits," *Little Sisters*, 591 U.S. at 709 (Kagan, J., concurring).

Third, the Religious Rule improperly covers publicly traded corporations, despite the Supreme Court having never held that RFRA covers them. The Agencies' explanation for their novel interpretation is too thin to justify the expansion. The Agencies arrive at their conclusion because, under RFRA, the government may not "substantially burden a person's exercise of religion," and under 1 U.S.C. § 1 "person" includes corporations. J.A. 27. Yet when the Court extended RFRA's protections to closely held corporations, section 1 was just a part of the Court's analysis. *See Hobby Lobby*, 573 U.S. at 707–09. Before the Court turned to section 1, the Court also considered the purpose of RFRA and the consequences of an alternate conclusion. *Id.* at 705–07. If section 1 were enough reason to extend RFRA to closely held corporations, the first half of the Court's reasoning in *Hobby Lobby* on this point would be superfluous. Nevertheless, the Agencies consider section 1 enough to extend RFRA even further than the Court did in *Hobby Lobby*.

Compounding the problem, when the Court extended RFRA to closely held for-profit corporations, it distinguished the foreign idea of "unrelated shareholders" running a corporation under a shared set of religious beliefs from closely held corporations doing so. *Id.* at 717. The Agencies quote language from *Hobby Lobby* in the Religious Rule noting the peculiarity of publicly traded companies coalescing around a shared religious tenet. J.A. 44–45. Nevertheless, in the Religious Rule, the Agencies claim that "the mechanisms for determining whether a [publicly

traded] company has adopted and holds certain principles or views, such as sincerely held religious beliefs, is a matter of well-established State law with respect to corporate decision-making." J.A. 27. But while some facets of corporate decisionmaking may be well settled, the discomfort that the Supreme Court displayed toward publicly traded corporations expressing a religious belief for RFRA purposes shows that how—or even whether—a publicly traded may do so is far from settled. Thus, the Agencies have not reasonably justified that including publicly traded corporations within the Religious Rule remedies any actual RFRA violations.

Finally, the Religious Rule allows employers to claim the exemption without providing any notice of that decision to the government, insurer, or TPA. J.A. 23.[7] Without a notice requirement, or something similar, the Religious Rule lacks any mechanism for evaluating the sincerity of an employer's religious belief. And the Religious Rule omits such a mechanism even though distinguishing sincere claims of substantial burden from insincere ones was an essential part of the Court's decision to extend RFRA to closely held corporations. *Hobby Lobby*, 573 U.S. at 717–18. Because courts can distinguish the two, the Supreme Court discounted concerns that for-profit entities would take advantage of RFRA, noting that "[t]o qualify for RFRA's protection, an asserted belief must be 'sincere'; a corporation's pretextual assertion of a religious belief in order to obtain an exemption for financial reasons would fail." *Id.* at 717 n.28. Under the Religious Rule, however, honest and pretextual beliefs, which in either case need not even be substantially burdened, qualify for the exception equally. And while *Hobby Lobby* Court criticized a failed bill that also lacked any mechanism for scrutinizing an objector's belief for "extend[ing] more broadly than the pre-existing protections of RFRA," *id.* at 719 n.30, the Religious Rule fails to acknowledge this.

[7] The same is true of the Moral Rule. J.A. 78–79.

In each of these ways, the Religious Rule is not a reasonable resolution of any conflicts that exist between the Guidelines' contraceptive coverage requirement and RFRA.

B. The Agencies Did Not Reasonably Conclude that the Religious Rule Resolves Any RFRA Violations

The Religious Rule suffers an additional flaw: the Agencies have not reasonably determined that the rule is needed to remedy any RFRA violations. Indeed, according to binding precedent, the Accommodation does not impose a substantial burden and so does not violate RFRA. *Real Alts.*, 867 F.3d at 359–66; *see also Pennsylvania*, 930 F.3d at 573 & n.30.

No Supreme Court ruling upsets *Real Alternatives*' weight in this Court. *Zubik* precedes *Real Alternatives*, and so does not warrant disregarding *Real Alternatives*. And *Little Sisters* is not inconsistent with *Real Alternatives*. The Supreme Court held that courts must accept the "sincerely held complicity-based objections of religious entities" for RFRA purposes. 591 U.S. at 681. But the Court did not say that courts must passively accept any claim that a religious entity is substantially burdened by the operation of a generally applicable rule, or that courts must accept that a burden exists when the claimed burden is premised on a faulty characterization of law. *See Real Alts.*, 867 F.3d at 356 (rejecting these positions). Nor did the Court say that the Accommodation imposes a substantial burden, or that it ever held as much in *Zubik*. *Little Sisters*, 591 U.S. at 681. Instead, the Court said only that it was appropriate for the Agencies, when revisiting the contraceptive coverage guarantee after *Zubik*, to consider what RFRA required. *Id.*

In the Religious Rule, the Agencies' evaluation of whether the Accommodation is substantially burdensome fails to acknowledge the Third Circuit's majority opinion in *Real Alternatives*, citing only to the dissent. J.A. 24 n.56. Ignoring *Real Alternatives* while extending RFRA into new territory is all the more remarkable because *Real Alternatives* was one of only two published decisions by a court of appeals addressing a RFRA challenge to the contraceptive

mandate following the remand in *Zubik* and prior to the issuance of the interim rules. *See Ozinga v. Price*, 855 F.3d 730, 735–36 (7th Cir. 2017) (dismissing challenge to mandate as moot in light of *Hobby Lobby*). RFRA, of course, is not a statute that any of the Agencies administers. Rather, conclusively resolving what RFRA requires is the job of the courts. Concluding that the Accommodation may substantially burden religious beliefs without addressing key judicial decisions constitutes unreasoned decisionmaking.

Exacerbating this error, the only decision other than *Hobby Lobby* that the Agencies cite to support that the Accommodation imposes a substantial burden is a decision of the Eighth Circuit. But the Agencies avoid that that decision was vacated by the Supreme Court following *Zubik*. *See* J.A.11; *see also HHS v. CNS Int'l Ministries*, 84 U.S.L.W. 3626 (2016) (vacating *Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927 (8th Cir. 2015)).

Even if the Accommodation substantially burdened religious exercise, the Agencies would need to have reasonably considered the governmental interests at stake and whether the Accommodation was the least restrictive means of accomplishing those interests before they concluded that the Accommodation violates RFRA. 42 U.S.C. § 2000bb-1(b). But the Agencies do not seriously grapple with either. As discussed in the following section, the Agencies' contention that there is no compelling interest at stake is both deficient on its own and an inadequately justified change of position. Moreover, the Agencies do not separately consider whether the Accommodation is in fact the least restrictive method of facilitating access to contraception.

Because the Agencies did not reasonably conclude that the Accommodation substantially burdens religious beliefs, the Agencies did not reasonably conclude the Accommodation implicates RFRA. And because the Agencies' conclusion on this point is unsupported, the

justification for promulgating a rule to remedy RFRA violations crumbles. Even if the Accommodation can impose a substantial burden, the Agencies did not justify their new view that the Accommodation is not the least restrictive way of furthering a compelling government interest. For any of these reasons, the Religious Rule is arbitrary and capricious.

