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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STATE OF CALIFORNIA, *et al.*, Plaintiffs, v. XAVIER BECERRA, Secretary of Health and Human Services, *et al.*, Defendants, and, THE LITTLE SISTERS OF THE POOR, ST. MARY'S HOME, *et al.*, Defendant-Intervenors	Case No.: 4:17-cv-5783-HSG **JOINT STATUS REPORT**

On August 17, 2021, the Court stayed this case and ordered the parties to file status reports every three months. ECF No. 467. The parties report as follows:

1. This case concerns the validity of two rules which create a moral exemption, and

expand a religious exemption, to the rules establishing the contraceptive coverage requirement. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,536 (Nov. 15, 2018); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,592 (Nov. 15, 2018).

2. The Court has before it fully briefed dispositive motions, *see* ECF Nos. 311, 366, 368, 370, as well as supplemental briefs addressing the Supreme Court's decision in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020), *see* ECF Nos. 433, 435, 437, 438, 440.

3. On August 3, 2021, the parties filed a joint status report, in which Federal Defendants asked the Court to stay the case to permit the defendant agencies to evaluate the issues presented by this litigation, as well as their regulatory and policy options. ECF No. 462. The Court had once previously held the motions in abeyance. ECF No. 454. Plaintiffs and intervenor March for Life did not object to the request. Intervenor Little Sisters objected.

4. On August 16, 2021, Federal Defendants announced that "[t]he Departments [of Health and Human Services, Treasury, and Labor] intend to initiate rulemaking within 6 months to amend the 2018 final regulations and obtaining public input will be included as part of the Departments' rulemaking process." CMS.Gov, Frequently Asked Questions, Affordable Care Act Implementation FAQs (Set 48) (Aug. 16, 2021) (available at https://perma.cc/2XH8-MDBX).

5. On August 17, 2021, the Court held a case management conference. The Court granted Federal Defendants' request to stay the case and directed "counsel . . . to e-file a joint status report every three months." ECF No. 467.

6. The Federal Defendants published a notice of proposed rulemaking on February 2, 2023, that would "amend regulations regarding coverage of certain preventive services under the Patient Protection and Affordable Care Act, which requires

non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage to cover certain contraceptive services without cost sharing." U.S. Dep't of Treasury, U.S. Dept't of Labor, & Dep't of Health & Human Servs., *Coverage of Certain Preventive Services Under the Affordable Care Act* (Feb. 2, 2023) (available at https://perma.cc/L58Q-VY4Q).

7. The Court held another status conference on February 7, 2023. After the conference, the Court (1) ordered that the case should remain stayed and (2) directed the parties to attach to this joint status report any comments on the notice of proposed rulemaking submitted by Plaintiffs or intervenors. ECF No. 489.
8. The comment period for the proposed rule closed on April 3, 2023. The Federal Defendants received more than 44,000 comments on the proposed rule.
9. Attached as Exhibit A to this status report are the comments of the Plaintiff States on the proposed rule. Attached as Exhibit B to this status report are the comments of the Becket Fund, counsel to Intervenor-Defendant Little Sisters of the Poor St. Mary's Home, on the proposed rule. Attached as Exhibit C to this status report are the comments of Alliance Defending Freedom, counsel to Intervenor-Defendant March for Life, on the proposed rule.
10. To allow time for a full evaluation of the more than 44,000 comments received, Federal Defendants propose that the case remain stayed and that Federal Defendants continue to file status reports every 90 days to apprise the Court of the status of the rulemaking and their position on the need for a continued stay. The next status report will therefore be due on August 1, 2023.
11. Plaintiff States do not oppose the case remaining in its current posture.
12. Intervenor-Defendant March for Life concurs in the federal government's proposal of a continued stay.
13. Intervenor-Defendant Little Sisters of the Poor believe the stay should be lifted and the Court should decide the long-pending motions for summary judgment.

The religious exemption is the law of the land, and it has been now for years. The federal government plans to keep it in place, and the States still purport to challenge it. Waiting an unknown number of months, for unknown tweaks to the law that may or may not ever be made, does not make sense. The 2024 presidential election is already starting and the contraceptive mandate issue is now in danger of lingering into a fourth presidential administration.

Dated: May 1, 2023

Respectfully submitted,

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Dated: May 1, 2022

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Dated: May 1, 2023

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EXHIBIT A

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April 3, 2023

Via Regulations.gov

The Honorable Janet Yellen
Secretary
U.S. Department of Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

The Honorable Julie Su
Acting Secretary
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
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RE: **Notice of Proposed Rulemaking, *Coverage of Certain Preventive Services Under the Affordable Care Act*, 88 Fed. Reg. 7236 (February 2, 2023).**

Dear Secretaries Yellen, Su, and Becerra:

We write on behalf of the Attorneys General of the states of Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New York, North Carolina, Oregon, Rhode Island, Vermont, and Washington, the Commonwealths of Massachusetts and Pennsylvania, and the District of Columbia ("the State AGs") regarding the proposed rulemaking by the U.S. Departments of the Treasury, Labor, and Health and Human Services ("the Departments") relating to the coverage of certain preventive services under the Affordable Care Act ("the ACA"). *See Coverage of Certain Preventive Services Under the Affordable Care Act*, 88 Fed. Reg. 7236 (Feb. 2, 2023) ("the Proposed Rule"). The Departments propose rescinding the moral exemption promulgated as part of the final rules in November 2018, which enabled entities with a moral objection to providing or covering contraception to be exempt from the contraceptive coverage mandate implemented

by the ACA and the Women's Health Amendment ("the 2018 Rules").[1] The Proposed Rule also seeks to establish a new individual contraceptive arrangement ("ICA") for individuals enrolled in plans or coverage that are sponsored, arranged, or provided by entities with a religious objection to providing or covering contraceptive services to obtain no-cost contraceptive coverage.

The State AGs applaud the Departments for their efforts to improve access to contraceptive coverage under the ACA. We support rescinding the moral exemption and offer recommendations on how to improve the ICA. However, we oppose the Departments' proposal to retain the expansive religious exemption promulgated by the 2018 Rules.

The State AGs have a substantial interest in protecting the medical and economic health of our residents and ensuring that all residents are free and able to fully advance their educational and economic goals. Contraception is necessary preventive healthcare that is vital for women, and everyone with capacity to become pregnant, to be able to aspire, achieve, participate in, and contribute to society based on their individual talents, capabilities, and timelines. The 2018 Rules created sweeping new exemptions that denied women across the country access to legally protected preventive healthcare. The 2018 Rules went far beyond what any court had deemed necessary to protect the rights of those with religious or moral objections, while also still ensuring that women "receive full and equal health coverage, including contraceptive coverage," as instructed by the Supreme Court.[2] The loss of contraceptive care is harmful not just to women and those with capacity to become pregnant, but also to their families, their communities, and taxpayers who bear the burden of publicly-funded programs that must supply health services in place of exempt entities.

The State AGs therefore strongly support rescinding the moral exemption as promulgated by the 2018 Rules, recommend narrowing the religious exemptions as expanded by the 2018 Rules, and commend the Proposed Rule's attempt to create an alternative means by which those who are covered under health plans sponsored by exempt employers or universities can access contraceptive services at no cost to the individual. We are disappointed to see that the Proposed Rule unnecessarily retains the overly broad religious exemption of the 2018 Rules. The State AGs thus urge the Departments to heed the recommendations and objections contained herein to ensure that all have access to no-cost contraceptive coverage as required by the ACA and the Women's Health Amendment.

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[1] *See* 83 Fed. Reg. 57536, 57592 (Nov. 15, 2018). Many of the State AGs who have joined this comment are currently involved in litigation challenging the November 2018 Rules as discussed, *infra* notes 13-17. In offering these comments, the State AGs are in no way conceding or abandoning the allegations and legal positions advanced in their respective lawsuits and reserve all rights to continue their respective litigations should they deem it necessary and appropriate based on the final result of the present rulemaking process. Nothing in this comment is intended to be a waiver of any such rights.

[2] *See Zubik v. Burwell*, 578 U.S. 403, 408 (2016).

In addition, while the ICA is a welcome step in the right direction, it requires significant improvements to deliver on its intended purpose of providing no-cost contraceptive care coverage to those who are currently without such coverage as a result of the 2018 Rules. The State AGs therefore propose several additions to the Proposed Rule with respect to the ICA that we believe are necessary for its operability. *See infra* Section III. In doing so, we hope the Departments will be able to ensure that all who would otherwise lack access to vital preventive services under the 2018 Rules will now have this access at no cost to the individual as required by the ACA and the Women's Health Amendment.

BACKGROUND

Among other reforms, the ACA sought to rectify historical inequities in women's health care by increasing access to preventative services like contraceptive coverage.[3] Before the ACA, "more than half of women delay[ed] or avoid[ed] preventive care because of its cost."[4] Thus, Congress passed the Women's Health Amendment as part of the ACA to require that group health plans and insurance issuers offering group or individual coverage must cover and "not impose any cost sharing requirements . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration."[5] Congress expected that eradicating these discriminatory barriers to preventive care—including contraceptive care—would result in substantially improved health outcomes for women.[6] Pursuant to the Women's Health Amendment, the Health Resources and Services Administration ("HRSA"), based on recommendations from the Institute of Medicine (now the National Academy of Medicine), implemented guidelines in 2011 that defined preventive services necessary for women's health, including all contraceptive services approved by the U.S. Food and Drug Administration. These services include the full range of FDA-approved contraception, sterilization procedures, and patient education and counseling.

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[3] 42 U.S.C. § 300gg-13(a); 155 Cong. Rec. S12027 (Dec. 1, 2009) (statement of Sen. Gillibrand) (explaining that the Women's Health Amendment sought to redress the discriminatory practice of charging women more for preventive services than men).

[4] *Id.*

[5] 42 U.S.C. § 300gg-13(a)(4). As part of the ACA, Congress carved out an exemption from the contraceptive coverage mandate for grandfathered plans—that is, certain health plans that were in effect when it passed the ACA.

[6] *See, e.g.*, 155 Cong. Rec. S12052 (Dec. 1, 2009) (statement of Sen. Franken) (describing "family planning services" as a "top priority," a "fundamental right of every adult American," and necessary for "women and families to make informed decisions about when and how they become parents," and stating "affordable family planning services must be accessible to all women in our reformed health care system"); *id.* at S12059 (statement of Sen. Cardin) ("General yearly well-women visits would be covered . . . [including] family planning services."); *id.* (statement of Sen. Feinstein) (same).

In 2010, the Departments promulgated and adopted rules requiring employers and plan sponsors to cover these necessary preventive services, including the full range of contraception set forth in the HRSA guidelines.[7] However, in an effort to accommodate those plan sponsors with religious objections to certain forms of contraception, the Departments exempted churches and closely-related entities from this contraceptive coverage mandate in its entirety ("the church exemption").[8] The Departments also created a separate "accommodation" process that allowed certain non-profit organizations that did not qualify for the church exemption to nonetheless provide notice of their religious objections to covering contraception and shift the burden for compliance with the mandate to their insurance carrier or third-party administrator ("TPA").[9] In this way, the issuer or TPA would exclude such contraception from the employer's group health plan and instead provide separate payments for any contraceptive services without cost to the insured. The issuer or TPA was also required to provide written notice to plan participants and eligible beneficiaries that the organization does not cover these benefits but that such benefits were available directly from the insurer. Shifting this burden to the issuer was not expected to impose additional costs on the issuer because it would yield cost savings from lower medical costs as a result of preventing unintended pregnancies.[10]

As a result of the accommodation process, unlike those covered by exempt entities, individuals covered by plans that utilized the accommodation still received notice and no-cost contraceptive coverage directly from their issuer or TPA. This provided seamless coverage for those employed by objecting entities that utilized the accommodation process to continue seeing their provider of choice and receiving medical care without disruption. The Departments later expanded the entities eligible for the accommodation to include closely-held for-profit entities following the Supreme Court's decision in *Burwell v. Hobby Lobby Stores*, 134 S. Ct. 2751 (2014).[11]

In 2018, the Trump Administration undermined and thwarted the Women's Health Amendment by implementing interim final rules and substantially similar final rules, which significantly expanded the scope of the existing exemption by allowing *any* non-governmental entity—including publicly traded corporations—to opt out of the mandate on the basis of a religious objection and, for the first time, allowed entities with a non-religious moral objection to opt out of the mandate as well.[12] These rules also rendered the accommodation process optional, thus eliminating the assurance that those who were insured by entities utilizing the accommodation would receive contraceptive coverage now that objecting entities could opt to

[7] 75 Fed. Reg. 41726 (July 19, 2010).
[8] 76 Fed. Reg. 46621 (Aug. 3, 2011).
[9] 78 Fed. Reg. 39870 (July 2, 2013).
[10] Since TPAs do not bear the costs for other benefits, such as coverage for unintended pregnancies, the regulations created a mechanism for the Department of Health and Human Services to reimburse TPAs for providing this coverage through user fees on the federally-facilitated exchange.
[11] 80 Fed. Reg. 41318 (July 14, 2015).
[12] 83 Fed. Reg. 57536 (Nov. 15, 2018).

use the exemption instead. Objecting entities were neither required to claim that compliance with the contraceptive coverage mandate would cause a substantial burden on their religious beliefs, nor to affirmatively notify the government or the issuer of that claim. The 2018 Rules, therefore, led to loss of contraceptive coverage for anyone covered by a plan sponsored by a religious or moral objector and did not provide a mechanism for obtaining contraceptive care without cost sharing from any other source.

Many of this comment's signatories initiated litigation against the Departments challenging the interim final rules and subsequent final 2018 Rules on both procedural and substantive grounds.[13] In the suit filed by 13 States and the District of Columbia, the district court issued a preliminary injunction, which was affirmed by the Court of Appeals for the Ninth Circuit.[14] In litigation brought by Pennsylvania and New Jersey, the district court issued a nationwide preliminary injunction of the 2018 Rules, which the Court of Appeals for the Third Circuit affirmed.[15] The Supreme Court, however, overturned the nationwide preliminary injunction and permitted the Departments to issue the religious and moral exemptions in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020). The majority opinion, however, declined to reach the merits of the Religious Freedom Restoration Act ("RFRA") claim.[16] The Court remanded that case to the lower court where it is presently stayed.[17]

In the Proposed Rule, the Departments propose rescinding the moral exemption and implementing an alternative means for individuals to obtain no-cost contraceptive coverage. This proposed mechanism, the ICA, is intended to enable a participant or beneficiary in a group health plan or individual coverage sponsored by an objecting entity to find a participating provider that will provide contraceptive coverage at no cost to the individual. Providers participating in the

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[13] States brought suit as to the final 2018 Rules as follows: Pennsylvania and New Jersey sued the President and the Departments in the Eastern District of Pennsylvania and secured a nationwide preliminary injunction, which was subsequently affirmed by the Third Circuit. *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019); *aff'd* 930 F.3d 543 (3d Cir. 2019). Massachusetts brought suit in the District of Massachusetts, which ruled in favor of the Departments on summary judgment. *See Massachusetts v. U.S. Dep't of Health & Human Servs.*, 513 F. Supp. 3d 215 (D. Mass. 2021). California, Connecticut, Delaware, Hawaii, Illinois, Maryland, Minnesota, New York, North Carolina, Rhode Island, Vermont, Virginia, Washington, and the District of Columbia brought suit in the Northern District of California and secured a preliminary injunction as to the litigant states, which the Ninth Circuit upheld. *See California v. Health & Human Servs.*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019); *aff'd*, 941 F.3d 410 (9th Cir. 2019).

