

April 3, 2023

Via Federal eRulemaking Portal

Xavier Becerra Secretary Attn: Title X Rulemaking U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Lisa M. Gomez Assistant Secretary Employee Benefits Security Administration U.S. Department of Labor 200 Constitution Avenue, NW Washington, D.C. 20210

Melanie R. Krause Acting Deputy Commissioner for Services and Enforcement Internal Revenue Service Department of the Treasury 1500 Pennsylvania Avenue, NW Washington, D.C. 20220

Re: EPPC Scholars Comment Opposing "Coverage of Certain Preventive Services Under the Affordable Care Act," RIN 0938-AU94, 1210-AC13, 1545-BQ35, CMS-9903-P

Dear Secretary Becerra, Assistant Secretary Gomez, and Acting Deputy Commissioner Krause:

We are scholars at the Ethics and Public Policy Center (EPPC), and we write in strong opposition to the Department of Health and Human Services', the Department of Labor's, and the Department of Treasury's (collectively, "the Departments") Proposed Rule "Coverage of Certain Preventive Services Under the Affordable Care Act" ("Proposed Rule").¹

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¹ 88 Fed. Reg. 7236.

The Departments fail to establish a need for the Proposed Rule. Despite many introduced bills, Congress has never directed the Departments to impose a contraceptive mandate. Nevertheless, the Departments claim that they have a compelling interest in providing seamless access to contraceptive services. Yet they fail to identify a single woman who in unable to obtain access to contraception because of the religious and moral exemptions. The Departments' proposal would funnel taxpayer dollars to Planned Parenthood. The proposed revocation of the moral exemption is gratuitous and un-American. The Departments should abandon and withdraw the Proposed Rule.

I. There is no need for the Proposed Rule.

For any rulemaking, EO 12866 requires that agencies identify the problem they intend to address.² To justify replacing current regulations, agencies must provide specific evidence as to how those regulations are causing harms or burdens and how the Proposed Rule would remedy the alleged defects *without* causing equal or greater harms and burdens.³ Here, the Departments have failed to meet that exacting standard in every respect. Specifically, the Departments fail to provide concrete evidence that the 2018 rules have or will cause harms or burdens necessitating the need for this rulemaking and that the proposed regulations will remedy that harm.

A. General claims of lack of access to contraceptive services do not create a need for rulemaking.

The need the Departments identify to justify this rulemaking is "access" to contraceptive services. Notably, the goal of the preventative services mandate (which, as discussed below, HHS unilaterally made to include a contraceptive mandate) is the prevention of disease. It is arbitrary and capricious to deem pregnancy a disease. But having done so, the Departments further ignore the text of the law to transform the preventative services mandate's statutory goal of "prevention" to "access."

The Proposed Rule explains: "By enabling individuals to directly receive contraceptive services at no cost, this proposal would provide them with *access* to all contraceptive services the plan or coverage would otherwise be required to cover, absent the exemption."⁴ The Proposed Rule further argues, "[e]nsuring access to contraception at no cost (other than the premium or contribution paid for health coverage) is a national public health imperative, as it is a means to prevent unintended pregnancies and help provide better health and economic outcomes for women, so that they can exercise control over their reproductive health and family planning decisions, particularly in states with prohibitions or tight restrictions on abortion."⁵

To establish this alleged "need," the Departments must demonstrate with specific evidence three things:

1. that qualifying women who want access to contraception have been unable to obtain access to contraception *but for* the existing regulations;

⁴ 88 Fed. Reg. at 7252.

 $^{^{2}}$ EO 12866 § 1(b) (establishing the principles of regulation, including that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.").

³ *Michigan v. EPA*, 135 S. Ct. 2699 (2015) (regulation is irrational if it disregards the relationship between its costs and benefits); *Alltelcorp v. FCC*, 838 F.2d 551, 561 (D.C. Cir 1988) ("a regulation perfectly reasonable and appropriate in the face of a given problem is highly capricious if that problem does not exist").

⁵ *Id.* at 7239-7240.

- 2. that such women became pregnant due to #1 and aborted their child (or continue to regret having their child); and
- 3. that any proposed regulatory amendments would significantly reduce both #1 and #2.