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

The Agencies conclude that the Religious Rule was a reasonable way to resolve conflicts with RFRA in part because of purported doubts about the safety, efficacy, and benefits of contraceptive care, which they claim undermine any compelling interest in facilitating access to that care. J.A. 13. Separately, both Rules rely on the Agencies' doubts about the health benefits of contraception to justify the exemptions. J.A. 17–21, 73–77. These doubts constitute a changed position for the Agencies, which until 2017 had consistently recognized that contraceptive methods and counseling services are safe, effective, and beneficial. *See* J.A. 173, 241–42, 256, 300–01. Indeed, the FDA, another component of HHS, has approved 18 different methods of contraception as safe and effective. J.A. 2344–67. And in prior rules, the Agencies had adopted the IOM's conclusions that contraception promotes healthier outcomes for mothers and children. *See* J.A. 241, 256, 300.

Agencies may "change their existing policies," *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016), but must provide a "reasoned explanation" and "show that there are good reasons for the new policy," *Fox Television*, 556 U.S. at 515. And when an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy" or "its prior policy has engendered serious reliance interests," the agency must provide "a more detailed justification." *Id.* Here, the Rules lack a detailed—or even reasoned—explanation for the Agencies' changed stance on the safety, efficacy, and benefits of contraceptive care.

Before 2017, the Agencies had determined that because women face unique health needs associated with the ability to become pregnant, and because unintended pregnancy poses health risks, contraception is a preventive service. J.A. 241, 256, 300. And because cost sharing is a barrier to effective contraception use, the Agencies also concluded that the contraceptive care requirement is necessary to remedy a critical gender disparity that prevents women from achieving equal health outcomes with men. *Ibid.* Those findings generated significant reliance interests: the Agencies acknowledge in the Religious Rule that between 55.6 million and 62.4 million women covered by private insurance currently have cost-free contraceptive coverage, J.A. 43, and concede that at least 70,515 women will lose coverage under the Rules, J.A. 43, 91.

In the challenged Rules, the Agencies backtrack. *See* J.A. 17–21, 73–77. Faced with comments asserting that contraception poses health risks to women, that some forms of contraception are "abortifacients," and that contraception has not reduced teen pregnancy, the Agencies decline to "take a position on the[se] empirical question[s]." J.A. 20; *accord* J.A. 75.[8] They likewise conclude that "it is not clear" that the Rules "will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate"—even though the Rules permit employers to dictate whether employees who want to use contraceptive care and services can enroll in insurance plans that cover those services without cost sharing. J.A. 20–21; *accord* 76–77.[9]

[8] Only some of the 22 total comments supporting the Rules raised these concerns with any specificity. *See* J.A. 1529–48, 1552–66, 1570–86.

[9] The Agencies had previously explained that the church exemption would likely not negatively impact women because houses of worship "are more likely than other employers to employ people of the same faith who share the same objection." J.A. 243. But the Agencies had rejected expanding the exemption to other employers precisely because female employees of non-religious employers are "less likely than individuals in plans of religious employers to share their employer's (or institution of higher education's) faith and objection to contraceptive coverage on religious grounds." J.A. 256. The Agencies have not abandoned that position.

The Agencies do not justify reversing course. In fact, their conclusions "run[] counter to the evidence before the agency." *State Farm*, 463 U.S. at 43. The Agencies do not identify any new evidence that all 18 forms of FDA-approved contraception are *categorically* unsafe for women, or any evidence contradicting their prior conclusion that unintended pregnancy is a health risk for women. The Agencies ignore the FDA's undisputed determination that the 18 approved methods of contraception are "proven safe and effective," J.A. 2364–67, even though all methods of contraception, like all medical services, must be individually prescribed, J.A. 2344 ("No one product is best for everyone. … This page lists FDA-approved and cleared methods for birth control. Talk to your healthcare provider about the best method for you."). The Agencies further ignore the overwhelming consensus of the medical community in support of contraception's safety and efficacy. *E.g.*, J.A. 628, 631–32, 641, 643, 647–48, 650–51, 659, 1662–76, 1667–1705, 1784–92. Instead, the Rules concoct a controversy to newly discover "uncertainty and ambiguity" about the safety, efficacy, and benefits of contraceptive care. J.A. 20.

Instead, the Agencies purport to identify some "empirical questions"—including how severe the side effects of contraceptive methods are and whether contraception increases or decreases unintended pregnancies—that they claim indicate that "significantly more uncertainty and ambiguity exists on these issues." J.A. 20; *see also* J.A. 75. But the suggestion of uncertainty, as to both side effects and efficacy, irrationally treats all 18 forms of FDA-approved contraception as indistinguishable. No one method of contraception is right for everyone; that one method might be contraindicated for one person does not mean that all 17 other approved methods will be too. Indeed, all safe and effective medication will have side effects and may be contraindicated for some patients. This is exactly why the Agencies had previously concluded that "[i]t is for a woman and her health care provider in each particular case to weigh any risks against the benefits in

deciding whether to use contraceptive services in general or any particular contraceptive service." J.A. 242; *see also* J.A. 2344 ("No one product is best for everyone. Some methods are more effective than others at preventing pregnancy.").

To further undermine the scientific consensus, the Agencies also point to comments that certain forms of contraception are "abortifacients." J.A. 19, 74. While the Agencies recognize the religious tenor of these comments, they nonetheless make commenters' religious views part of the rationale for reversing course on scientific and medical questions. *Ibid.* But the Agencies had previously concluded that "FDA-approved contraceptive methods, including Plan B, Ella, and IUDs, are not abortifacients within the meaning of federal law." J.A. 257. And while personal religious beliefs about how a form of medicine operates may matter for RFRA, they do not have a place in evaluating the health effects of contraception.

The Agencies' new position is contrary not just to science and prior positions, but also to HHS's current definition of pregnancy. *See* 45 C.F.R. § 46.202(f) (defining pregnancy as "the period of time from implantation until delivery"). HHS defines pregnancy consistently with the medical community. J.A. 712 (noting that since 1965, the American Congress of Obstetricians and Gynecologists (ACOG) has recognized that "the establishment of a pregnancy takes several days and is not completed until a fertilized ovum is implanted in the lining of the woman's uterus" (citations omitted)). As ACOG and many other commenters stated, "[e]very FDA-approved contraceptive method acts before implantation, does not interfere with an existing pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus." J.A. 647 (citations omitted); *see also, e.g.*, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997) (FDA's conclusion that "[e]mergency contraceptive pills are not effective if the woman is pregnant" and have no "adverse

effect on the fetus" if taken when a women is pregnant). The Agencies present no scientific evidence to support this redefinition of pregnancy.[10]

In addition, the Agencies decline to "take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy," but still use purported ambiguity over this empirical question to conclude that "it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general." J.A. 19; *accord* J.A. 75. For HHS, that position disregards an earlier conclusion that the 63% decline in teen pregnancy between 1990 and 2013 "is due to the combination of an increased percentage of adolescents who are waiting to have sexual intercourse and the increased use of effective contraceptives by teens." J.A. 2561–63. The studies cited by the Agencies do not suggest otherwise: that other factors have influenced the undisputed decline in teen pregnancy does not eliminate the role of increased access to contraception, and that many women who had abortions were using contraception when they got pregnant only highlights the problem of women inconsistently using less effective methods. *Cf.* J.A. 19–20, 75. Here, too, there is no evidence suggesting any "uncertainty and ambiguity" over the effectiveness of contraception.