[14] *California v. U.S. Dep't of Health & Human Servs.*, 941 F.3d 410 (9th Cir. 2019*); cert. granted, judgment vacated sub nom. Little Sisters of the Poor Jeanne Jugan Residence v. California*, 141 S. Ct. 192 (2020) (remanding case to the Ninth Cir. for further consideration in light of *Little Sisters*).

[15] *Pennsylvania v. President U.S.*, 930 F.3d 543 (3d Cir. 2019).

[16] *Little Sisters*, 140 S. Ct. at 2383.

[17] The multistate suit is currently stayed as well, while Massachusetts's suit is held in abeyance on appeal.

ICA must have a signed agreement with an issuer that will reimburse the provider for the cost of contraceptive services as well as administrative costs. Issuers will be able to seek reimbursement from the federal government through an adjustment to their fees associated with the federally-facilitated exchange or state exchange on the federal platform.[18] No action is required on behalf of the objecting entities as part of the ICA. This proposed arrangement would operate independently from any health plan.

The Proposed Rule otherwise retains the changes made by the 2018 Rules that made the accommodation optional and drastically expanded the religious exemption to apply to any entity that objects on religious grounds.

I. THE PROPOSED RULE'S RESCISSION OF THE MORAL EXEMPTION BETTER ENSURES ACCESS TO CONTRACEPTIVE SERVICES WITHOUT COST SHARING AS CONGRESS INTENDED.

The State AGs strongly support the proposed elimination of the moral exemption.[19] The State AGs further commend the Departments for acknowledging missteps in the 2018 rulemaking,[20] and their recognition that the moral exemption erected unwarranted barriers to accessing contraceptive services.

As noted above, the purpose of Section 2713(a)(4) of the Women's Health Amendment is to ensure that group health plans and health insurance issuers cover women's preventive healthcare needs in accordance with HRSA-supported guidelines.[21] The HRSA guidelines have continuously included contraception as a service that is "necessary for women's health and well-being,"[22] and it is therefore essential that exemptions and accommodations crafted in relation to group health plans and coverage not diminish the importance of contraception as an HRSA-recommended preventive service. The moral exemption, however, did precisely that by

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[18] 45 CFR § 156.50(d).

[19] *See* 88 Fed. Reg. 7247 ("the Departments propose to eliminate the exemption for entities with moral objections to contraceptive coverage at 45 CFR 147.133, and therefore to also make conforming edits to remove references to 45 CFR 147.133 that appear in paragraph (a)(1) of 45 CFR 147.130 and paragraph (a)(1)(iv) of 26 CFR 54.9815-2713, 29 CFR 2590.715-2713 and 45 CFR 147.130.").

[20] 88 Fed. Reg. 7243 ("[T]he Departments have determined that the November 2018 final rules failed to adequately account for women's legal entitlement to access preventive care, critically including contraceptive services, without cost sharing as Congress intended; the impact on the number of unintended pregnancies; the costs to states and individuals of such pregnancies; and the government's interest in ensuring women have access to this coverage.").

[21] *See* 42 U.S.C. § 300gg-13(a)(4); *see also Update to the Women's Preventive Services Guidelines*, 87 Fed. Reg. 1763 (Jan. 12, 2022) (the HRSA guidelines "address health needs specific to women").

[22] The HRSA-supported 2021 Women's Preventive Services Guidelines, *available at* https://www.hrsa.gov/womens-guidelines-historical-files.

depriving employees' access to necessary preventive care and screenings based on objecting employers' organizational views.

The moral exemption also suffers from critical legal infirmities — it is the product of unreasoned decision-making and discriminates against women in violation of Section 1557 of the ACA and Title VII of the Civil Rights Act. Rescission of the moral exemption falls squarely within the Departments' discretion, and they have provided reasoned justification in the Proposed Rule for doing so.

A. The Moral Exemption in the 2018 Rules is Arbitrary and Capricious in Violation of the Administrative Procedure Act.

As mentioned, many of the states that have joined this comment are currently involved in litigation challenging the 2018 Rules implementing the moral exemption as arbitrary and capricious and seeking to vacate it. Consistent with our position in those actions, we applaud the Departments' rescission of the moral exemption.

1. The Departments in 2018 provided no reasoned justification for the moral exemption.

The Departments justified the moral exemption in the 2018 Rules by relying on factors Congress did not intend them to consider, and consequently failed to provide a reasoned justification for the rule.[23] In October 2017, the Departments issued an interim final rule permitting employers with moral objections to forgo providing contraceptive coverage to employees.[24] Prior to the interim final rule, no moral exemption to the contraceptive mandate existed in any form. There is no religious or moral exemption in the text of the ACA or the Women's Health Amendment,[25] so the Departments justified the promulgation of the moral exemption by invoking unrelated instances of Congress respecting morally-informed objections to generally applicable laws.[26] The Departments deemed the moral exemption a reasonable exercise of agency discretion because of their history of using the discretion for religious exemptions.[27] They also noted that while Congress did not include conscience-based exemptions in the Women's Health Amendment, it also did not require that the Departments cover contraception.[28] The Departments hypothesized that had Congress known the Women's Health

[23] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider[.]").

[24] *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47838 (Oct. 13, 2017).

[25] *Pennsylvania*, 351 F. Supp. at 821.

[26] 82 Fed. Reg. 47844-45; 83 Fed. Reg. 57598-600.

[27] 83 Fed. Reg. 57597.

[28] 83 Fed. Reg. 57603.

Amendment would encompass contraception, then it would have included a conscience exemption as well.[29]

However, the legislative record for the Women's Health Amendment is replete with evidence that Congress *did* expect contraception would be covered.[30] Moreover, the more plausible inference to draw from Congress having explicitly created moral exceptions to other generally applicable laws, but not to the ACA, would be that the difference is intentional.[31] The Departments in the 2018 Rules, however, rejected this canon, reasoning that such an inference would "negate not just [the moral] exemptions, but the previous [religious] exemptions[.]"[32] The Departments failed to recognize at the time that the existence of RFRA, 42 U.S.C. § 2000bb, et seq., only creates an obligation to consider religious interests.[33] Congress's omission of religious exemptions from the ACA is irrelevant because RFRA applies to all federal statutes and regulations.[34] In *Little Sisters*, the Supreme Court indeed concluded that it was appropriate for HRSA to consider the possibility of required exemptions under RFRA as a reason for establishing the religious exemption.[35] Whereas, "there is no analogous need to heed the possibility of successful claims to a non-religious moral exemption, because there is no moral-exemption statute similar to RFRA."[36] Thus, the Departments' past practice of accommodating substantial burdens on religion has no bearing on whether the Departments should accommodate non-religious moral opposition to contraception.

In sum, the Departments' analysis of legislative intent in choosing to adopt the moral exemption was contrary to the available evidence and thus cannot "survive administrative law's

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[29] *Id.* (asserting that the Departments created the moral exemption because "[i]t is not clear to the Departments that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar [moral] exemptions. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases"); *see also id.* (calling the moral exemption "consistent with the scope of exemptions that Congress has established in similar contexts").

[30] *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 release of the first version of the Guidelines, which included contraception, Congress voted against adding conscience exemptions that functioned just as the moral exemption does. 158 Cong. Rec. 2621–34 (2012); *see also Hobby Lobby*, 573 U.S. at 719 n.30 (describing this legislative history).

[31] *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, ordinarily is intentional); *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 384 (2013) (applying same interpretive principles across statutes).

[32] 83 Fed. Reg. 57599.

[33] *Little Sisters*, 140 S. Ct. at 2382-84.

[34] 42 § U.S.C. 2000bb-3 (indicating that federal law adopted after 1993 is subject to RFRA, unless such law explicitly excludes application); *see Little Sisters*, 140 S. Ct. at 2383.

[35] 140 S. Ct. at 2383.

[36] 88 Fed. Reg. 7249.

demand for reasoned decision-making."[37] Insofar as the Departments unreasonably assumed Congress's expectations, the moral exemption in the 2018 Rules violated the Administrative Procedure Act (APA) limitations on agency rulemaking. And that is precisely what happened.

2. The Departments' analysis of the impact of the moral exemption in 2018 was arbitrary and capricious.

Moreover, the moral exemption in the 2018 Rules was premised on baseless assumptions about its impact. Specifically, the Departments neglected to conduct any reasonable analysis to estimate how many individuals would lose contraceptive coverage because of the moral exemption. At the time of the 2018 rulemaking, the Departments guessed without any data the number of employers that would be affected by the moral exemption.[38] And because the assumptions lacked any objective basis, the moral exemption failed to articulate "a rational connection between the facts found and the choice made" in violation of the APA.[39]

3. The Departments in 2018 failed to consider significant comments in creating the moral exemption.

The unreasonableness of the existing moral exemption is compounded by the Departments' failure in 2018 to address significant concerns raised by commenters in creating the moral exemption. No matter the substance of an agency's rule, an agency may not have arrived at its conclusions having "failed to consider an important aspect of the problem."[40] The Departments failed to respond to comments from the medical community that voiced concerns with many of the Departments' medical judgments. *See Pennsylvania v. Trump* (E.D. Pa. Case No. 2:17-cv-04540, ECF No. 253-3). Failure to address these significant comments is fatal to an agency's defense of the rule. *See Ass'n of Private Sector Colls. & Univs. v. Duncan,* 681 F.3d 427, 449 (D.C. Cir. 2012) (citing *Int'l Union, United Mine Workers v. Mine Safety & Health Admin.*, 626 F.3d 84, 94 (D.C. Cir. 2010).

Additionally, of the over 54,000 comments on the moral exemption received by the Departments, only ten comments were in support, none of which expressed the commenters'

[37] *Little Sisters*, 140 S. Ct. at 2397 (Kagan, J., concurring in the judgment).

[38] 83 Fed. Reg. 57626 ("The Departments . . . are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities."); *see also* 88 Fed. Reg. at 7249 ("[W]ithout data available to estimate the actual number of entities that would make use of the exemption for entities with sincere moral objections, the Departments assumed that the moral exemption would be used by nine nonprofit entities and nine for-profit entities. These assumptions were made in the absence of data.").

[39] *Motor Vehicle Mfrs.*, 463 U.S. at 43.

[40] *Id.*

own non-religious moral objections to contraception.[41] Put differently, just 0.018% of comments supported the moral exemption, and 99.98% opposed it. Yet nowhere in the final rule did the Departments acknowledge this overwhelming disparity, nor did they modify the moral exemption to increase contraceptive coverage as requested by the vast majority of commenters. Instead, the Departments treated these ten comments as bearing greater weight than the 54,000 comments opposing the moral exemption, effectively disregarding the vast majority of commenters.

While the number of comments on either side is not by itself dispositive, the imbalance of comments is relevant here because the Departments justified the moral exemption as responsive to comments.[42] Presenting the moral exemption as responsive to commenters' interests without addressing that the overwhelming weight of comments opposed the rules, and when none of the commenters in favor expressed their own non-religious moral objections to contraception, is a clear error of judgment.

B. The Moral Exemption Creates an Unreasonable Barrier to the Availability of Appropriate Medical Care in Violation of Section 1554 of the ACA.

Section 1554 of the ACA prohibits the Secretary of Health and Human Services from issuing any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care."[43] Contraception is, for many individuals, "appropriate medical care." Indeed, according to the HRSA, contraception is among the preventive services "necessary for women's health and well-being."[44]

But the moral exemption does exactly that by allowing employers to deny individuals access to contraceptive care based on non-religious, moral objections to providing such care, and by making it more difficult to obtain care that the HRSA guidelines consider essential.[45] Since the moral exemption allows employers to deny coverage for contraception, it "creates . . . barriers" for those who wish to access such care. That some individuals denied coverage may be

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[41] 83 Fed. Reg. 57596 (providing number of comments); *see also Pennsylvania v. Trump* (E.D. Pa. Case No. 2:17-cv-04540, ECF No. 253-8).

[42] 83 Fed. Reg. 57595 and n.5 (noting that commenters had supported a moral exemption prior to 2017).

[43] 42 U.S.C. § 18114(1).

[44] *See* 2019 HRSA Guidelines, *available at* https://www.hrsa.gov/womens-guidelines-historical-files.

[45] *See id.*; 87 Fed. Reg. 1763 at 1764 ("recommend[ing] that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve health outcomes"); Institute of Medicine 2011, *Clinical Preventive Services for Women: Closing the Gaps*, 108-09, Washington, D.C.: The National Academies Press, *available at* https://doi.org/10.17226/13181 (explaining that availability of insurance without cost-sharing requirement promotes access to contraceptive care).

able to surmount these barriers and obtain contraception elsewhere (often at a significantly higher cost) does not change that. By allowing employers to deny coverage, the moral exemption makes it more difficult for them to access the care they need. And as the Departments acknowledged in the 2018 Rules, the government is under no obligation to provide a moral exemption in the first instance.[46]

As a result, the moral exemption creates "unreasonable barriers to the ability of individuals to obtain appropriate medical care," and is therefore unlawful under the ACA. The Proposed Rule's rescission of the moral exemption removes this barrier and facilitates seamless coverage by enabling individuals whose employers hold moral objections to the contraceptive coverage mandate to access cost-free contraceptive care without jumping through hoops to obtain it.

C. The Moral Exemption Violates Section 1557 of the ACA and Title VII of the Civil Rights Act.

The Departments' much needed rescission of the moral exemption would put their regulations back in compliance with federal anti-discrimination statutes as they pertain to employers with moral objections to coverage of contraceptive care. The existing moral exemption, by contrast, conflicts with two federal statutes that prohibit discrimination on the basis of sex: Section 1557 of the ACA and Title VII of the Civil Rights Act. Section 1557 prohibits "discrimination under[] any health program or activity, any part of which is receiving Federal financial assistance," on several grounds, including "the ground prohibited . . . under title IX of the Education Amendments of 1972."[47] Title IX in turn prohibits discrimination "on the basis of sex" in education, 20 U.S.C. § 1681, and its implementing regulations make clear that it prohibits discrimination on the basis of pregnancy or related conditions.[48] Similarly, Title VII prohibits employers from discriminating on the basis of sex.[49] In 1978, Congress enacted the Pregnancy Discrimination Act (PDA), which amended Title VII to clarify that discrimination

[46] 83 Fed. Reg. 57592, 57598; *see also* 88 Fed. Reg. at 7249 ("The Departments' adoption of the moral exemptions was not legally required but rather an exercise of the Departments' discretion to protect moral convictions."); *id.* ("RFRA does not require any exemption for non-religious moral objections that do not result in a substantial burden on someone's exercise of religion.").