The Departments fail on all three accounts.

The Departments broadly and generally claim: "Access to contraception is an essential component of women's health care in part because contraception is effective at reducing unintended pregnancy."⁶ The Proposed Rule explains that without health insurance, contraception "*can be* prohibitively expensive" which "*may* deter women from obtaining needed care."⁷ And unintended pregnancies (which presumably could have been prevented with access to contraception) allegedly "have negative health consequences for both women and children."⁸ Yet the Departments fail to draw the necessary link between these speculative statements of "harm" and the current 2018 regulations and how the proposed regulations will remedy that specific harm.

The Departments fail to cite specific (or even estimated) numbers of women of childbearing age who are currently employed by employers exercising a religious or moral exemption that are seeking access to contraception and are unable to obtain access. Indeed, it has been several years since the 2018 Rule went into effect, providing the Departments sufficient time to assess the "on-the-ground" impact of those regulations. Speculative or general statements that women need access to free contraception, that lack of access to contraception may cause harms, or that the 2018 regulations may lead to these "harms" do not establish the need for regulatory action.

The Proposed Rule states that "the Departments have received a number of complaints and reports regarding *potential* violations of the contraceptive coverage requirement."⁹ Yet the Departments fail to provide an exact number of how many complaints they received from women unable to access contraception through their insurance plans and the number of those women who became pregnant and regretted it as a result. General complaints that insurance plans do not cover contraception are insufficient to establish need, especially if those plans are not subject to a religious or moral exemption under the 2018 rules. Likewise, the failure of women to utilize existing alternative mechanisms by which they can receive free or low-cost access to contraception when their plan is subject to a religious or moral exemption does not establish the need for this rulemaking. All these things and more must be established with evidence for the Departments to establish a need for rulemaking.

Further, the Proposed Rule claims as a benefit the "[p]otential reduction in unintended pregnancies and improved health outcomes for individuals."¹⁰ But this is a benefit the Departments have failed to establish, making the Departments' claim arbitrary and capricious.

B. *Dobbs* does not create a need for rulemaking.

To further justify the need for rulemaking, the Departments cite the recent Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, which held that there is no federal constitutional right to abortion and that the issue of abortion regulations is returned "to the people and their elected representatives."¹¹ Indeed, in its press release announcing the Proposed Rule, HHS claims that *Dobbs* "has placed a heightened importance on access to contraceptive services nationwide" and

⁶ *Id.* at 7241.

⁷ *Id.* (emphasis added).

⁸ Id.

⁹ *Id.* at 7245 (emphasis added).

¹⁰ *Id.* at 7261.

¹¹ No. 19-1392 (U.S. Jun. 24, 2022).

explained that the Proposed Rule would "bolster access to birth control at no cost."¹² The Proposed Rule likewise states that *Dobbs* "has placed a heightened importance on access to contraceptive services nationwide."¹³ Later, the Proposed Rule states that the Departments have "determined that it is necessary to provide these women with an alternative pathway to obtaining contraceptive services at no cost (other than the premium or contribution paid for health coverage) because of the public health interest in ensuring women's access to reproductive health care and contraceptive services without cost sharing, particularly in light of the Supreme Court's opinion in *Dobbs v. Jackson Women's Health Organization*."¹⁴

But *Dobbs* does not create a need for this rulemaking. As the majority made clear, that opinion was *not* about contraception. Rather, it was about whether there is a right to abortion in the U.S. Constitution. There is not. As the Court explained, "*Roe*'s defenders characterize the abortion right as similar to the rights recognized in past decisions involving matters such as intimate sexual relations, contraception, and marriage, but abortion is fundamentally different, as both *Roe* and *Casey* acknowledged, because it destroys what those decisions called 'fetal life' and what the law now before us describes as an 'unborn human being."¹⁵