Finally, the Agencies summarily conclude that the Rules "are not likely to have negative effects on the health or equality of women nationwide," after again declining to take a position on "those evidentiary issues." J.A. 21, 76–77. But the Agencies fail to provide any evidence contradicting their earlier conclusions that contraception "improves the social and economic status

[10] The Agencies also misrepresent how the FDA itself describes several methods of contraception. J.A. 19 n.39, 74 n.41. The FDA notes that several forms of contraception "may also work … by preventing attachment (implantation) to the womb (uterus)." J.A. 2363. The Agencies insert the words "of a human embryo after fertilization," which the FDA did not use. *See id.*

of women" and that contraceptive coverage without cost sharing is necessary to eliminate the "financial barriers that prevented women from achieving health outcomes on an equal basis with men." J.A. 242, 256, 301. Additionally, the Agencies provide no source supporting any ambiguity over the impact of contraception on reducing unintended pregnancy; their only source for claiming that state mandates "have not necessarily lowered rates of unintended pregnancy (or abortion) overall" is a law review article, not a research study. J.A. 20 n.53, 76 n.56. The Agencies ignore several comments proving that Colorado's contraceptive mandate, for example, reduced the unintended pregnancy and abortion rate, J.A. 799–800, 807, 1330, instead wrongly claiming that no commenter provided empirical data about state contraceptive equality mandates, J.A. 20, 76. The Agencies also ignore comments showing that the contraceptive coverage requirement has allowed women to choose longer-term and more effective forms of contraception, which decreases the risk of unintended pregnancies. *See, e.g.*, J.A. 1033, 1125, 1151–52, 1329–30.

The lack of sufficient explanation for the reversal of their position is magnified by the Agencies' failure to consider the reliance interests of the women who stood to lose contraceptive coverage, and to "weigh" these interests against competing policy objectives. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 33 (2020); *see also Fox Television*, 556 U.S. at 515. The Rules would cause approximately 70,515 to 126,400 women who were entitled to coverage under the prior regulations to lose that coverage. J.A. 40–47; J.A. 89–92. They would increase contraceptive costs and unplanned pregnancies, and decrease contraceptive choice and access to regular medical providers. *See* J.A. 43, 50; J.A. 12–13 (discussing potential impacts and summarizing comments on Rules). The Rules thus cause "serious harm" to women who, for years, have relied upon the mandate for access to critical contraceptive care and services. *Little Sisters*, 591 U.S. at 708 (Kagan, J., concurring) ("Rather than dispute HRSA's prior finding that the

mandate is 'necessary for women's health and well-being,' the Departments left that determination in place."); J.A. 19 ("The [Agencies] do not take a position on the scientific … [or] empirical question[s]" concerning contraception). Because the Agencies are "not writing on a blank slate," they are required to account for these interests in reversing their prior position, and to give a sufficient explanation for the change—rather than the unreasoned and unsupported explanation they provide. *Regents of the Univ. of Calif.*, 591 U.S. at 31–33; *Little Sisters*, 591 U.S. at 708–09 (Kagan, J., concurring).

At bottom, the Agencies fail to provide a reasoned explanation—much less a detailed justification—for their newfound view that contraception is not safe, effective, and beneficial for women. *See Fox Television*, 556 U.S. at 515. And all evidence cuts against the Agencies' conclusion. For these reasons, the Rules are arbitrary and capricious.

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

The Moral Rule has even more defects. As Justice Kagan observed in her concurring opinion in *Little Sisters*, the Moral Rule "give[s] every appearance of coming up short" when assessed under the reasonableness standard. 591 U.S. at 707. Specifically, the Agencies failed to heed Justice Kagan's direction to "weigh[] anew, in this different context, the benefits of exempting more employers from the mandate against the harms of depriving more women of contraceptive coverage." *Id.* at 710.

To begin, the Moral Rule is the product of the Agencies having "relied on factors which Congress has not intended [them] to consider." *State Farm*, 463 U.S. at 43. Given the history of challenges to the contraceptive guarantee under RFRA, it was proper for the Agencies to look to potential conflicts with RFRA to inform the exercise discretion that exists under the Women's Health Amendment. *Little Sisters*, 591 U.S. at 680–81. But RFRA does not apply to solely moral objections, *id.* at 709, and there is no history of litigation for moral objections like the history of

litigation that has transpired under RFRA. Nor does anything in the ACA direct the Agencies to consider moral objections to any covered health service during the exercise of their discretion under the Women's Health Amendment.

Without a statute like RFRA or any sign in the ACA that the Agencies should consider moral objections, the Agencies instead justify the Moral Rule by invoking unrelated instances of Congress respecting morally informed objections to generally applicable laws. J.A. 62–64. Of course, the ordinary inference to draw from Congress having created moral exceptions to other generally applicable laws, but not to the ACA, would be that the difference is intentional. *See, e.g.*, *Loughrin v. United States*, 573 U.S. 351, 358 (2014) (explaining Congress's use of language in one section of a statute, but not another, ordinary is intentional); *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 384 (2013) (applying same interpretive principles across statutes). Each reason the Agencies supply for departing from this ordinary inference is unsound.

The Agencies first explain that inferring anything from Congress's failure to include a moral exception in the ACA would prove too much because it would "negate not just [the moral] exemptions, but the previous exemptions provided for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation." J.A. 63. That conclusion is wrong. Congress's omission of religious exemptions from the ACA is irrelevant because RFRA applies to all federal statutes and regulations. Congress would have needed to explicitly exempt the ACA from RFRA's reach to make substantial burdens on religion an improper factor to consider. *Little Sisters*, 591 U.S. at 680–81. But RFRA does not apply to moral beliefs. *Id.* at 709–10. So, unlike religious beliefs, Congress needed to have affirmatively made moral beliefs a factor for the Agencies to properly consider them—but it did not.

Additionally, the Agencies deem the Moral Rule a reasonable exercise of discretion because of their history of using the discretion afforded under the Women's Health Amendment for religious exemptions. *See* J.A. 61. Yet the existence of RFRA makes the impetus for accommodating religious interests distinct. *Little Sisters*, 591 U.S. at 678–83. So the Agencies' past practice of accommodating substantial burdens on religion has no bearing on whether the Agencies should accommodate moral beliefs.