[47] 42 U.S.C. § 18116(a).

[48] 20 U.S.C. § 1681; *see* 34 C.F.R. § 106.40(b)(1) ("A recipient shall not discriminate against any student . . . on the basis of such student's pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom."). The Department of Education's 2022 Notice of Proposed Rulemaking regarding Title IX proposes an expansive definition of "pregnancy or related conditions" that includes medical conditions related to and recovery from pregnancy, childbirth, termination of pregnancy and lactation. *See* 87 Fed. Reg. 41390, 41515.

[49] 42 U.S.C. § 2000e-2(a).

because of "pregnancy, childbirth, or related medical conditions" is discrimination on the basis of sex.[50]

This same logic prohibits employers from treating contraception differently than analogous categories of health care. For example, if an employer provides prescription drug coverage to its employees, it cannot exclude contraceptive prescriptions without running afoul of Title VII.[51] Treating contraceptive benefits differently than other preventive services is unlawful because it discriminates on the basis of sex under Title VII and because it violates Congress's expressed intent that the PDA's protections should "extend[] to the whole range of matters concerning the childbearing process."[52]

Despite these statutes, the moral exemption authorizes differential treatment. Under the current rule, an employer who holds a non-religious moral objection may refuse to provide contraceptive coverage, even as that employer maintains an obligation to provide other preventive care and prescription benefits.[53] Section 1557 and Title VII each prohibit such discrimination, and the moral exemption, by *authorizing* that same discrimination, is unlawful under the APA.[54]

D. The Proposed Rescission of the Moral Exemption Comports with the APA.

The Departments' proposed elimination of the existing moral exemption is well within the Departments' authority and reasonably explained by the Proposed Rule. When an agency revises existing regulations, the agency needs to show that "the new policy is permissible under the statute," and "show that there are good reasons for the new policy."[55] The State AGs agree that the proposed rescission of the moral exemption is permissible under the ACA (and RFRA), and that the Departments provided a reasoned justification for their reversal on the exemption.

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[50] 42 U.S.C. § 2000e(k); *see also U.A.W. v. Johnson Controls, Inc.*, 499 U.S. 187, 199-200 (1991) (holding that in classifying employees based on their potential to become pregnant, employer's policy excluding women, except those determined to be infertile, from jobs involving exposure to lead violated Title VII's prohibition on sex discrimination).

[51] *See Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1269 (W.D. Wash. 2001) ("In light of the fact that prescription contraceptives are used only by women, [defendant's] choice to exclude that particular benefit from its generally applicable benefit plan is discriminatory."). *But see In re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 942 (8th Cir. 2007).

[52] *See* H. Rep. No. 95-948, at 5.

[53] *See* 42 U.S.C. § 300gg-13(a)(1); *id.* §§ 18022(b)(1)(F), (1)(I).

[54] *See* 5 U.S.C. § 706(2)(A); *see also Farrington v. Johnson*, 206 F. Supp. 3d 634, 635, 644 (D.D.C. 2016) (refusing to dismiss APA claim arising under Title VII); *Pima Cty. Cmty. Coll. Dist. v. EEOC*, No. 75-210, 1976 WL 548, at *2 (D. Ariz. 1976) (observing that Title VII is "certainly a relevant statute within the contemplation" of the APA).

[55] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

Initially, the Departments are under no legal obligation to provide moral exemptions under the ACA.[56] Section 2713(a)(4) of the Women's Health Amendment does not set forth any specific criteria or exemption to guide HRSA's formulation of the guidelines.[57] Congress granted broad discretion to the Departments to identify and craft exemptions,[58] so their proposal to remove the moral exemption falls well within their purview under the ACA. Moreover, there is also no moral-exemption statute similar to RFRA, so the Departments need not heed non-religious moral objectors without any congressional directive. In *Little Sisters*, the Supreme Court stated that the Departments may consider RFRA when framing the religious exemption because the ACA does not explicitly exempt RFRA, and the regulations implementing the contraceptive coverage mandate qualify as federal law that is subject to RFRA.[59] RFRA, however, does not require any moral exemptions that do not result in a substantial burden on someone's exercise of religion.[60]

In addition to acknowledging the above, the Proposed Rule further explains that the moral exemption in the 2018 Rules failed to adequately account for women's legal entitlement to access preventive care, the impact on the number of unintended pregnancies, the costs to states and individuals of such pregnancies, and the government's interest in ensuring women have access to this coverage.[61] The Proposed Rule also confirms that the moral exemption made assumptions in the absence of data regarding the number of employers and employees that would be affected by the moral exemption.[62] The Proposed Rule also explains that the Departments failed to consider potential harms to employees of objecting entities in the 2018 rulemaking, and their reliance on other statutory provisions seemingly demonstrating Congress's historical desire and intent to protect non-religious objections had factual flaws. Overall, the Proposed Rule rightfully reverses the moral exemption and reasonably explains how its rescission will eliminate barriers to accessing contraceptive coverage in accordance with the Women's Health Amendment and the ACA.

[56] 88 Fed. Reg. 7249.
[57] *Little Sisters*, 140 S. Ct. at 2380.
[58] *See* 42 U.S.C. § 300gg-13(a)(4); *see also Little Sisters*, 140 S. Ct. at 2380-81 ("By its terms, the ACA leaves the guidelines' content to the exclusive discretion of HRSA.").
[59] 140 S. Ct. at 2383.
[60] 88 Fed. Reg. 7249.
[61] 88 Fed. Reg. 7243.
[62] 88 Fed. Reg. 7249.

II. THE PROPOSED RULE'S RETENTION OF THE OVERBROAD RELIGIOUS EXEMPTION ESTABLISHED IN THE 2018 RULES IS UNWARRANTED AND INCONSISTENT WITH THE MANDATE OF PROVIDING NO-COST CONTRACEPTIVE COVERAGE.

While the State AGs agree with the Departments' decision to rescind the moral exemption, the State AGs do not support the Departments' proposal to maintain the religious exemptions from the 2018 Rules.[63] The religious exemptions are fatally overbroad in that they authorize exemptions from the contraceptive coverage mandate even when such exemptions are not compelled by an employer's sincerely held religious belief. As a consequence, the exemptions unjustifiably undermine the full and equal contraceptive coverage guaranteed by the ACA and thwart the ACA's purpose "to increase the use of preventive health services by making it as easy as possible for people to use them."[64] Moreover, the exemptions could be substantially narrowed in ways that would promote the Departments' goal of protecting and expanding access to contraceptive care while respecting the rights of religious objectors. The Departments must give careful consideration to these alternatives, and should the Departments decline to adopt them, the Departments must provide a sufficient justification in the Final Rule explaining their decision and explaining why the religious exemptions from the 2018 Rules are not fatally overbroad in their existing form for the reasons detailed below.[65]

A. The Departments Should Not Maintain the 2018 Religious Exemptions.

The State AGs strongly opposed the Departments' decision to create expanded religious exemptions in the 2018 Rules – and they continue to oppose those exemptions today. Among other problems, there is an unjustifiable "mismatch" between the scope of the exemptions and the problem that they were ostensibly created to address.[66] In the 2018 Rules, the Departments argued that it was necessary to create expanded exemptions to the contraceptive coverage mandate in order to address complicity-based objections to the accommodation.[67] The Departments asserted that, despite the ACA's mandate of full and equal contraceptive coverage, requiring employers with complicity-based objections to participate in the accommodation

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[63] 88 Fed. Reg. 7247 ("This proposed rule would maintain the religious exemption from the November 2018 Religious Exemption final rules…The proposed changes in no way narrow the scope of the exemption…").

[64] Br. for Respondents at 74, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14-1418), 2016 WL 537623.

[65] *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 541 (D.C. Cir. 2009) (rulemaking must be both "reasonable" and "reasonably explained"); *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 (D.C. Cir. 1987) ("It is well settled that an agency has a duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives… The failure of an agency to consider obvious alternatives has led uniformly to reversal.").

[66] *Little Sisters*, 140 S. Ct. at 2398-2400 (Kagan, J., concurring in the judgment).

[67] 83 Fed. Reg. 57542, 57545.

violated RFRA.[68] But the Departments did not craft exemptions that were responsive to this narrow concern. Rather than exempting employers with complicity-based objections to the accommodation, the Departments "exempted all employers with [any] objections to the [contraceptive] mandate, even if the accommodation met their religious needs."[69] The Departments acknowledged that expanding the exemptions in this manner would deprive tens of thousands of women of the coverage they were receiving under existing regulations. As Justice Kagan observed in her concurring opinion in *Little Sisters*, this "all costs…no benefits" approach to rulemaking was "hard to see as consistent with reasoned judgment."[70]

Given that the Proposed Rule recognizes the shortcomings in the 2018 Rules, the Departments' proposal to maintain the religious exemptions in the same form is seriously problematic. The Departments acknowledge that the 2018 Rules "failed to adequately account" for the "critical importance" of contraceptive coverage and the harm the expanded exemptions would cause.[71] The Proposed Rule recognizes that protecting and expanding access to contraceptive services is a "national public health imperative."[72] In particular, the Departments find, correctly, that "access to contraception is an essential component of women's health care"[73]; that improving access to contraceptive care is "critical" to narrowing "racial-ethnic disparities…in reproductive health access and outcomes"[74]; that the Women's Health Amendment was enacted by Congress to ensure that all "women have seamless cost-free coverage of contraceptives…"[75]; and that this coverage is even more critical in light of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. __ (2022).[76] And yet, the Departments are proposing to maintain exemptions that they acknowledge have resulted in well over 100,000 women losing contraceptive coverage – and which have disproportionately burdened low-income women of color.[77]

The State AGs acknowledge that the Departments have broad discretion to implement the Women's Health Amendment,[78] but that discretion is constrained by the APA's requirement of

[68] 83 Fed. Reg. 57545.
[69] *Little Sisters*, 140 S. Ct. at 2398-99 (Kagan, J., concurring in the judgment).
[70] *Id.* at 2399.
[71] 88 Fed. Reg. 7243.
[72] 88 Fed. Reg. 7240-41.
[73] 88 Fed. Reg. 7240.
[74] 88 Fed. Reg. 7241.
[75] 88 Fed. Reg. 7254.
[76] 88 Fed. Reg. 7240.
[77] 88 Fed. Reg. 7261 (accepting that at least 126,400 women lost coverage as a result of the 2018 expanded religious exemption); *id.* at 7241 (discussing impact on low-income/women of color).
[78] *Little Sisters*, 140 S. Ct. at 2381-82.

reasoned rulemaking.[79] Here, the Departments cannot exercise their discretionary authority to maintain overbroad exemptions that unnecessarily deprive women of their "legal entitlement to access preventive care, critically including contraceptive services, without cost sharing as Congress intended."[80] The State AGs strongly encourage the Departments to reconsider and pursue an alternative course that will minimize the impact on access to contraceptive coverage nationwide.[81]

To be clear, the State AGs do not support maintaining discretionary exemptions to the contraceptive mandate. The State AGs agree with the Departments' assessment that protecting and expanding access to contraceptive care is a "national public health imperative." The State AGs further agree with the nine federal Courts of Appeals that have concluded that the combination of the contraceptive mandate and the accommodation does not impose a substantial burden on religious exercise or violate RFRA.[82] The State AGs do not agree that the "possibility" that RFRA "might" require some type of exemption for "some objecting entities" in "some circumstances" [83] justifies rulemaking that imposes real, continuing, and immediate harm on tens of thousands of people needing access to contraceptive care.

B. Any Religious Exemption Must be Significantly Narrowed to Avoid Imposing Unnecessary Burdens on Women.

If the Departments choose to maintain a religious exemption, it must be no broader than necessary to address "religious objections to the contraceptive coverage requirement and the

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[79] *See Michigan v. EPA*, 576 U.S. 743, 750 (2015); *see also Little Sisters*, 140 S. Ct. at 2400 (Kagan, J., concurring in the judgment) ("Even in an area of broad statutory authority—maybe especially there—agencies must rationally account for their judgments.").

[80] 88 Fed. Reg. 7243; *see also Little Sisters*, 140 S. Ct. at 2400 (Kagan, J., concurring in the judgment).

[81] *See Little Sisters*, 140 S. Ct. at 2399 (Kagan, J., concurring in the judgment) (recognition that contraceptive mandate is "necessary for women's health and well-being" should have committed agencies to "minimizing the impact on contraceptive coverage, even as they sought to protect employers with continuing religious objections").

[82] *California v. Dep't of Health & Human Servs.*, 941 F.3d 410, 429-30 (9th Cir. 2019); *Eternal World Tel. Network, Inc. v. Sec'y of Health & Human Servs.*, 818 F.3d 1122, 1148 (11th Cir. 2016); *Mich. Catholic Conf. & Catholic Family Servs. v. Burwell*, 807 F.3d 738, 749-55 (6th Cir. 2015); *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 218 (2d Cir. 2015); *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1180 (10th Cir. 2015); *E. Tex. Baptist Univ. v. Burwell*, 793 F.3d 449, 463 (5th Cir. 2015); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 615 (7th Cir. 2015); *Geneva Coll. v. Sec'y of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015); *Priests for Life v. Health & Human Servs.*, 772 F.3d 229, 252 (D.C. Cir. 2014); *Mich. Catholic Conf. & Catholic Family Servs. v. Burwell*, 755 F.3d 372, 390 (6th Cir. 2014); *Univ. of Notre Dame v. Sebelius*, 743 F.3d 547, 559 (7th Cir. 2014); *Eternal World Tel. Network, Inc. v. Sec'y of Health & Human Servs.*, 818 F.3d 1122, 1141-42 (11th Cir. 2016).

[83] 88 Fed. Reg. 7249-50.

existing accommodation."[84] This means that the Departments must, at a minimum, limit eligibility for any exemption to entities with complicity-based objections to the accommodation. Extending exemptions to entities that have "no religious need" for one does nothing to protect religious liberty,[85] but does "serious harm" to women's access to essential health care.[86] Narrowing the exemption will significantly reduce the number of individuals who lose coverage without imposing *any* burden on religious objectors. According to the Departments' analysis in the Proposed Rule, it seems likely that many of those who have lost coverage as a result of the 2018 expanded exemptions did so because their employers switched from using the accommodation to an exemption.[87] Given that many of these employers were previously using the accommodation without raising an objection, it seems likely that few had legitimate complicity-based objections to the process.[88]

In addition, employers should be required to certify their sincere religious objection to the Departments[89] in order to receive an exemption from the mandate and/or opt out of the accommodation. Without such notice, the Departments lack the basic information necessary to enforce the mandate or effectively regulate. The Departments now acknowledge that the

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[84] 88 Fed. Reg. 7254.