The Proposed Rule points out that the Departments noted in the 2018 rules that "[t]he Church Amendments were enacted in the wake of the Supreme Court's decision in *Roe v. Wade.*"¹⁶ The Church Amendments provide conscience protections for individuals and entities related to abortion, sterilization, and certain other health services.¹⁷ The Proposed Rule states that when Congress passed the Church Amendments it "was acting in an environment in which there were, or were about to be, fewer restrictions on reproductive health."¹⁸ This point is inapposite. Congress said that the federal government must respect the conscience rights of health care professionals and entities, full stop. For example, nothing in the Church Amendments describes any conditions under which a public official or entity can require an individual to perform an abortion or sterilization procedure in violation of his or her religious beliefs or moral convictions.¹⁹ Congress has unambiguously established federal laws to protect the rights of health care professionals and entities that protect the rights of health care professionals and entities and protect the rights of health care professionals and entities and protect the rights of health care professionals and entities are protect the rights of health care professionals and entities are protect the rights of health care professionals and entities are protect the rights of health care professionals and entities that have religious or moral based opposition to certain medical procedures and drugs.

The Departments further "find it significant that those statutory provisions were enacted before the Supreme Court's opinion in *Dobbs*."²⁰ The Departments reason that given *Dobbs* and "the consequent threat to women's access to abortion and their ability to exercise control over their reproductive health care decisions, it is now all the more critical that women have access to contraceptive coverage."²¹ To the contrary, Congress has unambiguously passed on every opportunity it has had to establish a federal right to abortion and, as discussed below, contraception.

¹² Press Release, U.S. Dep't Health & Human Servs., Biden-Harris Administration Proposes New Rules to Expand Access to Birth Control Coverage Under the Affordable Care Act (Jan. 30, 2023),

https://www.hhs.gov/about/news/2023/01/30/biden-harris-administration-proposes-new-rules-expand-access-birth-control-coverage-under-affordable-care-act.html.

¹³ 88 Fed. Reg. at 7241.

¹⁴ *Id.* at 7252.

¹⁵ Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 5 (2022).

¹⁶ 88 Fed. Reg. at 7250 (quoting 83 Fed. Reg. 57592, 57599).

¹⁷ 42 U.S.C. § 300a-7.

¹⁸ 88 Fed. Reg. at 7250.

¹⁹ See 42 U.S.C. § 300a-7(b).

²⁰ 88 Fed. Reg. at 7250.

²¹ Id.

Post-*Roe and* post-*Dobbs*, Congress has not established any interest in protecting abortion access. With regard to abortion, Congress has long provided exemptions for medical professionals who cannot participate in abortion based on conscience or religious beliefs and has consistently refused to fund abortion (with a few minor exemptions). Relevant here, Congress ensured that insurers would not be required to cover abortions under the Affordable Care Act (ACA).²² Even in a *Roe*-world, courts have long held that the right to an abortion does not include the right to an abortion at another's expense.²³

Surely the Departments can only rely on interests that Congress has affirmed. Here, it is critical that the Departments recognize that there is no federal right to abortion. As the Supreme Court recognized in *Dobbs* last year, "the Constitution does not confer a right to abortion."²⁴ "The inescapable conclusion is that a right to abortion is not deeply rooted in the Nation's history and traditions. On the contrary, an unbroken tradition of prohibiting abortion on pain of criminal punishment persisted from the earliest days of the common law until 1973," when the Supreme Court improperly removed that question from the democratic process.²⁵ Laws regulating abortion are entitled to a "strong presumption of validity," and "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests."²⁶ Such "legitimate interests include respect for and preservation of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability.²⁷ Nothing in the Constitution and nothing in federal law established a federal right to abortion, let alone as an interest that mandates increased contractive access.

Further, nothing in federal conscience protection laws gives HHS the authority to balance those rights against anything—let alone policy objectives Congress has rejected again and again. The Departments reliance on *Dobbs* is therefore "incompatible with the expressed or implied will of Congress," where the executive branch's "power is at its lowest ebb."²⁸ To suggest otherwise, makes the Departments rationale arbitrary and capricious.

To support its proposal to remove the moral exemption (discussed more below), the Departments concluded "in light of the Supreme Court's decision in *Dobbs*, … that it is all the more critical now to ensure women's access to reproductive health care and contraceptive services without cost sharing, and have determined that it is necessary to provide women enrolled in plans with respect to which the sponsor or issuer has non-religious moral objections to contraceptive coverage, with such coverage directly through their plan."²⁹ Yet the Departments admit that they "are of the view that few entities make use of the moral exemption at this time and that providing moral exemption "likely affects very few individuals."³⁰ Indeed, the Departments estimated in the 2018 rules that "approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules."³¹

²² See 42 U.S.C. § 18023.