Next, the Agencies note that while Congress did not include conscience-based exemptions from the Women's Health Amendment, Congress also did not require that the Agencies cover contraception. J.A. 67. From there, the Agencies hypothesize that had Congress known the Women's Health Amendment would encompass contraception, then Congress would have included a conscience exemption too. *Id.* Yet the Agencies' inferences about congressional intent fail to address evidence suggesting that each conclusion—that Congress would have been surprised by HRSA's Guidelines and that, if Congress had known contraception would be covered, it would have included exemptions—is wrong. The legislative record for the Women's Health Amendment is replete with evidence that Congress expected contraception would be covered. *See, e.g.*, 155 Cong. Rec. 28,841 (2009) (Sen. Boxer); *id.* at 28,843 (Sen. Gillibrand); *id.* at 28,844 (Sen. Mikulski); *id.* at 29,070 (Sen. Feinstein); *id.* at 29,311 (Sen. Nelson). And after the first version of the Guidelines, which included contraception, was released, Congress voted against adding conscience exemptions that functioned just as the Moral Rule does. 158 Cong. Rec. 2621–34 (2012); *see also Hobby Lobby*, 573 U.S. at 719 n.30 (describing this legislative history). The best, then, that can be said about the Agencies' analysis of legislative intent is that it ignores important evidence. More accurately, however, that analysis is contrary to the available evidence.

Finally, the Agencies note that other federal agencies and States have allowed for exceptions to neutral laws based on moral objections. J.A. 65. The Agencies likewise comment on founding-era respect for conscientious objections. J.A. 66. Whether the Agencies' account of those sources is accurate, it is beside the point. Any discretionary agency action must be based on the specific factors Congress has made relevant to that action. *State Farm*, 463 U.S. at 43.

For any of these reasons, the Moral Rule is the product of unreasonable decisionmaking.

E. The Agencies Failed To Meaningfully Consider Other Reasonable Alternatives To Protect Employers and Women's Access to Contraceptive Coverage

The Agencies also acted in an arbitrary and capricious manner by failing to meaningfully consider reasonable alternatives that "accommodate[] [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." *Zubik*, 578 U.S. at 408 (cleaned up). Consistent with hornbook principles of administrative law, if there are "significant and viable and obvious alternatives" that address employers' objections to the mandate and Accommodation but reduce harm to women, the Agencies need to explain sufficiently why they did not adopt them. *District Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015); *see also Little Sisters*, 591 U.S. at 708–09 (Kagan, J., concurring in the judgment) (explaining that the Agencies' decision to maintain the mandate and underlying findings "committed them[] … to minimizing the impact on contraceptive coverage, even as they sought to protect employers with continuing religious objections"). Failure to give these alternatives serious consideration would therefore fall far short of a requisite justification. *See City of Brookings Mun. Telephone Co.*, 822 F.2d 1153, 1169 (D.C. Cir. 1987) (agency must provide a "reasoned explanation" for rejecting "reasonable alternatives"); *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 106 (2015) ("APA requires an agency to provide

more substantial justification when ... its prior policy has engendered serious reliance interests that must be taken into account" (cleaned up)).

That is what happened here: the Agencies failed to explore multiple significant alternatives to their chosen action—including making "more limited" changes to existing policy—and to provide a reasoned explanation for rejecting them. *See Nat'l Shooting Sports Foundation, Inc. v. Jones*, 716 F.3d 200, 216 (D.C. Cir. 2013); *see also Regents of the Univ. of Calif.*, 591 U.S. at 30 ("reasoned analysis" must include consideration of more limited alternatives "within the ambit of the existing policy").

First, the Agencies could have limited the expansion of the exemptions to employers with complicity-based objections to the Accommodation, which was the specific religious objection underlying the litigation leading up to the Rules. *See Little Sisters*, 591 U.S. at 670–71 (the expanded exemptions represent the Agencies' most recent attempt to "comply with *Zubik*"); *see also* J.A. 26 (expanded religious exemptions are the "appropriate administrative response … to the litigation challenging [the contraceptive mandate]"); J.A. 66 (discussing litigation by non-religious entities). The Agencies' own analysis suggests that this approach would significantly reduce the number of women who would lose coverage, J.A. 43 (estimating most women (~64,000) who would lose coverage under the Rules have employers participating in the Accommodation), as employers previously using the Accommodation without objection are unlikely to have complicity-based objections to the process, *see id.* (explaining that "the [Agencies] assume there is no overlap between" entities that are using the Accommodation and entities that have been involved in litigation involving the mandate or Accommodation); *see also* J.A. 125 (noting that there were few barriers to litigating objections to the Accommodation because "multiple public

interest law firms public [offered to provide pro bono] … legal services for entities willing to challenge the Mandate").

Instead, the Agencies demand uniform exemptions for all employers, summarily dismissing any alternative, on the ground that they wanted to "avoid inconsistency in respecting religious objection in connection with the provision of contraceptive coverage." J.A. 7 (acknowledging and responding to public comments objecting that the expanded exemptions were "too broad"). But courts have made clear that the "vague desire for uniformity" is no substitute for reasoned analysis, *See Delaware Dep't of Nat. Resources & Envtl. Ctrl. v EPA*, 785 F.3d 1, 17 (D.C. Cir. 2015), and the Agencies insufficiently grapple with the fact that multiple employers are simply not identically situated. Moreover, treating employers with different objections differently is not inconsistent; it is "reasoned judgment," *Little Sisters*, 591 U.S. at 708–09 (Kagan, J., concurring), particularly because the Agencies do not deny their mandate to ensure access to contraceptive care.

Second, the Agencies could have "expand[ed] or adjust[ed] the [A]ccommodation" to address employers' complicity-based objections. J.A. 7 (acknowledging comments to Religious Exemption Rule); J.A. 68 (acknowledging comments to Moral Exemption Rule). For example, the Agencies could have exempted any employer that submitted a notice of its sincere religious or moral objection to the Accommodation. *See* Transcript of Oral Argument at 29, *Little Sisters*, 591 U.S. 657 (2020) (No. 19-431) (Little Sisters have no "objection to simply objecting" in order to acquire exemption).[11] Or the Agencies could have drafted the Rules to make exemptions available only "to the extent" an employer has a sincere religious or moral objection to the Accommodation.

[11] https://www.supremecourt.gov/oral_arguments/argument_transcripts/2019/19-431_d1o2.pdf.

See J.A. 23 (discussing the use of this limiting language elsewhere in the regulations). These alternatives refute the Agencies' conclusion that it is impossible to create an accommodation that provides "seamless" coverage for women and "eliminate[s] the…objections of all [employers]." J.A. 9; *see also* J.A. 68 (addressing moral objections). Indeed, the issue here is not a binary choice between religious objections and contraceptive coverage—it is Rules that needlessly deprive tens of thousands of women of any coverage despite viable alternatives.