[85] Rather than lifting a burden on religious exercise, the religious exemptions in the 2018 Rules grant employers an improper religious veto over employees' access to contraceptive care. *See* 77 Fed. Reg. 8728 (exempting objecting employers from the contraceptive mandate would subject "employees to the religious views of the[ir] employer"). The record establishes that some employers have communicated to the Departments that they will seek to exempt themselves from any program that has the "purpose or effect of providing access to or increasing the use of contraceptive services." *See FAQs About Affordable Care Act Implementation Part 36*, at 7 (Jan. 9, 2017). The 2018 religious exemptions authorize employers to do exactly that: an employer may refuse to participate in the accommodation, and claim an exemption, not because of any complicity-based burden on their own religious exercise, but simply to deter employees from using contraception. Granting employers such authority is directly inconsistent with the Departments' stated goal of improving access to contraceptive care. 88 Fed. Reg. 7240-41.

[86] *Little Sisters*, 140 S. Ct. at 2399 (Kagan, J., concurring in the judgment); *see also* 88 Fed. Reg. 7240 ("Access to contraception is an essential component of women's health care.").

[87] In the 2018 Rules, the Departments projected that most women who would lose contraceptive coverage would do so because their employers would switch from using the accommodation to an exemption. 83 Fed. Reg. 57578. In the Proposed Rule, the Departments accept the 2018 projections. 88 Fed. Reg. 7260-61.

[88] 83 Fed. Reg. 57578 (explaining that the Departments "assume there is no overlap between" employers that were using the accommodation and employers that had been involved in litigation raising objections to the mandate or accommodation); *see also* 82 Fed. Reg. 47819 (acknowledging that there were few barriers to litigating objections to the accommodation including because "multiple public interest law firms publicly [offered to provide pro bono] … legal services for entities willing to challenge the Mandate").

[89] Alternatively, the Departments could require employers to notify their insurer or TPA of their objection and then separately require the insurer or TPA to notify the government. This approach – while more administratively complicated – is consistent with the "alternative approach" discussed below.

provision of no-notice exemptions under the 2018 Rules has created a situation where the Departments do not know whether employers are complying with the mandate in general, as required by federal law; nor do they know how many employers are claiming religious exemptions, or how many employees have lost coverage as a result.[90] This lack of information continues to impede the Departments' ability to develop regulations that ensure women receive contraceptive coverage while respecting religious objections to offering that coverage.

Employers would have no good-faith basis to object to this approach. In the *Little Sisters* oral argument, counsel for Little Sisters repeatedly confirmed that the organization had no "objection to simply objecting," or to the government independently arranging for insurers to provide coverage directly to their employees.[91] Similarly, in *Priests for Life v. U.S. Department of Health & Human Services*, then-Judge Kavanaugh endorsed a version of the accommodation in which an objecting entity could "submi[t] a simple notice to the Secretary of Health and Human Services in writing that it…holds itself out as religious and has religious objections to providing coverage for contraceptive services… [From there], the Government can independently determine the identity of the organizations' insurers and thereby ensure that … [they] provide contraceptive coverage."[92] Such approaches require nothing more from employers than simple notice and therefore cannot be subject to a complicity objection.

C. The Departments Should Also Make Adjustments to the Accommodation So That More People Retain Access to Seamless Contraceptive Coverage.

The Departments should also expand or adjust the accommodation to limit complicity objections, further reducing the need for harmful exemptions. The "alternative approach" for fully insured plans outlined in the Proposed Rule is an example of this approach. Under that plan, the contraceptive coverage requirement would apply directly to the health insurance issuer if a group health plan, a group health plan sponsor, or an institution of higher education is an objecting entity.[93] This proposed "alternative approach" should result in all those with fully insured plans receiving "seamless access to contraceptive coverage."[94] The Departments should implement this program (with the addition of the notice requirement discussed above).

An "alternative approach" should likewise be implemented for self-insured plans. The Proposed Rule fails to provide any satisfactory explanation for limiting the "alternative

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[90] *See* 88 Fed. Reg. 7245 (discussing concerns about noncompliance with mandate); *id.* at 7264 (Departments are unable to reliably estimate costs of regulation because they "do not know" how many employers have claimed an exemption or how many women have lost coverage).

[91] Tr. at 29, *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania* (No. 19-431) (explaining that the Little Sisters would have no objection to "just …an opt-out form, an objection form").

[92] 808 F.3d 1, 23-24 (D.C. Cir. 2015) (Kavanaugh, J., dissenting).

[93] 88 Fed. Reg. 7248 (describing alternative approach).

[94] 88 Fed. Reg. 7248.

approach" to fully insured plans.[95] In *Zubik v. Burwell*, the Departments represented to the Supreme Court that they had the ability to "relieve self-insured employers of any obligation to provide contraceptive coverage" through a regulatory process in which "the government … designate[d] the employer's [TPA] as a 'plan administrator' responsible for separately providing the required coverage…"[96] The State AGs acknowledge that in order to make this designation the government must know the identity of an employer's TPA.[97] But the Departments appear to have been able to identify TPAs without significant problem in the past.[98] And the Proposed Rule provides no explanation for why the Departments would be unable to make regulatory adjustments to improve their ability to identify TPAs as necessary moving forward. For example, the Departments could "make changes to … existing regulations" to require TPAs that administer plans that do not include the "contraceptive benefits guaranteed under the ACA" to provide notice of this fact to the government.[99] As the Departments acknowledge, TPAs would be well positioned to provide this notice because plan documents required by ERISA must disclose limits on coverage, including the exclusion of coverage for "a subset of contraceptive services."[100] Requiring this notice would help the Departments identify "potential violations of the contraceptive coverage requirement" – and facilitate the provision of coverage through an

[95] The State AGs acknowledge that the Departments have addressed questions about similar adjustments to the accommodation in the past. *See, e.g.*, *FAQs About Affordable Care Act Implementation Part 36*, at 9-10 (Jan. 9, 2017). But the Departments' responses do not adequately address the "alternative approach" discussed in the Proposed Rule and below. Further, the Departments' current willingness to pursue an "alternative approach" for fully insured plans indicates that its prior assessment of the costs and "complications" inherent in such an endeavor must be re-evaluated. *Id*. at 5-9 (discussing issues with alternative approaches to providing coverage for women in fully insured plans).

[96] Supplemental Br. for Respondents at 16-17, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14-1418), 2016 WL 1445915.

[97] The State AGs are aware that the Departments have also stressed that "without a written plan instrument…there is no mechanism to designate a third-party administrator as the ERISA plan administrator for the purpose of arranging or providing separate payments for contraceptive services." *See FAQS About Affordable Care Act Implementation Part 36*, at 10 (Jan. 9, 2017). But the Departments have also indicated that a "written designation sent by the government to the TPA" satisfies this requirement. *Id.* at 9. The State AGs, therefore, understand that the only obstacle to the "alternative approach" is the fact that it "requires the government to know the TPA's identity." *Id*.

[98] Following *Wheaton College v. Burwell*, 573 U.S. 958 (2014), the Departments operated the accommodation in this manner. After *Wheaton College*, employers were permitted to provide the Departments with notice of objections to the contraceptive mandate without identifying their insurer or TPA. *Id.* at 958. This does not appear to have prevented the Department of Labor from carrying out its responsibility under then-existing regulations to notify TPAs of the employer's objection and arrange for the provision of alternative coverage through the accommodation. *See* 26 C.F.R. § 54.9815-2713AT(b)(2) (2014).

[99] 88 Fed. Reg. 7245 (acknowledging authority to make regulatory changes to help ensure that "women covered under group plans or health insurance coverage have access to contraceptive services at no cost").

[100] 88 Fed. Reg. 7253 n.128.

"alternative approach" where the exclusion was based upon a self-insured employer's sincere religious objection.[101]

The Departments have other options still. For example, some self-insured employers have acknowledged that their complicity-based objections would be eliminated if employees were required to affirmatively request coverage in order to trigger the accommodation.[102] Such a system could work by having an employee (rather than an employer) provide the Departments with notice of loss of coverage, after which the Departments could initiate the regulatory process of designating the employer's TPA as a plan administrator responsible for separately providing the required coverage.[103] In the past, the Departments have declined to pursue options such as this on the ground that it would not provide "seamless" coverage for women and "eliminate the … objections of all [employers]."[104] But in the Proposed Rule, the Departments are proposing to maintain exemptions that will deprive tens of thousands of individuals of *any* coverage, and they acknowledge that the ICA, as proposed, will "not achieve the Women's Health Amendment's goal of ensuring that women have seamless cost-free coverage of contraceptives, because [it] would require some additional action by the affected women and could require them to obtain contraceptive care from providers other than those from whom they typically receive health care."[105] At a minimum, then, the Departments should consider whether the accommodation can be altered to satisfy *some* employers' objections so that *some* women may retain coverage.

*

There is no justification for maintaining the 2018 expanded religious exemptions in their entirety.[106] The Departments should narrow the exemptions in ways that would better "achieve the … goal of ensuring that [more] women have seamless, cost-free coverage…[while respecting] religious objections to the contraceptive requirement."[107] The Departments must give careful consideration to these alternatives and must address the significant issues raised by the State AGs concerning the fatal overbreadth of the 2018 expanded religious exemptions.[108]

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[101] *Id.* The Proposed Rule also provides no explanation for why the Departments could not require objecting entities to identify their TPAs, either in order to acquire an exemption or in connection with other regulatory filings, such as IRS Form 5500.

[102] *See, e.g.*, *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 612 (7th Cir. 2015).

[103] *Id*. Alternative versions of the accommodation that impose any burden on women should only be available to employers with complicity-based objections to the existing accommodation.

[104] 83 Fed. Reg. 57544.

[105] 88 Fed. Reg. 7254; *see infra* Section III (describing ways the ICA could be improved).

[106] *Motor Vehicle Mfrs.*, 463 U.S. at 43 (Departments must "articulate a satisfactory explanation for … [their] action[s]").

[107] 88 Fed. Reg. 7254.

[108] *Motor Vehicle Mfrs.*, 463 U.S. at 43 (Departments must "articulate a satisfactory explanation for … [their] action[s]").

III. THE ICA IS A STEP IN THE RIGHT DIRECTION BUT NEEDS IMPROVEMENT IF IT WILL SUCCEED IN SERVING ITS INTENDED GOAL.

The State AGs commend and support the Departments' attempt to create an alternative mechanism, the ICA, to increase access to no-cost contraceptive coverage. However, while the ICA will aid in reducing some of the harms of the religious exemptions in the 2018 Rules, we are concerned that, without improvements, it will fall short of the goal of providing effective access to contraceptive services for those who do not have insurance coverage.[109]

As the Departments acknowledge, access to contraceptive care has considerable benefits for women and their families.[110] Broad insurance coverage helps women access the contraceptive of their choice, increasing proper contraceptive use, which in turn reduces unintended pregnancies.[111] Those who experience unintended pregnancies have "higher rates of postpartum depression and mental health problems later in life."[112] And unintended pregnancies are associated with increases in low birthweight and preterm births, and those children are more likely to fare worse in school achievement and have less success when they enter the labor market.[113] Reducing unintended pregnancies is especially crucial in light of the current limited access to abortion for millions of women caused by *Dobbs*. In the aftermath of the *Dobbs* decision, many states have rushed to criminalize and severely restrict abortion, eliminating a core component of basic health care. Total or near-total bans on abortion are currently in effect in twelve states; still more have restrictions that impose severe penalties. Health care providers, clinic staff, and those seeking abortion suddenly face the prospect of both criminal and civil liability merely for obtaining or providing necessary health care. Given this landscape, it is crucial that women have full access to contraceptives to control their reproductive autonomy. The ICA will assist—in a narrow way—in fulfilling that goal.[114]

However, the State AGs have considerable concerns that the ICA, as proposed, will not be successful and effective. The State AGs recommend the Departments make the following changes in the Final Rule: A) expand the number of individuals eligible to participate in the ICA; B) publicize the ICA to increase use by eligible individuals, providers, and issuers; C) increase protections for eligible individuals who use the ICA; and D) improve the ICA's appeal for providers. Although the Departments acknowledge that the ICA will "not achieve the Women's Health Amendment's goal of ensuring that women have seamless cost-free coverage of contraceptives,"[115] implementing the State AGs' recommendations will help mitigate the harms of the religious exemption in the 2018 Rules and will increase access to coverage.

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[109] 83 Fed. Reg. 57536 (2018).
[110] 88 Fed. Reg. 7261-62.
[111] *Id.*
[112] *Id.* (collecting articles).
[113] *Id.*
[114] 42 U.S.C. § 300gg-13(a).
[115] 88 Fed. Reg. at 7254.

A. The Departments Should Expand Access to the ICA to a Wider Spectrum of Individuals who Lack Contraceptive Coverage.

The Departments should expand the ICA to include a wider spectrum of individuals who are excluded from contraceptive coverage, not just those with objecting employers. Specifically, the ICA should be available to individuals enrolled in grandfathered plans,[116] individuals in plans under the church exemption,[117] and plans where the employer has entered into a settlement with the federal government to omit contraceptive coverage.[118] The ICA should also be accessible to individuals without any insurance and those who reside in states where Medicaid does not cover the full range of contraceptive options. As noted above, contraceptive care confers significant benefits, and the Departments should do everything possible to increase access to this care. Further, the more people eligible for the ICA, the greater the incentive for providers and issuers to participate in the ICA.

B. The Departments Should Create a Publicity Campaign About the ICA.

The State AGs are concerned that eligible individuals in objecting plans will not know that the ICA exists, that they are eligible to participate in the ICA, or how to find an ICA-participating provider.[119] We are further concerned that providers will be unaware of the ICA or how to enroll. We offer some proposals to address these concerns.