²³ See Harris v. McRae, 448 U.S. 297 (1980) (upholding the Hyde Amendment, which restricts government funding for abortions).

²⁴ Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2279 (2022).

²⁵ *Id.* at 2253-54.

²⁶ *Id.* at 2284.

²⁷ *Id*. (cleaned up).

²⁸ Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 637-38 (1952).

²⁹ 88 Fed. Reg. at 7243.

³⁰ *Id.* at 7249.

³¹ *Id.* at 57592 and 57627.

It is arbitrary and capricious for the Departments to claim that *Dobbs* justifies eliminating the moral exemption. They Departments fail to provide any evidence that elimination of the moral exemption will, if fact, allow women increased access to contraceptive services. Indeed, the Departments acknowledge that there are only a few employers that would likely claim a moral exemption, limiting the number of possible women that would be affected. Next, the Departments fail to explain whether these women are in states that are limiting or expanding access to abortion or how laws prohibiting certain abortions prevent these women from obtaining contraceptive services.

C. Advancing equity does not support a need for rulemaking.

The Departments cite to Executive Order 13985 on "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" to support the need for rulemaking.³² The Departments claim the Proposed Rule would "increase health equity, given the disproportionate burden of out-of-pocket spending on contraceptive services currently faced by low-income individuals (as those individuals with lower incomes must spend a greater percentage of their incomes on contraceptive services)."33

But as the Proposed Rule acknowledges, "low-income women also have the least access to contraception through employer-sponsored health insurance."³⁴ The Departments fail to explain why these women, whom they state are disproportionately "non-white," do not have access to contraception via their employer's health plan. It cannot be assumed that any lack of access is because of the religious and moral exemptions. Indeed, it is more likely that many of these low-income women do not have fulltime jobs that provide health insurance benefits from their employers.

The Proposed Rule also points to health disparities in access to health care in general and alleged "racial biases in health care." Tragic as these are, the Departments fail to explain how these harms are the result of the 2018 rules and how their proposal will eliminate those harms. In addition, the Proposed Rule claims that "disparities in maternal health among women of different races can be addressed in part by removing financial barriers to accessing contraceptive services."³⁵ Yet, the Departments fail to provide evidence that women who face disparities in maternal health are employed by employers who claim a religious or moral exemption. Without providing such evidence, it is arbitrary and capricious for the Departments to claim that their proposal will increase access to contraceptive services for those women, lead to improved maternal health, and decrease existing disparities. General statements about purported benefits of access to contraceptive services—such as "wide-ranging economic effects for women, from increased educational attainment to increases in labor force participation and lifetime earnings"³⁶—do not establish that the Proposed Rule will provide those benefits. It is arbitrary and capricious for the Departments to claim otherwise.

The Proposed Rule claims as a benefit the "[p]otential increase in health equity, given the expected reduction in out-of-pocket spending on contraceptive services by individuals."³⁷ But the Departments acknowledge that their proposal "would have marginal effects on the overall level of health inequity."38 Based on the lack of specific evidence that low-income or racial minority women are unable

³⁵ *Id*.

³² *Id.* at 7240.

³³ *Id.* at 7262.

³⁴ *Id.* at 7240.

³⁶ Id.

³⁷ *Id.* at 7261. ³⁸ *Id.* at 7262.

to access contractive services *because of* the 2018 regulations, it is arbitrary and capricious for the Departments to claim any "potential" benefit of "marginal effects."

In accord with the Biden administration's push for equity in federal programs per E.O. 13985, the agencies should consider the impact of their rule on religious minorities who have objections to contraception in general or certain contraceptives that can act as abortifacients.

The mission of HHS is to "enhance the health and well-being of *all* Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."³⁹ There is nothing in HHS's mission statement about "health equity,"⁴⁰ rather, the law imposes equal protection and nondiscrimination obligations. The Departments cannot pursue equity at the expense of unlawful discrimination in violation of First Amendment free exercise rights.