Third, the Agencies could have separated the religious and moral exemptions and provided more limited exemptions, or just the Accommodation, for entities with moral objections to the contraceptive mandate. *See* J.A. 67 (acknowledging public comments arguing that no moral exemptions should be provided; that the expanded moral exemptions are "too broad"; and that only an accommodation should be provided for moral objections). While the Agencies rejected this alternative to "avoid the stark disparity that may result from respecting religious objections … but not respecting parallel objections for moral convictions … at all," J.A. 67–68, none of the statements, statutes, or precedents cited by the Agencies even arguably applies to the contraceptive mandate, J.A. 62–66; *see Little Sisters*, 591 U.S. at 710 (Kagan, J., concurring) (RFRA "does not apply to those with only moral scruples"). With no legal foundation for the moral exemption, *supra* at 29–32, the Agencies "should have weighed anew … the benefits of exempting more employers from the mandate against the harms of depriving more women of contraceptive coverage," *Little Sisters*, 591 U.S. at 710 (Kagan, J., concurring). At the very least, they should have explained why they would refuse to distinguish *at all* between religious and moral scruples when federal statutory law already embraces distinctions between the two.

Fourth, the Agencies could have created an entirely separate process for women of exempt employers to obtain contraceptive coverage, such as that in the Agencies' now-withdrawn 2023

Proposed Rule. *See* 88 Fed. Reg. 7236, 7243 (Feb. 2, 2023) (proposing "an independent pathway through which women enrolled in plans or coverage sponsored, arranged, or provided by objecting entities can access contraceptive services at no cost"). Specifically, the 2023 Proposed Rule "would create a pathway, independent from the employer, group health plan, plan sponsor, or issuer, through which individuals could obtain at no cost from a willing provider of contraceptive services (that meets certain requirements), contraceptive services for which their plan or issuer would otherwise be required to provide coverage absent the religious exemption," known as the Individual Contraceptive Arrangement. *Id.* The ICA would make contraceptive coverage available to women of exempt organizations "without the plan sponsor or issuer having to take any action that would facilitate the coverage to which it objects," thereby avoiding any complicity-based objections. *Id.*

This alternative was never considered by the Agencies in connection with the Rules, even though employers have acknowledged that their complicity-based objections would be eliminated if employees were required to affirmatively request coverage from insurers. *See, e.g.*, *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 612 (7th Cir. 2015) (the University would have "no problem" with a system in which "each of its female employers [and students] signed and mailed … a form [to its insurer or third party administrator] saying 'I have insurance through Notre Dame, but the university won't cover contraceptive services, so now you must cover them.'"); J.A. 179; *see* Transcript of Oral Argument at 40–41, *Little Sisters*, 591 U.S. 657 (2020) (No. 19-431) (Little Sisters would have no objection to an approach in which insurance companies were required to reimburse employees for expenses). The point is not that the Agencies are statutorily compelled to adopt this approach; it is that they had to at least consider it, and explain why they would not select this obvious and reasonable alternative to ensure access to care.

These errors in failing to consider reasonable alternatives are especially egregious in light of the underlying statutory obligation, in Section 1554 of the ACA, to avoid issuing 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." 42 U.S.C. § 18114(1), (2); *see Mayor of Baltimore v. Azar*, 973 F.3d 258, 288 (4th Cir. 2020) (finding requirement that recipients of Title X funding refrain from referring women for abortion care "creates 'unreasonable barriers' to 'appropriate medical care,' and 'impedes timely access' to health care services."). The Agencies in their rulemaking summarily dismissed claims that the Rules conflicted with Section 1554 by arguing Section 1554 does not preclude the creation of exemptions, J.A. 17, but this misses the point. The point is not whether exceptions are ever permitted. The problem is that the Agencies had to avoid creating "unreasonable barriers" to care. Adopting exceptions without at least *considering* the reasonable alternatives to protecting access to contraceptive care while still addressing the very interests the exceptions exist to serve is textbook arbitrary decisionmaking. Given how far these Agencies strayed from their obligation under Section 1554, and their inability to fully explain the choices they made to deny access to coverage beyond what was necessary to address employers' objections, this Court should find that the Agencies violated the APA.

F. The Agencies Failed to Consider Significant Comments

No matter the substance of an agency's rule, an agency may not arrive at its conclusions having "failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. An agency must provide "a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made," and may not "ignore 'an important aspect of the problem." *Ohio v EPA*, 603 U.S. 279, 292–93 (2024) (quoting *State Farm*, 463 U.S. at 43) (finding State likely to succeed on claim that agency failed to provide reasoned response to concern raised by commenters). That means an agency must "respond in a reasoned manner to those [comments]

that raise significant problems." *City of Waukesha v. EPA*, 320 F.3d 228, 257 (D.C. Cir. 2003)); *see also United States v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). These responses "enable the Court to see what major issues of policy were ventilated and why the agency reacted to them as it did." *Am. Coll. of Emergency Physicians v. Price*, 264 F. Supp. 3d 89 (D.D.C. 2017) (cleaned up). "[F]ailure to address these comments, or at best its attempt to address them in a conclusory manner, is fatal to its defense." *Ass'n of Priv. Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012) (cleaned up).

Of the 110,000 comments recognized by the Agencies, only 22 comments (representing 17 unique individuals or organizations) supported the religious and moral exemptions. J.A. 5, 60 (providing number of comments); *see also* J.A. 1502–93 (collecting all unique comments supporting the Rules). Put differently, only 0.025% of comments supported the Rules; 99.96% opposed them. Yet the Agencies nowhere acknowledge this significant disparity nor consider any alternatives to preserve access to contraceptive coverage supported by the majority of commenters.

Indeed, while supportive comments represent only a quarter of one percent of the thousands of comments submitted, the Agencies present them as equivalent, if not more significant, than the thousands of comments opposing the Rules. *See*, *e.g.*, J.A. 7, 23, 31–32, 67–68, 85 (scope and definition of exemptions); J.A. 11–13 (compelling interest in seamless coverage); J.A. 15, 70–71 (burden on state or local governments); J.A. 16, 72 (burden of unintended pregnancies); J.A. 16–17 (impact to provision of medical care); J.A. 17, 72–73 ("widely divergent" views on public policy concerns); J.A. 17–20, 73–75 (health effects of contraception and pregnancy); J.A. 20–21, 75–77 (health and equality effects); J.A. 27–29, 81–83 (exemption for for-profit entities and non-governmental employers); J.A. 32–34, 85–87 (individual exemption); J.A. 34–36, 87–88 (optional accommodation process); J.A. 37–38, 87, 89 (regulatory impact and state laws); J.A. 11–13, 69

(weight of objections compared to interest in contraceptive coverage); J.A. 13–14, 69–70 (burden on women); J.A. 77 (state laws).

In doing so, the Agencies elevated these few supportive comments above the significant and substantive concerns of those with expertise in providing access to reproductive health care:

- The American medical community—including the American Academy of Family Physicians (J.A. 628–29), the American Academy of Nursing (J.A. 630–39), the American College of Nurse-Midwives (J.A. 640–42), the American College of Physicians (J.A. 643–45), the ACOG, the American Academy of Pediatrics, the Society for Adolescent Health and Medicine (J.A. 646–55), and the American Public Health Association (J.A. 656–62)—unequivocally opposed the Rules as anti-science and harmful to women. But the Agencies nowhere acknowledge the importance of comments by medical professionals in Rules impacting the medical needs of women.