1. The Departments should engage in outreach to individuals and beneficiaries.

The Final Rule should explicitly outline a public information campaign to ensure that eligible individuals know about the ICA. Among other things, the Departments should create a website that explains ICA eligibility and how the ICA works. The Departments could model such a website from the Centers for Medicare & Medicaid Services' ("CMS") website for the No Surprises Act.[120] The ICA website—and all informational material—should emphasize that use of the ICA involves no extra fees or costs on the part of the individual.[121] We also suggest that the Departments work with state agencies to create short informational pamphlets in multiple

[116] *Contra* 88 Fed. Reg. 7253.
[117] 76 Fed. Reg. 46621.
[118] *See, e.g.*, *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015) (permanently enjoining the federal government from enforcing the contraceptive mandate against March for Life); *Little Sisters v. Azar*, Case No. 13-cv-02611, Dkt No. 82 (D. Colo. May 29, 2018) (granting stipulated permanent injunction enjoining the federal government from enforcing the contraceptive mandate against Little Sisters of the Poor).
[119] 88 Fed. Reg. at 7252.
[120] *Ending Surprise Medical Bills,* Ctrs. for Medicare & Medicaid Services (Dec. 5, 2022), https://www.cms.gov/nosurprises.
[121] 88 Fed. Reg. at 7253.

languages[122] that participating providers can use to explain the ICA to individuals who visit participating providers.

The Final Rule should also require issuers to inform individuals in objecting plans about the ICA so that impacted employees and their beneficiaries can learn about the ICA and where to go for additional information. As the individuals will likely not obtain information about the ICA from their objecting employer, the issuer should be required to provide information about what the individual's plan does not cover and how to access the coverage. To that end, issuers should provide this information to eligible individuals and their beneficiaries to ensure widespread knowledge about the ICA.

2. The Departments should do more provider outreach.

The Departments should also work to ensure providers know about the ICA and how to sign up. The Departments should coordinate with state insurance commissioners, as well as state departments and boards that interact with providers, to ensure that providers receive information about the ICA. The ICA website should contain relevant information in a separate provider section. Any promotional materials should emphasize that providers will receive full reimbursement for actual costs and administrative costs incurred.[123]

As the Departments acknowledge, the result of a lack of provider participation will be especially acute for "people of color (and low-income people) [who] are more likely to live in areas in which the proportion of reproductive-aged residents have a lack of, or difficulty obtaining, reproductive and contraceptive health care—referred to as 'contraception deserts.'"[124] These contraception deserts also often include more rural and underserved areas,[125] where increasing provider participation is particularly essential.

3. The Departments should make it easier for individuals to find a participating provider.

The State AGs agree with the Departments' concern that individuals will not know how to find a participating provider once they determine they are eligible.[126] As such, we recommend requiring issuers to maintain lists of participating in-network providers, ideally through a website

[122] Outreach to individuals and beneficiaries must comply with Section 1557 of the ACA which requires recipients of federal financial assistance to provide meaningful access to health programs to limited English proficient persons.

[123] *Id.*

[124] 88 Fed. Reg. at 7262.

[125] Committee on Health Care for Underserved Women, Number 586, Am. College of Obstetricians and Gynecologists (Mar. 2009, Reaff'd 2021) (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/02/health-disparities-in-rural-women).

[126] 88 Fed. Reg. at 7252.

portal. Insurance plans already provide enrollees and their beneficiaries with information on participating providers.[127] We further recommend that the Departments publicly identify participating providers on the Departments' ICA website. Providers should be able to opt out of public identification but the default should be opt-in. As the Departments are well aware, delays in finding care through a provider can result in care being denied for an individual seeking to access contraceptive coverage.

C. The Departments Should Make the ICA Easier for Providers to Join.

The State AGs are concerned about whether a sufficient number of providers will participate in the ICA, especially given the burdens of entering into an agreement with a variety of issuers and a complicated reimbursement process. Therefore, the State AGs recommend that the Departments do as much as possible to increase the number of participating providers. As outlined below, the Departments should (1) make the ICA easy to join, (2) specify reimbursement rates, (3) handle disputes and specify the speed of reimbursement, and (4) continuously monitor provider participation to ensure adequate coverage for all.

1. <u>The ICA should be easier to join.</u>

The State AGs have concerns about the difficulties in becoming a participating provider because the ICA requires individual arrangements and additional contracting with issuers.[128] The Departments should do more to make provider contracting with issuers as frictionless as possible. For example, the Departments could create and publicly offer a proposed contractual addendum for use by providers and issuers. Or generally, the Departments could create a baseline fee schedule in a geographical area that issuers can opt-into. Therefore, a provider who agrees to be reimbursed based upon the baseline fee schedule can send the bill directly to a participating issuer who has opted into the fee schedule without having to engage in individual contracting.

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[127] *See, e.g.*, Cal. Health & Saf. Code § 1367.27 ("[A] health care service plan shall publish and maintain a provider directory or directories with information on contracting providers that deliver health care services to the plan's enrollees, including those that accept new patients); Cal. Ins. Code § 10133.15 ("[A] health insurer that contracts with providers . . . shall publish and maintain provider directory or directories with information on contracting providers that deliver health care services to the insurer's insureds, including those that accept new patients"); N.J. Admin. Code § 11:24C-4.5(a) (requiring carriers to maintain accurate and current information on all providers and make that information available to members and prospective members through network directories). Meanwhile, Pennsylvania relies on several different statutory authorities, including the Unfair Insurance Practices Act, 40 P.S. § 1171.1 et seq., and 40 P.S. § 991.2111(12) (requiring that a managed care plan shall "[p]rovide a list of health care providers participating in the plan to the department every two (2) years or as may otherwise be required by the department") to mandate insurers provide up-to-date provider directories.

[128] 88 Fed. Reg. at 7243.

2. The Departments should provide more guidance for reimbursement rates.

The Departments should provide additional guidance on fair reimbursement rates and administrative costs for participating providers.[129] For example, the Departments could establish that the reimbursement rate must be greater than the issuer's median commercial contracted reimbursement rate for in-network providers providing similar services, with the high floor being set to account for the providers' administrative costs. Ensuring reimbursement rates through rulemaking is important to encourage more providers to participate.

3. The Departments should engage in bill disputes and increase the speed of reimbursement.

The Departments should create a process for providers to dispute payments from issuers. It is entirely foreseeable that providers may not receive prompt payment from issuers. The Departments should remedy that by regulating strict timing for prompt payment by the issuer and allowing for any disputes to be remedied through a process handled by the Departments. Under the current proposal, an issuer would only be required to reimburse a provider within 60 days of receiving an adjustment to its user fee. These fees are collected monthly,[130] which can create up to 31 days of additional delay between when an issuer first requests a fee adjustment and the 60 day requirement for reimbursing the provider begins to run. Any delay by the issuer in requesting an adjustment—or processing delay by the government—will be felt by the provider. This is no way to recruit voluntary participation. A significant reduction in timing for reimbursement is necessary.

As noted, the proposed ICA's success and effectiveness will depend on providers' willingness to participate. Providers are already burdened by having to learn a new, separate, parallel billing process to participate in the ICA. Difficulty obtaining timely reimbursement for services rendered will further discourage providers from participating in the program.

4. The Departments should monitor provider participation.

The Departments should also continuously monitor provider participation and identify areas with low to no participating providers. The Departments should also monitor whether those geographic areas have overburdened participating providers because of the limited total number of participating providers. In the Final Rule, the Departments should outline the affirmative steps they will take to increase provider participation in "ICA provider deserts."

[129] 88 Fed Reg. at 7253.
[130] 45 C.F.R. § 156.50(c)(1).

D. Patients Should Have Additional Patient Protections.

The State AGs recommend additional patient protections to ensure that individuals who use the ICA will be properly protected. Specifically, the Final Rule should have additional provisions relating to privacy, protection from retaliation, and a process for contesting medical bills.

1. The Departments should protect the privacy of individuals using the ICA.

The Final Rule should explicitly state that HIPAA protections apply to individuals and beneficiaries who use the ICA. While providers and health plans are already mandated to maintain the privacy of patients, the Departments should make clear that these protections apply to protect individuals employed by objecting employers.[131]

The Final Rule should also make explicit that privacy protections extend to documents that an individual uses to confirm eligibility to participating provider(s). This should include the summary of benefits or attestation provided by the individual to the provider to confirm eligibility for the ICA.[132] Failure to maintain confidentiality may result in retaliation from the individual's employer, as discussed below.

2. Individuals using the ICA should be protected from retaliation.

The State AGs are also concerned that even with privacy protections, individuals may face retaliation or discrimination from their objecting employer if they are found to be using the ICA. As such, the Final Rule should explicitly state the ACA's Section 1557 anti-discrimination provisions apply to individuals who choose to utilize the ICA.[133] As the states have long argued, the religious exemption in the 2018 Rules violates Section 1557 because it licenses employers to discriminate on the basis of sex by permitting them to exclude women from full and equal participation in their employer-sponsored health plan and deny women full and equal health care benefits.[134] Permitting discrimination by employers against individuals who exercise the ICA would thus be discrimination based upon sex.[135] The Final Rule should protect individuals from such discrimination.

[131] *See generally* 42 U.S.C. § 1320d-1.
[132] 88 Fed. Reg. at 7253.
[133] 42 U.S.C. § 18116(a).
[134] *See, e.g.*, *California, et al. v. Azar, et al.*, Case No. 4:17-cv-05783-HSG, Dkts. Nos. 24, 311, 433.
[135] *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1739, 1741 (2020).

3. The Departments should create a process for contesting medical bills.

The State AGs are concerned that individuals using the ICA will receive erroneous medical bills or will be charged co-pays by participating providers, when those bills should have been paid for by the participating issuer.[136]

The Departments should plan for this and create a process through which individuals can report improper billing and participate in a medical bill dispute resolution process. This process should be widely advertised and easily accessible to consumers. Among other locations, the Departments should discuss the process and permit participation in the process through the proposed ICA website. Information about the process should also be included on any ICA pamphlets and issuer-provided materials. The Departments should also maintain a staffed phone number an individual can call to report a contested medical bill.

It is important that individuals have clear information on where to submit contested bills, and assurances that, under the ICA, individuals should not pay out-of-pocket for contraceptive coverage or associated co-pays. There should also be clear information that the individuals should not pay these disputed bills out-of-pocket while the dispute resolution process is pending.[137]

The Final Rule should also explicitly state that individuals who receive a bill when they attend a follow-up with a provider who previously participated in the ICA but is no longer a participating provider during the individual's subsequent appointments are still covered by the ICA. The individual should not have to pay out of pocket when the individual had a good-faith belief that they were visiting a participating provider.

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[136] 88 Fed. Reg. 7243.

[137] The State AGs further recommend that the Departments make this dispute resolution process open to all individuals who receive bills for contraceptive coverage, not just those with objecting employers. The State AGs have received reports of health plans—that are not established or maintained by objecting employers—that are violating the ACA by failing to cover all forms of contraception. *See* The Biden Administration Must Ensure the Affordable Care Act Contraceptive Coverage Requirement is Working for All, Nat'l Women's Law Ctr. (Oct. 14, 2021), https://nwlc.org/wp-content/uploads/2021/11/NWLC_BC_AffordCareAct-Oct_2021.pdf (discussing the thousands of women who have reported difficulty in accessing their ACA contraceptive coverage, indicating that the women who have reported difficulties are a fraction of the women who are not receiving proper coverage). Individuals with ACA compliant plans should not be paying out-of-pocket for services their health plan should be covering. The State AGs also support the revision to 45 CFR § 147.132 (a)(1)(iv) that would clarify that a health insurance issuer may not offer coverage that excludes some or all contraceptive services to any entity or individual that is not an objecting entity or objecting individual. 88 Fed. Reg. 7247-48.

In short, it is important to ensure that the ACA protects individuals' ability to access the contraceptive of their choice—via the ICA—without out-of-pocket expenses.[138] As the Departments note, the implementation of the ACA has led to out-of-pocket savings on contraceptive pills of approximately $1.4 billion between 2012 to 2013.[139] As a result, some studies have concluded that "[w]omen now save an average of 20% annually in out-of-pocket expenses, including $248 savings for IUDs and $255 for the contraceptive pill."[140] The Final Rule should ensure that women retain these savings. And, as discussed above, access to contraception is fundamental to ensuring women can exercise control over their lives, avoid unintended pregnancies, and fully participate in society.

CONCLUSION

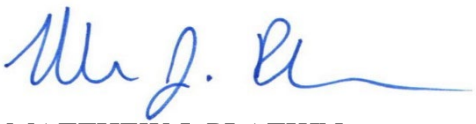
The State AGs thank the Departments for the opportunity to comment. The State AGs support the Proposed Rule's rescission of the moral exemption from the 2018 Rules and commend the creation of the ICA so that individuals enrolled in plans sponsored or covered by objecting entities can obtain access to no-cost contraceptive coverage. We, however, strongly oppose the unwarranted retention of the expansive religious exemptions from the 2018 Rules and recommend significantly narrowing these exemptions. Finally, the State AGs propose several additions to the ICA to expand access, ensure individuals, providers, and issuers will participate in the ICA, and provide additional patient protections. For the foregoing reasons, the signatory State AGs urge the Department to swiftly adopt our recommendations in the Final Rule to ensure access to no-cost contraceptive coverage as required by the ACA and the Women's Health Amendment.

Sincerely,

ROB BONTA
California Attorney General

ANDREA JOY CAMPBELL
Massachusetts Attorney General

[138] 88 Fed. Reg. 7261.
[139] *Id.*
[140] N.V. Becker, et al., *Women Saw Large Decrease In Out-of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing*, Health Affairs (2015), http://content.healthaffairs.org/content/34/7/1204.abstract#aff-2.).



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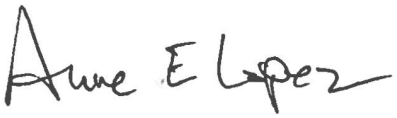

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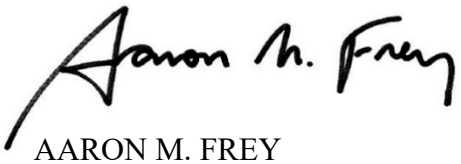

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EXHIBIT B

BECKET
Religious Liberty for All

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202-955-0095 / @BecketLaw
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April 3, 2023

Via Federal eRulemaking Portal

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS—9903—P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Coverage of Certain Preventive Services Under the Affordable Care Act, CMS-9903-P.

To Whom It May Concern:

The Becket Fund for Religious Liberty submits this comment regarding the notice of proposed rulemaking of the Departments of Treasury, Labor, and Health and Human Services, (the Departments) published at 88 Fed. Reg. 7236 (Feb. 2, 2023).

Becket is a nonprofit, nonpartisan law firm that protects the free expression of all religious faiths. Becket has represented agnostics, Buddhists, Christians, Hindus, Jains, Jews, Muslims, Santeros, Sikhs, and Zoroastrians, among others, in lawsuits across the country and around the world. Since the initial regulations regarding coverage of certain preventive services (the contraceptive mandate) were promulgated by the Departments under the Affordable Care Act, Becket has represented clients who have sincere religious objections to including in their health plans certain items and services that would make them complicit in sin. *See, e.g.*, *Zubik v. Burwell*, 578 U.S. 403 (2016); *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). Becket currently represents two homes of the Little Sisters of the Poor in ongoing litigation. The Little Sisters are defending the religious exemption granted to them in the 2018 regulations in litigation brought by several states challenging the exemption. *See Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367 (2020); *California v. Health and Human Services*, No. 4:17-cv-05783-HSG (N.D. Cal.) (amended complaint filed Nov. 1, 2017).