- Many commenters explained that other state- and federal-funded programs cannot meet an increased need for contraceptive coverage. *E.g.*, J.A. 600–05, 634–37, 653, 660–62, 1065–69, 1184–88, 1337–41, 1355–59, 1463–67. In particular, commenters stated that Title X is insufficiently funded to meet existing needs, much less absorb an increase from women who lose access due to objecting employers. *E.g.*, J.A. 600–02, 634–37, 653, 660–61, 1065–66, 1184–86, 1337–39, 1355–56, 1463–65. But the Agencies ignored these concerns, insisting only that then-proposed changes to Title X "could further reduce any potential effect of these final rules on women's access to contraceptives." J.A. 16, 69.

- The contraceptive mandate required coverage not just for contraceptive methods but for contraceptive counseling. A number of commenters noted the specific importance of contraceptive counseling, "during which an individual could discuss her specific health history and contraceptive needs in private with a healthcare provider." J.A. 1184; *see, e.g.*, J.A. 1222, 1167. As the IOM Report adopted by the Agencies recognized, "[e]ducation and counseling are important components of family planning services because they provide information about the availability of contraceptive options, elucidate method-specific risks and benefits for the individual woman, and provide instruction in effective use of the chosen method." J.A. 432. In the Rules, the Agencies note only that "[s]ome commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling." J.A. 21. They focus only on the financial cost of losing coverage for contraceptive *methods*, failing entirely to examine how the inability to even discuss contraception will impact women.

Ignoring these significant comments is fatal to an agency's defense. *Duncan*, 681 F.3d at 449.

Further, the mere acknowledgment of comments or concerns is not sufficient, because "awareness itself is not an explanation." *Ohio v EPA*, 603 U.S. at 295. As the Supreme Court

explained, simply acknowledging the existence of concerns without addressing how the Rules will in fact impact those concerns "d[oes] not address the [concern] so much as sidestep it." *Id.* That is exactly the case here. For example, the Agencies note comments raising significant concerns over the financial and health burdens the moral and religious exemptions would cause to women, states and local governments, *see supra* at 39 (such burdens include higher contraceptive costs, fewer contraceptive options, lack of consistent use of contraceptives, unintended pregnancies, workplace, economic and social inequality, and higher costs to State and local government in providing birth control to women), but discount entirely or fail to provide any analysis of how the articulated burdens comport with HRSA's finding that "the mandate is 'necessary for women's health and well being, and the commitment to "minimizing the impact on contraceptive coverage." *Little Sisters*, 591 U.S. at 708–09 (Kagan, J., concurring).

This failure to provide reasoned explanations and consider significant comments renders the Rules arbitrary and capricious.

G. The Agencies' Regulatory Impact Analysis is Arbitrary and Capricious

Finally, the Rules are premised on faulty assumptions about their impact. The Agencies estimate that between 70,515 and 126,400 women will lose contraceptive coverage because of the Rules. J.A. 40–47, 89–92. Although nominally used to calculate the annual financial impact of the final Rules, the Agencies also use these figures to support their narrative that the Rules will have only a minimal impact. *E.g.*, J.A. 16 n.26, 71. But the Agencies reach these estimates by relying on a series of unsupported assumptions. Because the assumptions and analyses are faulty, the Agencies cannot articulate a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43.

First, the Agencies exclude an entire class of people who may lose coverage. The Agencies assume that each individual policyholder has at least one dependent, J.A. 41, 91, and acknowledge

that the individual exemption extends "to family coverage covering the participant and his or her beneficiaries enrolled under the plan," J.A. 33; *accord* J.A. 86. As a result, any individual who objects to contraceptive coverage—whether under the individual exemption, because he or she shares a moral objection with his or her employer, or through self-employment—will cause his or her female dependents to lose coverage too. J.A. 44, 90, 2372. These dependents should have factored in the Agencies' analysis, but they were not.

Second, the Agencies make irrational assumptions about the entities using the Accommodation. In both the interim and final rules, the Agencies assumed that no more than 209 entities were using the Accommodation. J.A. 40, 123. In the interim Religious Rule, the Agencies had used data from 2015 to estimate that 1,027,000 employees and beneficiaries were covered by these 209 accommodated insurance plans. J.A. 124–26. But in the final Religious Rule, the Agencies use data from 2017 to estimate that 2,907,000 employees and beneficiaries were covered by the 209 accommodated insurance plans. J.A. 42. Assuming, as the Agencies do, *see* J.A. 41, that each policyholder has only one dependent, the data the Agencies relied on suggests that those 209 employers employed on average 7,000 more people in 2017 than they did in 2015. The Agencies fail to provide any explanation—let alone a reasoned one—for this significant shift.

Third, the Agencies assume without any basis that most people currently working for an accommodated employer will not lose contraceptive coverage. They speculate that 100 of the 209 entities using the Accommodation will continue to do so in spite of the new exemptions, and that these 100 employers employ 75% of all people covered by accommodated plans. J.A. 41–42. Both assumptions are premised on religious hospitals continuing to use the Accommodation instead of the exemption. J.A. 42. But the Agencies only justification is that when the Accommodation was the only option, some religious hospitals stated they did not oppose using it. J.A. 41. The Agencies

provide no reason why many employers who used the Accommodation would not take advantage of the exemption, which would impact at least 256,025 women.[12]

Finally, even after deflating the number of women who may be affected in these three ways, the Agencies double-counts yet another assumption to cut the estimated impact by two-thirds. To calculate the maximum number of women the rule will affect, the Agencies first estimated that 379,000 women of childbearing age who use contraception work for an employer that: (1) is eligible for the Religious Rule's exemption, (2) may actually have a religious objection to arranging for contraceptive care, (3) did not voluntarily cover contraception before the Guidelines guaranteed that coverage, (4) does not use a self-insured church plan, and (5) is not already exempt under the church exemption. J.A. 43–45.

For the third condition—whether the employer covered contraception before that coverage was required—the Agencies relied solely on survey data showing that 6% of respondents did not provide contraceptive coverage before the Guidelines, even though 31% of respondents in the same survey were unsure of their past practices. J.A. 44. The Agencies used the 6% figure for its calculations—leading to a significantly lower estimate of effected women—because, the Agencies reasoned, a respondent unsure whether it covered contraception before the Guidelines was unlikely to have a sincere religious objection to contraception, and thus unlikely to make use of the Religious Rule's exemption. J.A. 44 n.103.

After determining that 379,000 women work for an employer reasonably likely to use the exemption, the Agencies then reduced this estimate by two-thirds. J.A. 45. The Agencies assumed that many of the employers that had not provided contraceptive coverage before the Women's

[12] That figure reflects that of the 2,907,000 people covered under accommodated insurance plans, 20.2% of them are women of childbearing age, of which 43.6% use contraceptive covered under the Guidelines. J.A. 46 & n.116.

Health Amendment, but had done so since, would continue to provide that coverage. *Id*. That conclusion, in turn, reflected speculation that, of the employers that had not covered contraception before the Guidelines, most failed to do so for reasons other than religious objections to contraception. J.A. 45–46. But the Agencies already baked that assumption into their estimates by using 6% for the rate of employers that had not provided contraception before the Guidelines precisely because that low number captured only the employers "likely to have omitted such coverage on the basis of religious beliefs." J.A. 44 n.103. Thus, the Agencies twice used the same fact to discount the Religious Rule's consequences.