The contraceptive mandate litigation has been a failure for the federal government. Religious parties have always obtained judicial protection, including several times at the United States Supreme Court. Over more than a hundred cases involving thousands of religious entities, the government has not succeeded in forcing any of them to comply with the mandate. In addition to the wasted time of its own lawyers for over a decade, the federal government has been forced to pay millions of dollars in attorney's fees. The nation has endured more than a decade of needless conflict, with many religious entities suffering through years of litigation, and the federal government has gained nothing.

The Departments seek comment on "challenges or concerns" regarding an "alternative approach" that would "continue to apply" the "contraceptive coverage requirement" "directly to the health insurance issuer," thus "[r]equiring the health insurance issuer to independently provide coverage for contraceptive services" on fully-insured plans. 88 Fed. Reg. at 7248.

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This alternative approach would likely exacerbate, rather than end, the long-running litigation the Departments claim to want to resolve. That is because any such approach is likely to depend on insurance companies using the employer's plan information—employee names and addresses, beneficiary information, etc.—to provide contraceptive coverage. Even if the Departments can find a way to make such an approach "feasible," it is likely that many of the same parties who objected to the so-called "accommodation" would object to such use of their health plans and information. After all, the mandate as a whole relies on religious objectors contracting with their insurer or third-party administrator (TPA) to provide contraceptive coverage through their own plan infrastructure. Failure to contract for such a plan, either outright, or via the accommodation, results in large fines under 26 U.S.C. § 4980D ($100/day per person) and 26 U.S.C. § 4980H(c)(1) ($2000 per employee, per year)—the same fines that constituted a substantial burden in *Hobby Lobby*. 573 U.S. at 691 ("If these consequences do not amount to a substantial burden, it is hard to see what would.").

The initial "accommodation" did not lighten this burden on religious employers. Instead, it still made them complicit because in fact, the "accommodation" did not allow for the provision of "separate coverage," but rather used the infrastructure of employer plans. The "accommodation" required that religious objectors execute documents to obligate their insurers to provide contraceptives to their employees through their plan infrastructure. 45 C.F.R. § 147.131(d). For many employers with insured plans, this use of the plan meant that they were not simply opting out of the mandate. They were providing plans that used what the Departments called their "coverage administration infrastructure" to achieve the mandate's coverage goal. 80 Fed. Reg. 41,318, 41,328 (July 14, 2015). That is why the Solicitor General eventually admitted to the Supreme Court that contraceptive coverage under the accommodation was, in fact, "part of the same plan" as the religious employer's coverage.[1]

In order to avoid the same problem as the "accommodation," the alternative approach would have to, among other things, ensure that plan issuers would not use the plan infrastructure that objecting employers contract for when they pay for employee insurance. It would likely raise significant religious liberty problems, for example, if the provision of contraception used religious objector's employee rolls, including contact information for employees and dependent children, to provide objectionable items to their employees and dependents.

The Departments spent many years litigating more than 100 lawsuits against thousands of entities—and did not succeed in forcing any of them to comply with the prior "accommodation." It is difficult to see how or why the Departments would want to engage in a similar losing effort to advance this alternative approach.

For this and other reasons, we believe that in the event of litigation, the alternative approach would be vulnerable in court, as the "accommodation" has been. Since the Supreme Court's *Zubik* order, several cases involving religious employers who object to the mandate have been litigated to completion and resulted in injunctions against the Departments under the

[1] Brief for the Respondents at 38, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14-1418) (quotations omitted).

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Religious Freedom Restoration Act.[2] This is to say nothing of potential Free Exercise Clause claims and other potential remedies. *See, e.g.*, *Fulton v. Philadelphia*, 141 S. Ct. at 1877 (2021) (explaining that a law "lacks general applicability if it prohibits religious conduct while permitting secular conduct that undermines the government's asserted interests in a similar way"). The "alternative approach" is therefore likely to spur litigation that will result in continued losses for the federal government, and be harmful to society, with no discernible benefits.

Sincerely,

/s/ Mark Rienzi
Mark Rienzi
The Becket Fund for Religious Liberty

[2] *See, e.g.*, *Wheaton Coll. v. Azar*, No. 1:13-cv-8910 (N.D. Ill. Feb. 22, 2018), Dkt. 119 at 3 ("enforcement of the contraceptive mandate against Wheaton would violate Wheaton's rights under" RFRA); *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611 (D. Colo. May 29, 2018), Dkt. 82 at 1-2 ("enforcement of the mandate against Plaintiffs, either through the accommodation or other regulatory means . . . violated and would violate the Religious Freedom Restoration Act"); *Reaching Souls Int'l, Inc. v. Azar*, No. 13-cv-01092 (W.D. Okla. Mar. 15, 2018), Dkt. 95 at 3-4 ("enforcement of the contraceptive mandate against Plaintiffs . . . violated and would violate RFRA").

EXHIBIT C

ALLIANCE DEFENDING FREEDOM
FOR FAITH. FOR JUSTICE.

April 3, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services,
U.S. Department of Health and Human Services
Attention: CMS-9903-P
P.O. Box 8016
Baltimore, MD 21244-8016

VIA REGULATIONS.GOV

RE: Coverage of Certain Preventive Services Under the Affordable Care Act CMS–9903–P; RIN 0938–AU94; CMS-2023-0016-0001

Dear Administrator Brooks-LaSure,

We write in opposition to the proposed rule, Coverage of Certain Preventive Services Under the Affordable Care Act, 88 Fed. Reg. 7,236 (Feb. 2, 2023) (the proposed rule). We ask that the Departments of HHS, Labor, and the Treasury (the agencies) withdraw the proposed rule and leave the existing regulations in place.

Alliance Defending Freedom (ADF) is an alliance-building legal organization that advocates for the right of all people to freely live out their faith. It pursues its mission through litigation, training, strategy, and funding. ADF has handled many legal matters involving the agencies' application of the women's preventive services requirement to cover contraceptives (the contraceptive mandate), and its interaction with the Religious Freedom Restoration Act (RFRA), the First Amendment, federal healthcare conscience rights, and other legal principles. Several ADF cases are discussed in the proposed rule, including *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). The vast majority of plaintiffs in these cases were successful.

There is no need to engage in this rulemaking because the rules finalized in 2018 and upheld by the Supreme Court in 2020 have effectively resolved the situation. *See Little Sisters of the Poor Saints Peter & Paul Home* v. *Pennsylvania,* 140 S. Ct. 2367 (2020). The proposed rule and the suggestions in it will lead to more litigation because they will violate the legal rights and religious and moral consciences of persons and groups throughout the country. This will cause more lawsuits that the agencies will lose and will resolve fewer lawsuits, which the agencies already won the first time around. That outcome is not a legitimate reason to reverse a regulatory position.

I. The "alternative approach" to oblige issuers to provide contraception to persons covered by a religiously objecting plan is illegal and should be rejected.

The agencies quickly described an "alternative approach" to the religious exemptions to the contraceptive mandate. In the approach, where there is a religious objection by a plan sponsor, "the health insurance issuer would still be required to fulfill its separate and independent obligation to provide contraceptive coverage." Proposed rule at 7,248. "The Departments seek comment on all aspects of this alternative approach." *Id.* This approach is legally flawed and would increase litigation risk for the agencies for several reasons.

A. The "alternative approach" hijacks religious entities' plans.

The alternative approach would violate RFRA. It would hijack religious objectors' health plans and coverage to provide for contraceptives and abortifacients to which they object. The issuer they hired to provide coverage would be the entity providing objectionable contraceptive and abortifacient items to persons covered by that plan. The issuer's obligation to provide those items to those persons would inextricably derive from the religious objector's arrangement of the health coverage through that issuer. In short, the coverage would be part of the plan as a matter of religious ethics and common sense. That will be true even if the agencies declare through some legal fiction that the obligation, coverage, and payments are somehow separate.

After twelve years of public discussion and litigation, it is clear that "seamlessness" and "separation" are incompatible. The agencies' goal of "seamless" coverage is absent from this statute, and in any event it cannot be achieved while keeping the coverage "separate" from the plan sponsors who object. The agencies essentially admit this when they describe the proposal to keep the religious exemptions (not the alternative approach) as being "[c]ritically . . . independent" and "completely separate" from religious plans. The agencies notably fail to use those same descriptors for the alternative approach, since it is neither independent nor separate from objectors' plan arrangements. When the coverage is not separate, it is simple to conclude that the mandate substantially burdens the employer's exercise of religion. That mandate will be enjoined under RFRA.

B. The "alternative approach" is not supported by a compelling government interest.

The alternative approach would violate RFRA's compelling interest test. The agencies already stated there is no compelling interest under RFRA to impose a

mandate like the alternative approach, nor to impose the mandate on religious objectors in any way. 83 Fed. Reg. at 57,546. The fact that the agencies may disagree with that conclusion now, five years later, cannot reinstate a compelling interest where none existed. A compelling interest must be one "of the highest order" and exists "only in rare cases." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah,* 508 U.S. 520, 546-47 (1993). Compelling interests do not toggle in and out of existence like quarks. The election of a president from a different party cannot make an interest compelling, especially when it derives from an obscure guidance not mandated by the statute in question.

The other flaws in the agencies' compelling interest would continue to exist under this alternative approach. The agencies still propose to do nothing to give contraception, seamless or otherwise, to millions of women in grandfathered plans, in comparison to what the agencies estimate is a much smaller number of women in religious plans. The agencies propose to pay for contraceptives for women in religious plans by diverting marketplace user fees, but the agencies admittedly are not extending that arrangement to women in grandfathered plans.

The agencies offer no plausible rationale why the user fees scheme, if it is legally sound, cannot be applied to benefit women in grandfathered plans, nor why the women in those plans have less of a need than women in religious plans. Marketplace user fees have no greater relationship to religious employer-based plans provided than they have to grandfathered employer-based plans. In choosing to not extend this benefit to the latter, the agencies are once again leaving their interest unpursued on a far grander scale than in religious plans. That flaw continues to negate the agencies' compelling interest under RFRA.

C. The "alternative approach" would also violate the First Amendment.

For the similar reasons, any attempt by the agencies to impose the alternative approach would be unlawful under the First Amendment's Free Exercise Clause. *See Fulton v. City of Philadelphia*, 141 S. Ct. 1868 (2021); *Tandon v. Newsom*, 141 S. Ct. 1294, 1296 (2021) (*per curiam*). HHS must prove that it has a compelling interest in applying the mandates to the religious objectors—"the particular claimant[s] whose sincere exercise of religion is being substantially burdened." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 726 (2014) (quoting *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430-31 (2006)). No broadly stated interest "in ensuring nondiscriminatory access to healthcare" is enough. *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1148 (D.N.D. 2021).

If it pursues the alternative approach, the agencies would be improperly targeting religious entities while leaving millions of other women in grandfathered plans without the same treatment. *Masterpiece Cakeshop, Ltd. v. Colo. C.R. Comm'n*, 138 S. Ct. 1719, 1730 (2018) ("The treatment of the conscience-based objections at issue in these three cases contrasts with the Commission's treatment of Phillips' objection."). The approach would be neither neutral nor generally applicable under Free Exercise Clause jurisprudence. The government would be leaving millions of women without user-fee-subsidized contraception while insisting it has an interest "of the highest order" to hijack religious entities' plans to make sure their women get the contraception.

D. The "alternative approach" is not the least restrictive means of achieving the government's purported interest.

This proposed rule also proves that there is a less restrictive means of advancing the government's alleged interest: that the federal government pay for contraceptives itself through actually separate channel. Note that the least restrictive means test does not ask what the *executive branch* can do under its existing statutes—it asks what the *federal government* could do. Congress *could* pass legislation that buys contraception for women who do not get it from their health plans. See, for example, Title X of the Public Health Service Act. The fact that Congress has not passed such legislation in no way negates this option as a less restrictive means under RFRA. On the contrary, the agencies' primary approach set forth in this proposed rule to set up a new contraceptive arrangement by diverting marketplace user fees is a concession that less restrictive means exist.

E. The "alternative approach" would be illegal as imposed on entities protected by court injunctions.

It would be contempt of court for the agencies to impose the alternative approach on religious entities protected by court injunctions. Most of those injunctions specify that the agencies cannot use the women's preventive services statute to impose a contraceptive mandate on those protected by the injunction. The alternative approach would impose an obligation that funnels objectionable contraception through their health coverage arrangements. That would violate the injunctions.

Moreover, several of those injunctions apply to organizations that religious entities can join to receive protection from the injunction, including Catholic Benefits Association and Christian Employers Alliance. The agencies cannot violate the injunctions for those organizations, and therefore its alternative approach will not likely advance the government's interests in a significant way.

F. There is no logical outgrowth from the proposed rule to impose this "alternative approach" in the final rule.

There is no logical outgrowth from the proposed rule to impose the alternative approach in the final rule. The agencies failed to set forth proposed regulation language on how the alternative approach would work. The agencies express uncertainty about several important questions concerning what the effect of this approach would be on religious entities. As a result, the public has not been afforded adequate notice of what the alternative approach would do, how it would work, what its legal basis would be, how it would fare under RFRA and or the First Amendment, and how it would impact regulated entities. Given this lack of attention, the public has not been given a meaningful opportunity to comment on the alternative approach.

The comments the agencies receive on this alternative approach cannot demonstrate that the government gave the public adequate notice. Instead, those comments only show that the agencies partially described an approach and raised many questions in the public's mind. They do not show that the agencies provided full and necessary information about the approach. Of course the public can comment generally on a partial idea. In fact, the more vague and amorphous an idea is, the more possible things commenters can say and ask about it. But the APA requires that the agencies give the public an opportunity to comment on all of the important aspects of a proposed rule, such as its regulatory text, its operational details, its legal implications, and its regulatory impacts, costs, and benefits. The proposed rule does not meet that threshold for the alternative approach. If the agencies wish to pursue the alternative approach, they would need to issue a new proposed rule setting it forth in full detail and opening another comment period.

II. Repeal of the moral exemptions is illegal, unnecessary, and inconsistent with administration policy.

The proposed rule's repeal of the moral exemptions to the mandate is not legally sound, despite the agencies' assertions. Nor is it necessary to achieve the agencies' goals. It also conflicts with broader administration policy that otherwise acknowledges the legitimacy and importance of business corporations pursuing social goals.

A. Eliminating the moral exemptions violates the First Amendment.

The proposed elimination of the moral exemptions to the contraceptive mandate is illegal. *First*, it violates the First Amendment right to freedom of speech

and association with respect to non-profit organizations. The First Amendment guarantees the right of Americans to form non-profit advocacy organizations. March for Life is a typical example. As explained in the successful lawsuit we filed against the agencies on this issue, see *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015), March for Life is a non-religious non-profit organization formed to promote the sanctity of each human life from the moment of conception—that is, from the fertilization of sperm and ovum, which is when a unique human life comes into existence.

The First Amendment freedoms of speech and association protect the right to form and operate such an organization. If the agencies exercise their purported discretion to force such organizations to perform acts that directly contradict their advocacy mission and their reason for associating, the agencies are violating the First Amendment rights of those groups. *See Hurley v. Irish–Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557 (1995). Such groups will be forced to contradict their message by complying with the mandate or, alternatively, they will be forced to cease operations and therefore stop speaking and associating.

In upholding the moral exemptions rule in *Little Sisters of the Poor* in 2020, the Supreme Court determined that there is no legal requirement that the agencies impose the contraceptive mandate at all, much less that they impose it on morally objecting entities. Absent such a legal requirement, the agencies cannot justify the infringement of these First Amendment rights of non-profit organizations that object to compliance with this mandate.

This is especially true when the agencies have already acknowledged the primacy of these First Amendment rights in their 2017 and 2018 moral exemptions rules. For over five years, the agencies have taken the position that it is wrong to coerce non-profit organizations that morally oppose the contraceptive. This conclusion does not dissolve simply by stating that the agencies have changed their minds. Constitutional rights do not change based on the outcome of an election.

Second, eliminating the moral exemptions will constitute unlawful viewpoint discrimination between moral and religious views. Under the proposed rule (setting aside the alternative approach), if companies oppose coverage of contraceptives on religious grounds they may be exempt. But if they oppose contraceptives on grounds that are exactly the same, but are based on non-religious moral convictions, they will not be exempt. Discriminating against an organization that takes exactly the same position as another—but merely has a different ideological motive for its position—is an unlawful targeting of its viewpoint.

The agencies conceded their hostility to the viewpoint of moral organizations that object to early-abortion causing drugs when they said that for morally objecting employers, "in light of the Supreme Court's decision in *Dobbs* . . . it is necessary to provide women" contraceptives funded "directly through their plan." This demonstrates that it is the pro-life position of morally objecting organizations that the agencies are targeting. Targeting pro-life positions is illegitimate under the First Amendment, even when purporting to regulate the practice of healthcare. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361 (2018). Likewise, nothing about *Dobbs* or its aftermath makes direct provision of contraceptives "necessary" for morally objecting employers but not for religiously employers or grandfathered plans that have no principled objection at all.

B. Eliminating the moral exemptions serves no rational government interest.

Eliminating the moral exemptions also serves no rational government interest. The agencies themselves conceded this in their 2017 and 2018 rules. The government's goal in the contraceptive mandate is to provide coverage of contraceptives to women who want and will use that coverage. By definition, women working at morally objecting non-profit entities don't want and won't use the coverage.

The court in the *March for Life* case held that imposing the contraceptive mandate on a non-profit organization like March for Life "makes no rational sense." 128 F. Supp. 3d at 128 (D.D.C. 2015). Where a group exists and hires people to oppose abortion, including certain items in the contraceptive mandate, no interest of the government is advanced by imposing the mandate on that group. The only "goal" the government pursues in that case is to suppress the existence of a viewpoint that the government disfavors. That is not a permissible goal.

The agencies claim they would still be achieving a rational goal because maybe some beneficiaries of morally exempt plans might be able to obtain contraception if the mandate is imposed on such entities. That is not a legitimate conclusion, however, for two reasons. *First*, the organization has the First Amendment right to only hire people who do not undermine their mission, and therefore they have a First Amendment right to only maintain in their employment people whose plan beneficiaries will not use the plan for objectionable purposes. In other words, they have a First Amendment right to fire employees if the employee's plan beneficiaries use their health plan for abortifacient contraceptives. So the government cannot constitutionally pursue this goal through that organization.

Second, there is no reasonable likelihood that the people working for these groups will actually have dependents who use this coverage to get contraception. The notion that the government will achieve such a goal within this tiny population hostile to the government's viewpoint is speculative and absurd. An organization that makes these strongly held views central to its mission will not likely have employees whose dependents will use contraceptives provided under that plan. The agencies' rationale is arbitrary and capricious and lacks reasoned decision-making under the Administrative Procedure Act (APA).

C. The government cannot finalize its proposal based on flawed assumptions about the number of moral objectors that exist.

The agencies would be relying on flawed assumptions if they finalize the repeal of the moral exemptions based on the notion that there may not be enough of such objectors to justify keeping it. That rationale is flawed for three reasons.

First, the existing number of objectors under the moral exemptions presents the wrong denominator to measure the impact of the rule. New people are born in the United States every day. New non-profit and for-profit organizations are formed and dissolved every day. Existing organizations change their corporate goals and missions every day. There was a day in U.S. history when the organization March for Life did not exist, and then a day later when it did exist. Asking how many organizations exist today who use the moral exemptions is not an adequate measure of the impact of the proposed rule. Even if there were zero organizations using the moral exemptions today, another ten companies could form tomorrow that want to use the exemptions. For this reason it was rational for the agencies to assume there are some organizations using the exemptions.

Polls support the likelihood that at least a few entities use the moral exemption. Polls have suggested that fewer Americans identify as religious, and that a steady percentage of Americans identify as pro-life. This implies more Americans are adopting non-religious pro-life views. There are several prominent pro-life organizations that do not seem to identify as religious. They have names such as Secular Pro-Life, Progressive Anti-Abortion Uprising, Pro-Life San Francisco, the Equal Rights Institute, Feminists for Life, and Democrats for Life of America. Whether they use the moral exemptions is not known by this commenter. The point is that people with their views are increasingly common, and those people have the right to conscientiously object to buying insurance coverage for items they believe can destroy a human life.

Second, there is no reason to think there is reliable data on the number of entities using the moral exemptions. For very good reasons, the agencies did not

require exempt entities to submit documentation to claim the exemption. Citizens should not have to register with the government to be exempt from a mandate that violates their conscience about the sanctity of human life. Registration would likely subject them to unwarranted public scrutiny under FOIA, and to the risk of government employees abusing or improperly disclosing their information.

But absence of data is not data of absence. The agencies cannot assume that because they don't know how many entities use the moral exemptions, there are none who use them, and therefore that rescinding the exemptions causes no harm. Nor can the agencies assume that because this proposed rule was posted in the federal register, any entities using the moral exemptions would submit a comment to identify themselves. The politically charged nature of this controversy is a deterrent to some entities identifying themselves publicly as taking this position. Moreover, the fear of the agencies compiling records against them and engaging in retaliation or cancellation is also a deterrent. Consequently, it would be improper for the agencies to assume that no entities are using the moral exemption other than those that identify themselves in these public comments.

Third, even though the agencies should assume some entities are using the exemptions, it is reasonable to assume the number of those entities is statistically small as in comparison to the employer sponsored insurance field overall. Perhaps tens, or a low number of hundreds, of women of childbearing age might be covered in such plans. Many or most of them might not object to the exemption, and might support it. The number of entities using the moral exemptions is likely to be sufficiently large that the coercion of their consciences is unjustified and causes legal liability to the agencies, and sufficiently small compared to the market so that the alleged benefits of coercing those entities is not large enough to justify the agencies' proposed rescission of the exemptions.

If the agencies finalize the elimination of the moral exemptions, they may find out the hard way that entities were using it or want to use it, by answering lawsuits in federal court as they did in the *March for Life* case.

D. The agencies' justification for removing the moral exemptions is inadequate and fails to adequately consider alternatives.

The agencies do not have a sufficient justification for rescinding the moral exemptions, and have not adequately explored alternatives.

For the reasons explained above and in the *March for Life* ruling, no plausible government interest is served in eliminating the exemption for non-profit entities. As to for-profit entities, the number of entities using the exemptions now

and in the future has a very small statistical effect on coverage nationwide, or compared with the number of women impacted by the agencies' continual failure to address grandfathered plans.

For related reasons, the agencies' reliance on RFRA's inapplicability for targeting moral employers is inadequate. Although RFRA does protect religious plans, it does not protect grandfathered plans as such. Yet the government is not heeding the alleged necessity it has identified to assist the millions of women in those plans. The contours of religious liberty claims are therefore not a legitimate rationale to explain the agencies' proposed course of action.

The government's citation to *Dobbs* is also an invalid reason to target morally objecting plans. Nothing in *Dobbs* or in the post-*Dobbs* situation supports a distinction between the alleged need to impose "direct" coverage on morally objecting plans when the government has chosen not to it on religious or grandfathered plans, especially since the latter cover millions more women.

These basic facts show there is no need for the regulation under ordinary regulatory standards. *See* OMB Circular A-4. The agencies lack any need to rescind the moral exemptions because the government has eschewed its alleged need in parallel plans that cover many more women. This lack of proportion is irrational, and evinces hostility to the viewpoint of morally objecting entities.

Finalizing the proposed rule to eliminate the moral exemptions would be even more irrational in light of the agencies' plan to use marketplace user fee adjustments to provide free contraceptives to women in religious plans. There is no rationale why the agencies cannot simply apply that approach to morally exempt plans instead of eliminating the moral exemption. There is nothing about religious plans that makes the agencies' goal of seamlessness or directness less "necessary" than it would be for moral plans. The fact that religious entities can sue under RFRA and morally objecting entities cannot is not such a reason, because that reason has nothing to do with the alleged interest in seamlessness. Nor can the price of applying the user fees adjustments to morally exempt entities support eliminating the moral exemptions, since statistically that price will likely be negligible compared to the approximately $50 million the agencies estimate it will cost to apply user fees adjustments for persons covered by religious entities. Adding morally exempt plans to the user fees adjustments will likely result in a very small cost because: (1) there seem to be far fewer such plans; (2) those plans seem to be held by small employers; and (3) as to non-profit entities and the owners and decision-makers in for-profit companies, there will be few if any users who want contraceptives so as to pursue those reimbursements.

This point also illustrates the agencies' failure to consider and rebut alternatives to eliminating the moral exemption, namely: (1) not eliminate it because so few people are affected, to protect the deep convictions of the companies using it; (2) not eliminate it and apply the user fees adjustments to persons in morally exempt plans the same way they would be applied to persons in religiously exempt plans; (3) announce enforcement discretion, under which morally objecting entities will not have to comply with the mandate; or (4) keep the moral exemptions for non-profit entities, especially considering their First Amendment rights and the lack of any likely advancement that mandate would achieve towards the government's goal of providing coverage to women who want it. The agencies have not considered these alternatives adequately because they have not considered the disproportionality of their focus on this small number of plans compared to the religious and grandfathered plans where the agencies are pursuing similar alternatives.

Reducing litigation is not a rationale that supports the proposal to rescind the moral exemptions. There are no lawsuits against the agencies from persons who are in morally exempt plans and have been denied coverage as a result. States challenging the exemptions lost in in *Little Sisters of the Poor* three years ago and have made no significant litigation progress since. In contrast, whenever the agencies have imposed this mandate they have faced a far larger number of lawsuits and much less success.

There is also no evidence that the moral exemptions are actually depriving particular women of contraceptive coverage that they want. If that were happening, it should be no trouble for the pro-mandate states to actually provide proof—even one example—of such a woman. They have failed to do so. They have even failed to show that women in religious plans are using public funds to gain contraceptives outside their employer-based coverage. And those states have provided zero evidence of any cost or harmful result from the moral exemptions specifically. Those states have produced zero evidence proving that women covered by morally objecting plans exist in their states, or have needed to seek coverage from state funded programs. This is partly because nearly all of those states have contraceptive mandates in state law. Those state laws make it practically impossible for the moral exemption to impact persons in those states because morally objecting entities tend to be small and therefore are extremely unlikely to self-insure to avoid state contraceptive mandates.

E. Eliminating the moral exemptions is inconsistent with the government's ESG efforts.

Eliminating the moral exemptions contradicts this administration's emphasis of corporate environmental, social, and governance efforts (ESG). In other policies, the administration is aggressively promoting the view that companies should take moral positions—often or usually on non-religious grounds—to advance what the companies see as environmental or social policy goals, and diversity, equity, and inclusion in governance. See, for example, Prudence and Loyalty in Selecting Plan Investments and Exercising Shareholder Rights, 87 Fed. Reg. 73,822 (Dec. 1, 2022); Enhanced Disclosures by Certain Investment Advisers and Investment Companies About Environmental, Social, and Governance Investment Practices, 87 Fed. Reg. 36,654 (June 17, 2022).

But in this proposed rule, the agencies would eliminate moral exemptions entirely as to the contraceptive mandate while possibly leaving religious exemptions in place. The agencies offer the rationale that it is acceptable to eliminate moral exemptions because companies' views on this issue are unacceptable to the government. But that is inconsistent with the administration's support for companies to advance other moral goals that go beyond profit-seeking.

Moreover, the agencies' approach here is viewpoint discriminatory. The administration would be discriminating against companies that adopt this particular moral view on some or all contraceptives, while favoring and rewarding companies for taking other moral views in furtherance of ESG.

F. The agencies' reasons for disagreeing with enactment of the moral exemptions are flawed.

The agencies claim that the Church Amendments' protection for moral objectors should not be analogized to the moral exemptions because Congress did not apply the provisions of Church "to private entities that typically do not accept funds from or do business with the government."

This reasoning is flawed. In the Church Amendments, there was no statute or regulation that violated conscience to which the Church Amendments provided relief. In the Church Amendments, Congress took the situation of the courts legalizing abortion and added conscience protections, but did so only to the extent Congress was constitutionally authorized to do so—using Spending Clause authority by applying the protections to federally funded entities. The final outcome was that more conscience protection existed, and it is highly relevant here that Congress included moral objections in that package.

Here, the ACA added no conscience violation to remedy, because it contains no contraceptive mandate. It was the agencies that created a conscience violation by creating an unnecessary contraceptive mandate and imposing it on entities not receiving federal funding. Initially the agencies refused to respect conscientious objections, but in 2017 and 2018 they did the right thing and fully protected rights of conscience. Those exemptions naturally applied beyond federally funded entities because the mandate itself applied beyond federally funded entities. The parallel that the agencies drew to the Church Amendments in 2018 was therefore fully appropriate: where a conscience violation exists, how does Congress respond? In the Church Amendments, Congress applied moral exemptions to the full extent of its authority. Because it did not create the conscience violations, the Spending Clause was the authority Congress could maximize. Here, where the agencies imposed a conscience violation based on its authority over private employers, the Church Amendments teach that the agencies should respect moral and religious conscience for all those employers. If the agencies believe Spending Clause authority is a limit on the agencies' actions, the agencies should limit the contraceptive mandate itself to federal funding recipients. Since they are not proposing to do that, it is not legitimate to categorically exclude moral protections from entities just because the underlying contraceptive mandate is not limited to federally funded entities.