For the Moral Rule, the Agencies neglected to conduct a thorough analysis, apparently assuming (without saying so) that no employer pre-ACA declined to offer contraceptive coverage for moral reasons. J.A. 91–92.

In total, the Agencies' assumptions, omissions, and arbitrary speculations render their economic assessment of the Rules arbitrary and capricious.

II. The Rules Should be Vacated

A court shall "hold unlawful and set aside" agency action that is "contrary to law" or otherwise violates the requirements of the APA. 5 U.S.C. § 706(2). This section requires that the Rules here be vacated. *See Regents of the Univ. of Cal.*, 591 U.S. at 36 n.7 (explaining the Court had no need to "examine the propriety of the nationwide scope of the injunctions" against DACA recession memo because the Court was affirming a separate order vacating the same memo); *see also Pennsylvania*, 930 F.3d at 575.[13]

[13] Earlier this year, the Supreme Court granted certiorari in a case in which the court of appeals had granted relief under the APA on a so-called "universal" basis, but pointedly declined to consider the scope of relief entered in the case, notwithstanding the government's request that it do so. *See Dep't of Educ. v. Career Colls. & Sch. of Texas*, No. 24-413, 2025 WL 65914 (U.S. Jan. 10, 2025) (granting certiorari only on Question 1 (the merits)).

As argued in Section I, the Rules are arbitrary and capricious and therefore violate the requirements of the APA, necessitating vacatur. *See* 5 U.S.C. § 706(2). Indeed, vacatur is necessary when failure to do so would "leave in place a rule that is causing the very adverse effect that [the agency] is charged with preventing" and the court would otherwise be "legally sanction[ing] an agency's disregard of its statutory or regulatory mandate." *Comité de Apoyo a los Trabajadores Agricolas v. Perez*, 774 F.3d 173, 188 (3d Cir. 2014) (cleaned up). That is exactly the case here: leaving the Rules in place would violate the Agencies' charge to guarantee cost-free contraceptive to female employees by rendering the Accommodation optional and legally sanction this violation. *See id.*

Nor is there any alternative basis to sever certain parts of the Rules. When only some parts of a regulation are unlawful, they may be set aside and the rest of the regulation saved. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988). But severance is possible only if a regulation's flawed elements are confined to discrete provisions and to the extent that they operate independently. *See API v. EPA*, 862 F.3d 50, 71 (D.C. Cir. 2017) (*quoting Davis Cnty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997)) ("[W]e have severed provisions when 'they operate[d] entirely independently of one another'"). The principal defects here—the failure to craft rules that reasonably respond to a reasonably identified problem and the failure to conform with the law—infect the Rules in their entirety. No aspect of the Rules is spared from the flaws in the rationale the Agencies have offered for the Rules or their inadequately explained change of position such that the Rules could operate independently. *See API*, 862 F.3d at 71.

As such, the Court should vacate the Rules in their entirety.

CONCLUSION

For the reasons set forth above, the States' Motion for Summary Judgment should be granted and the Rules vacated.

March 11, 2025

Respectfully submitted,

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Exhibit 177

Women's Preventive Services Guidelines

Affordable Care Act expands prevention coverage for women's health and well-being

The Affordable Care Act (ACA)—the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010—helps make prevention services affordable and accessible for all Americans by requiring most health insurance plans to provide coverage without cost sharing for certain recommended preventive services. Preventive services that have strong scientific evidence of their health benefits must be covered and plans can no longer charge a patient a copayment, coinsurance or deductible for these services when they are delivered by a network provider.

Under the ACA, most private health insurers must provide coverage of women's preventive health care—such as mammograms, screenings for cervical cancer, prenatal care, and other services—with no cost sharing. Under section 2713 of the Public Health Service Act, as modified by the ACA, non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose.

The law recognizes and HHS understands the unique health needs of women across their lifespan. The purpose of WPSI is to improve women's health across the lifespan by identifying preventive services and screenings to be used in clinical practice and, when supported by HRSA, incorporated in the Guidelines.

HRSA-supported Women's Preventive Services Guidelines: Background

The HRSA-supported Women's Preventive Services Guidelines (Guidelines) were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM).

Since the establishment of the Guidelines, there have been advancements in science and gaps identified in clinical practice. To address these, in 2016, the Health Resources and Services Administration (HRSA) awa five-year cooperative agreement, the Women's Preventive Services Initiative (WPSI), to the American College of

Obstetricians and Gynecologists (ACOG) to convene a coalition of clinician, academic, and consumer-focused health professional organizations to conduct a scientifically rigorous review to develop recommendations for updated Guidelines in accordance with the model created by the NAM Clinical Practice Guidelines We Can Trust. The American College of Obstetricians and Gynecologists (ACOG) formed an expert panel, also called the WPSI, for this purpose.

In March 2021, ACOG was awarded a subsequent cooperative agreement to review and recommend updates to the Guidelines. Under ACOG, WPSI reviews existing Women's Preventive Services Guidelines at least once every five years, or upon the availability of new evidence, as well as new preventive services topics. New topics for future consideration can be submitted on a rolling basis at the Women's Preventive Services Initiative website.

HRSA-supported Women's Preventive Services Guidelines

HRSA supports the Women's Preventive Services Guidelines (Guidelines) listed below that address health needs specific to women.

In December 2024, HRSA approved updates to the Guidelines for two listed preventive services: Screening and Counseling for Intimate Partner and Domestic Violence and Breast Cancer Screening for Women at Average Risk. HRSA also approved a new guideline for Patient Navigation Services for Breast and Cervical Cancer Screening. The Guidelines are provided in the table.

Updated guidelines

Type of Preventive Service	Current Guidelines	Updated Guideline Beginning with Plan Years Starting in 2026
Screening and Counseling for Intimate Partner and Domestic Violence	WPSI recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.	The Women's Preventive Services Initiative recommends screening adolescent and adult women for intimate partner and domestic violence, at least annually, and, when needed, providing or referring to intervention services. Intimate partner and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and appropriate supportive services.
Breast Cancer	WPSI recommends that average-risk women initiate mammography	The Women's Preventive Services Initiative recommends that women at average risk of

Screening for Women at Average Risk	screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening. These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.	breast cancer initiate mammography screening no earlier than age 40 years and no later than age 50 years. Screening mammography should occur at least biennially and as frequently as annually. Women may require additional imaging to complete the screening process or to address findings on the initial screening mammography. If additional imaging (e.g., magnetic resonance imaging (MRI), ultrasound, mammography) and pathology evaluation are indicated, these services also are recommended to complete the screening process for malignancies. Screening should continue through at least age 74 years, and age alone should not be the basis for discontinuing screening. Women at increased risk also should undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

New guideline

Type of Preventive Service	New Guideline Beginning with Plan Years Starting in 2026
Patient Navigation Services for Breast and Cervical Cancer Screening	The Women's Preventive Services Initiative recommends patient navigation services for breast and cervical cancer screening and follow-up, as relevant, to increase utilization of screening recommendations based on an assessment of the patient's needs for navigation services. Patient navigation services involve person-to-person (e.g., in-person, virtual, hybrid models) contact with the patient. Components of patient navigation services should be individualized. Services include, but are not limited to, person-centered assessment and planning, health care access and health system navigation, referrals to appropriate support services (e.g., language translation, transportation, and social services), and patient education.

Current guidelines

Type of Preventive Service	Current Guidelines

Screening for Anxiety	WPSI recommends screening for anxiety in adolescent and adult women, including those who are pregnant or postpartum. Optimal screening intervals are unknown and clinical judgement should be used to determine screening frequency. Given the high prevalence of anxiety disorders, lack of recognition in clinical practice, and multiple problems associated with untreated anxiety, clinicians should consider screening women who have not been recently screened.
Screening for Cervical Cancer	WPSI recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.
Obesity Prevention in Midlife Women	WPSI recommends counseling midlife women aged 40 to 60 years with normal or overweight body mass index (BMI) (18.5-29.9 kg/m2) to maintain weight or limit weight gain to prevent obesity. Counseling may include individualized discussion of healthy eating and physical activity.
Breastfeeding Services and Supplies	WPSI recommends comprehensive lactation support services (including consultation; counseling; education by clinicians and peer support services; and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding. Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and supplies as clinically indicated to support dyads with breastfeeding difficulties and those who need additional services.
Contraception *	WPSI recommends that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve birth outcomes. Contraceptive care includes screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period).** Contraceptive care also includes follow-up care (e.g., management, evaluation and changes, including the removal, continuation, and discontinuation of contraceptives). WPSI recommends that the full range of U.S. Food and Drug Administration (FDA)- approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care. The full range of contraceptives includes those currently listed in the FDA's Birth Control Guide***: (1) sterilization surgery

	for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), 7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate), and any additional contraceptives approved, granted, or cleared by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.****
Counseling for Sexually Transmitted Infections (STIs)	WPSI recommends directed behavioral counseling by a health care clinician or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for STIs. WPSI recommends that clinicians review a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors include, but are not limited to, age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgment.
Human Immunodeficiency Virus Infection (HIV)	WPSI recommends all adolescent and adult women, ages 15 and older, receive a screening test for HIV at least once during their lifetime. Earlier or additional screening should be based on risk, and rescreening annually or more often may be appropriate beginning at age 13 for adolescent and adult women with an increased risk of HIV infection. WPSI recommends risk assessment and prevention education for HIV infection beginning at age 13 and continuing as determined by risk. A screening test for HIV is recommended for all pregnant women upon initiation of prenatal care with rescreening during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.
Well-Woman Preventative Visits	WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure the provision of all recommended preventive services, including preconception and many services necessary for prenatal and interconception care, are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors. These services may be completed at a single or as part of a series of visits that take place over time to obtain all necessary services depending on a woman's age, health status, reproductive health needs, pregnancy status, and risk factors. Well-women visits also include prepregnancy, prenatal, postpartum and interpregnancy visits.

Screening for Diabetes in Pregnancy	The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) to prevent adverse birth outcomes. WPSI recommends screening pregnant women with risk factors for type 2 diabetes or GDM before 24 weeks of gestation—ideally at the first prenatal visit.
Screening for Diabetes after Pregnancy	The WPSI recommends screening for type 2 diabetes in women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum. Women who were not screened in the first year postpartum or those with a negative initial postpartum screening test result should be screened at least every 3 years for a minimum of 10 years after pregnancy. For those with a positive screening test result in the early postpartum period, testing should be repeated at least 6 months postpartum to confirm the diagnosis of diabetes regardless of the type of initial test (e.g., fasting plasma glucose, hemoglobin A1c, oral glucose tolerance test). Repeat testing is also indicated for women screened with hemoglobin A1c in the first 6 months postpartum regardless of whether the test results are positive or negative because the hemoglobin A1c test is less accurate during the first 6 months postpartum.
Screening for Urinary Incontinence	The Women's Preventive Services Initiative recommends screening women for urinary incontinence annually. Screening should assess whether women experience urinary incontinence and whether it impacts their activities and quality of life. If indicated, facilitating further evaluation and treatment is recommended.

Implementation considerations

While not included as part of the HRSA-supported guidelines, the Women's Preventive Services Initiative, through ACOG, also developed implementation considerations, available at the Women's Preventive Services Initiative website, which provide additional clarity on implementation of the guidelines into clinical practice. The implementation considerations are separate from the clinical recommendations, are informational, and are not part of the formal action by the Administrator under Section 2713.

Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these Guidelines beginning with the first plan year (in the individual market policy year) that begins on or after one year from the date the updated Guidelines are accepted by the HRSA Administrator. In the interim, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the Guidelines as previously updated.

* With respect to religious and moral exemptions in connection with coverage of certain preventive health services, see 45 CFR 147.132 and 45 CFR 147.133.

** Education and counseling includes all methods of contraception, including but not limited to, hormonal, devices, surgical, barrier, and fertility-based awareness methods, including lactation amenorrhea.

*** FDA's Birth Control Guide
This refers to FDA's Birth Control Guide as posted on December 22, 2021 with the exception of sterilization surgery for men, which is beyond the scope of the WPSI.

**** Notice
This sentence, included at the end of the "Contraception" section of the previous Guidelines, remains at the conclusion of the "Contraception" section of the 2021 Guidelines per a Final Order issued on December 6, 2022, in *Tice-Harouff v. Johnson*, Eastern District of Texas (Tyler Division), Case No. 6:22-cv-201-JDK. This is consistent with footnote **above, which indicates that education and counseling within the "Contraception" section of the 2021 Guidelines includes fertility awareness-based methods, including lactation amenorrhea.

Contact

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Learn more

- HRSA/MCHB Preventive Guidelines and Screening for Women, Children, and Youth
- Historical Files
- 2019 Guidelines
- 2016 Guidelines
- Institute of Medicine: *Clinical Preventive Services for Women (2011)*
- Bright Futures
- Advisory Committee on Heritable Disorders in Newborns and Children

Date Last Reviewed: January 2025

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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*; 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-DeREMER, *in her official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA. Defendants.	**No. 2:17-cv-04540-WB**

[PROPOSED] ORDER

AND NOW, this _____day of _____, 2025, upon consideration of the Motion for Summary Judgment filed by Plaintiffs Commonwealth of Pennsylvania and State of New Jersey, any response thereto, and for good cause shown, it is hereby **ORDERED** that the Motion is **GRANTED**.

It is further **ORDERED** that the following Rules issued by Defendants are **VACATED**:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (82 Fed. Reg. 47,792 & 83 Fed. Reg. 57,536); and

2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (82 Fed. Reg. 47,838 & 83 Fed. Reg. 57,592).

BY THE COURT:

_____

WENDY BEETLESTONE, J.