The agencies also failed to account for *Welsh* v. *United States,* 398 U.S. 333 (1970), which was another explicit reason the agencies gave for enacting moral exemptions. There the Court would not allow the government to exempt a religious objector to the military draft but not exempt a "'sincere and meaningful belief which occupies in the life of its possessor a place parallel to that filled by the God of those admittedly qualifying for the exemption.'" *Id.* at 339 (quoting *United States v. Seeger*, 380 U.S. 163, 176 (1969)). The agencies propose to do here what the Court said the government cannot do in a much more urgent situation.

The agencies' refusal to comply with *Welsh* and *Seeger* would be exacerbated by the existence of the grandfathering exemption, which exempts plans that encompass millions of women but have no principled objection at all. Rescinding the moral exemptions here would be like imposing a military draft with religious exemptions, adding an exemption for people whose last names begin with A through G, and then vigorously punishing a handful of sincere, secular pacifists.

III. The agencies should not define contraceptives as "emergency services" or eliminate protections for that reason.

The agencies "seek comment on the circumstances under which contraceptive services would constitute emergency services, as well as whether to continue to apply the protections." To the extent the agencies are suggesting that by defining

contraceptives as emergency services they can override any of the religious or moral exemptions, they are mistaken.

Under the applicable statute at 42 U.S.C. § 300gg-13, the mandate can only include "preventive" services, not emergency services. There is no basis to interpret that statutory provision as including emergency services, much less to force religious or moral objectors to comply with the contraceptive mandate on that basis. The U.S. District Court for the Northern District of Texas recently issued preliminary and permanent injunctions against HHS for attempting to create a new abortion mandate under the aegis of emergency services. *Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525 (N.D. Tex. Aug. 23, 2022 and Jan. 13, 2023). Any attempt to shoehorn the contraceptive mandate into a newly discovered "emergency" mandate will subject the agencies to similar legal liability.

IV. The marketplace user fees diversion scheme is illegal.

The agencies' plan to expand diversion of marketplace user fees in the proposed rule, and the agencies' existing use of that fee structure, are illegal. Entities that are deprived of an exemption based on this proposed rule will be able to challenge the rule as being contrary to law.

As HHS has previously explained, Section 1311 of the ACA allows an exchange to charge user fees "to support its operations." 42 U.S.C. § 18031(d)(5)(A). *See* 78 Fed. Reg. 15,409, 15,412 (Mar. 11, 2013). But these user fees have nothing to do with supporting the operations of federal (or state) exchange. The persons receiving free contraception under this scheme are in employer-based plans, not marketplace plans. Paying for women in employer-based plans to have free contraception, and giving insurance companies and contraceptive distributors 15% profits on top of that, does not support the operations of marketplaces. Therefore, the diversion of those funds is not authorized by Section 1311.

Agencies can only act if Congress has authorized them to act in that way. *See, e.g.*, *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) ("Agencies have only those powers given to them by Congress"); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). No federal statute authorizes HHS or other agencies to create and run a reimbursable system of free contraception as set forth in the proposed rule. HHS is authorized to not impose the contraceptive mandate, and the agencies may exempt entities from such a mandate. But they are not authorized to create a system of contraceptive distribution funded by marketplace user fees. Especially in the context of a statute such as the ACA, which sets up a host of healthcare programs and payment mechanisms, the "statutory silence" wherein the agencies are given no authority to create a contraception fund with marketplace user fees

can only be interpreted to exclude the agencies' authority to do so. *Cf. Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 223 (2009).

The agencies' rationale for diverting these fees for a similar purpose on a smaller scale in 2013 is inadequate. There the agencies claimed that the fees could be diverted to advance "the goals of the Affordable Care Act," "improving the health of the population, reducing health care costs, providing access to health coverage," and "the governmental interests in promoting public health and in promoting gender equality." 78 Fed. Reg. 8,456, 8,465 (Feb. 6, 2013). By this rationale, the agencies could divert user fees to set up a system to freely distribute any drug, device, or service to any citizen with no connection to the marketplaces, simply to advance the generic goal of "promoting public health." That rationale has no limiting principle and will not sustain the legality of this scheme. Section 1311 and the ACA do not authorize the agencies to create new programs to give away goods and services and then to fund those programs by diversion of user fees collected for the purpose of supporting the operation of the exchange.

Nothing in OMB Circular No. A25-R supports this system. That circular advises that each provision of goods or resources by the government be "self-sustaining." But it does not provide independent authority for delivery of those goods or services in the first place. Nor could it, since the circular is a creation of the President, not of Congress, and only Congress can authorize agencies to act. *West Virginia*, 142 S. Ct. at 2609. Similarly, 31 U.S.C. § 9701 does not independently authorize the government to provide goods and services, but merely authorizes the collection of fees if the government is otherwise authorized to do such business.

The use of unappropriated user fees to create a new unauthorized program likely violates the Appropriations Clause of the Constitution. "The Appropriations Clause is . . . a bulwark of the Constitution's separation of powers among the three branches of the National Government. It is particularly important as a restraint on Executive Branch officers." *U.S. Dep't of Navy v. Fed. Lab. Rels. Auth.*, 665 F.3d 1339, 1347 (D.C. Cir. 2012) (Kavanaugh, J.) The agencies' lack of statutory authority to divert user fees to create a new program is exacerbated by the fact that only Congress is empowered to fund new programs, yet HHS will be operating this new program with funds over which Congress has no appropriations authority. Where Congress allows user fees for a specific purpose, agencies transgress Congress' appropriations authority by using those fees collection arrangements to fund an unauthorized purpose.

This flaw in the proposed rule creates legal liability for the agencies in connection with any elimination of exemptions from the status quo. This includes the proposal to repeal moral exemptions and deny them access to the user fees

scheme. The agencies might be able to diminish this liability if they leave the moral exemptions in place, however (and either apply the user fees arrangement to those plans or not), because entities using the moral exemption might be less likely to bring suit if they are still exempt.

The Supreme Court is poised to rule in cases against the U.S. Department of Education's attempt to forgive half a trillion dollars in student loans. See, for example, *Biden v. Nebraska*, S. Ct. Docket No. 22-506. As discussed at oral argument, the Court will likely rule on the question of whether and when a statute authorizes an agency to create a new program. Given the lack of statutory authority for the proposed scheme here, even as compared to the law at issue in those cases, the agencies should not finalize this proposed rule at least until after the Supreme Court rules in the student loan cases. If the Court strikes down the agency's action there, the agencies here should refrain from withdrawing any existing exemption under these rules.

V. The underlying contraceptive mandate is illegal under the APA.

The agencies' proposed repeal or negation of exemptions is illegal because the underlying contraceptive mandate violates the APA. The APA requires that agency rules undergo notice and comment. 5 U.S.C. § 553. The mandate is unquestionably a rule under the APA. But although regulations about *exemptions* to the mandate have undergone notice and comment, the underlying contraceptive mandate itself has never undergone notice and comment consistent with the APA. HRSA's "guidelines" have only ever been promulgated by posting them on their website and updating them repeatedly through a non-governmental organization.

The Supreme Court has acknowledged this embarrassing fact. *Little Sisters of the Poor*, 140 S. Ct. at 2382 n. 8 ("HRSA has altered its Guidelines multiple times since 2011, always proceeding without notice and comment."). This leaves the agencies with no room to argue that somehow the contraceptive mandate had undergone notice and comment. The U.S. District Court for the Eastern District of Texas, on similar grounds, granted a preliminary injunction against HRSA based on its failure to use the notice and comment process to promulgate the contraceptive mandate. *Tice-Harouff v. Johnson*, No. 6:22-CV-201-JDK, 2022 WL 3350375, at *11 (E.D. Tex. Aug. 12, 2022). HHS subsequently consented to a permanent court order and did not appeal.

The failure to subject the contraceptive mandate to notice and comment rulemaking also caused the government to fail to engage in reasoned decision-making. It is obvious based on years of controversy that such public participation would have led to robust debates of significant issues. By refusing to conduct notice

and comment rulemaking in issuing or revising the contraceptive mandate, HHS denied the public the opportunity to comment on questions such as: whether the thing that contraception prevents (pregnancy) is a disease or illness that qualifies the items as a preventive service under the statute; whether each specific method in the mandate is appropriately included, such as most recently male condoms, which the agency claimed it had no authority to mandate for a decade; whether and to what extent some methods can destroy newly formed human embryos, and therefore are not (or not merely) contraceptive but abortive in violation of other ACA provisions and conscience laws; and many other important policy questions. HHS unlawfully deprived the public of the opportunity to raise all of these questions. Imposing this mandate on any objecting entity will create a new and ongoing injury based on that underlying illegal action.

The contraceptive mandate also violates the Vesting Clause of the Constitution, often referred to as the non-delegation doctrine. The Supreme Court noted in *Little Sisters of the Poor* that under the statute "HRSA has virtually unbridled discretion," and the Court left the non-delegation question unanswered by observing that it simply had not been raised in that case. 140 S. Ct. at 2380, 2382. That objection will likely be raised if the agencies impose this mandate on currently exempt entities. Entities will also likely raise claims that the mandate violates the Appointments Clause. *See, e.g.*, *Kelley v. Azar*, No. 4:20-CV-00283-O, 2021 WL 4025804 (N.D. Tex. Feb. 25, 2021) (denying HHS's motion to dismiss Appointments Clause and Vesting Clause claims). The agencies failed to discuss these legal issues in the proposed rule.

VI. If the final rule rescinds or weakens exemptions, it cannot be applicable for most plans until January 2024.

Under the preventive services mandate, 42 U.S.C. § 300gg-13(b), newly imposed coverage obligations cannot go into effect until the next plan year that begins one year after their promulgation. The agencies have embraced this one-year delay period since the beginning of the mandate. 75 Fed. Reg. 41,726, 41,729 n.4 (July 19, 2010). The agencies repeated this one-year period of delayed applicability in footnote two of this proposed rule, and the agencies gave no indication that it would not be followed if these rules are finalized.

As a result, any finalization that rescinds or weakens exemptions—whether in the repeal of the moral exemptions or an adoption of the alternative approach to the religious exemptions—cannot go into effect until the plan year beginning one year after the finalization of those rules. For plans that operate on a calendar year, that will likely mean these rules cannot go into effect until the January 2024 plan year.

The agencies have no basis to sidestep this effective date. Five years have passed since the existing rules were finalized in 2018. The agencies did not propose these rules on an interim final basis or assert good cause for the need to eliminate ordinary timelines. They also did not give the public any notice in this proposed rule that the final rules would not follow the one-year delay, nor did they give a rationale for handling the mandate differently than it was handled in the past. If the agencies wish to apply these final rules sooner, they will need to resubmit the proposed rules for a new comment period so that the public may comment on the agencies' explanation of why the one-year delay will not be followed.

Notably, in the past where *exemptions* were added the one-year delay in § 300gg-13(b) did not apply. This was correct because the delay only applies when a new recommendation or guideline is added requiring coverage, because a new coverage obligation takes time to implement. This one-year delay is not designed for a decision to remove a coverage requirement, which is what an exemption does. Since rescinding an exemption imposes a new obligation that is not currently present, it is subject to the one-year delay to ensure time for implementation. Therefore, the one-year delay would apply to rescinding the moral exemptions or imposing the alternative approach to the religious exemptions.

VII. There is a history of failure to enforce the preventive services guidelines with respect to fertility awareness-based methods of family planning.

The agencies asked for comment on "information regarding potential noncompliance with these requirements" including the requirement to cover instruction on fertility awareness-based methods (FABM) of family planning. It is common practice for issuers to refuse to comply with their obligation under the women's preventive services guidelines to cover FABM instruction. This may be due to issuers not knowing of the requirement, or to the agencies' inconsistent inclusion of mention of that requirement in their guidance letters. More information about this is included in other public comments (*see, e.g.*, tracking number let-1jo5-xz94).

The agencies should, as the proposed rule preamble suggests, engage in "additional oversight and enforcement actions . . . to ensure health plans and issuers are complying with" their obligation to cover FABM instruction specifically. General attempts to inform issuers of their overall obligations to cover women's preventive services or contraception have proven insufficient. Those general attempts tend to emphasize non-FABM methods, so that the requirement to cover instruction on FABM methods gets lost in the message. Outreach and enforcement specifically with respect to FABM coverage is needed.

VIII. The agencies should not add the non-statutory phrase "evidence-informed" to the regulatory requirements.

The agencies should not add the phrase "evidence-informed" to 45 C.F.R. § 147.130(a)(iv). It is not in the applicable statutory paragraph, 42 U.S.C. § 300gg-13(a)(4). Notably, Congress did include "evidence-based" under (a)(1) and "evidence-informed" under (a)(3). Where Congress uses a phrase in one sentence and omits it from another sentence of the same statutory section, those uses and omissions are deemed intentional by the courts.

The reason to omit the language is to avoid narrowing the authorization for the provisions and to avoid confusion. The agencies have committed both errors in proposing this language when they stated, "these proposed rules would help ensure that plans and issuers are required to cover recommended preventive items and services, without cost sharing, only when evidence supports the items' or services' value as preventive care." That rationale causes confusion for insurers because it raises the question whether there are some items that explicitly fall into the mandate that plans nevertheless need not cover because someone considers them not "evidence-informed." Given the agencies' own stated concern to reduce insurer non-compliance, it is inconsistent for the agencies to add this language because it invites noncompliance with a mandate otherwise clearly listed in the guidelines.

In addition, the broad authority that allows the agencies to include religious and moral exemptions is potentially undermined if the phrase "evidence-informed" is added where Congress did not add it. Congress intended to let the agencies craft the mandate so as to encompass concerns that are not based solely on scientific evidence—including concerns of religious liberty and moral conscience. Adding this phrase creates legal liability because it suggests the agencies are backhandedly repealing all of the exemptions based on someone's interpretation of what constitutes "evidence-informed" guidelines.

The agencies' attempt to clarify this in footnote 91 is insufficient. If, as the agencies claim, Congress meant "evidence-based" means a decision "solely" based on scientific evidence, and "evidence-informed" means a decision considering scientific evidence and other standards, then Congress must have meant to give the agency even more leeway in using *neither phrase* under the paragraph applicable to this mandate. By adding this language the agencies would be denying that Congress gave them even more leeway than for example it gave them under subparagraph (a)(3). That conclusion is not supported by the statutory text and is therefore contrary to the agency's statutory authority.

For all these reasons, the agencies should abandon the proposed rule.

Respectfully submitted,

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