D. The Departments fail to establish the need to add the phrase "evidence-informed."

The Departments proposed adding the phrase "evidence-informed" to the reference of comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).⁴¹ Footnote 91 of the Proposed Rule explains, "The Departments interpret 'evidence-based' to require that the standards be based solely on scientific 'evidence,' while, as discussed later in this preamble, 'evidence-informed' means that they are informed by a consideration of scientific evidence, but such evidence need not be the only basis for its standards."⁴² "Evidence-informed" is not defined in the proposed regulations. The addition of this phrase, according to the Proposed Rule, "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."⁴³ The Departments acknowledge that under current practice the comprehensive guidelines are already "evidence-informed": "HRSA's process for developing clinical guidelines for women's preventive services is, and has historically been, evidence-based."⁴⁴

The Departments claim that the phrase's addition "would more precisely describe the process through which the HRSA-Supported Guidelines are established and ensure the Guidelines continue to be evidence-informed in the future."⁴⁵ But the Departments claim falls short. The Departments fail to explain who will determine which evidence should be considered or how to evaluate conflicting evidence or factors that are permitted to also be considered. While we are not opposed to evidence-informed decision-

³⁹ U.S. Dep't Health & Human Servs., *Introduction: About HHS*, <u>https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html#mission</u> (emphasis added).

⁴⁰ For example, several states employed discriminatory racial set asides for their federally funded COVID-19 vaccine distribution to promote "health equity." EPPC, along with Boyden Gray & Associates, filed a complaint on behalf of a New Hampshire resident whom the state prohibited from receiving a COVID-19 vaccine solely because of his race. *Cf.* EPPC and Boyden Gray & Associates Demand HHS Hold New Hampshire Accountable for Unlawful Racial Set-Asides in COVID-19 Vaccine Distribution, <u>https://eppc.org/news/eppc-and-boyden-gray-associates-demand-hhs-hold-new-hampshire-accountable-for-unlawful-racial-set-asides-in-covid-19-vaccine-distribution/. Despite the clear violations of Section 1557 and Title VI of the Civil Rights Act of 1964, HHS inexplicably dismissed the complaint without any conclusions of law. Nevertheless, HHS states in the Proposed Rule that "ensuring nondiscriminatory access to health care, vaccines, and protective equipment during a public health emergency will more effectively and expeditiously end the emergency for everyone." 87 Fed. Reg. 47831. ⁴¹ 88 Fed. Reg. at 7246.</u>

⁴² *Id.* at 7246 n.91.

⁴³ *Id.* at 7246. Notably, as we mention above, pregnancy is not a disease that needs to be prevented.

⁴⁴ Id.

⁴⁵ *Id.* at 7247.

making in theory, the addition of the phrase here adds nothing of value. There is no requirement explaining the quality or scope of the evidence to be considered. Something could be "evidence-informed" without it being the best or even a beneficial option. Indeed, merely requiring that scientific evidence be *considered* does not mean that the ultimate determination must follow that evidence.

We urge the Departments not to adopt the ill-defined and unnecessary phrase "evidence-informed."

II. HHS's Title X Rule undercuts the Departments' claim that access to contraceptives is a compelling government interest.

It is arbitrary and capricious for the Departments to claim that providing access to contraception is a compelling government interest while simultaneously removing methods of obtaining it.

For example, Title X is particularly well suited to extending access to those who work for employers with religious or moral exemptions. Title X—"The National Family Planning Program"—is operated by HHS.⁴⁶ The Title X program has an annual budget of over \$286 million and is "dedicated solely to providing individuals with comprehensive family planning and related preventive health services."⁴⁷

Indeed, HHS already uses Title X to guarantee minors free contraceptives without parental consent. While 42 U.S.C. § 300a-4(c) instructs HHS to give "priority" to "low-income families" in awarding Title X grants, Congress explicitly gave the Secretary of HHS broad discretion to define "low-income family" "in accordance with such criteria as he may prescribe."⁴⁸ HHS is exercising this authority today, ignoring the Poverty Guidelines in order to advance its policy objectives. HHS has rewired its definition of "low-income family" to include "unemancipated minors who wish to receive [family planning] services on a confidential basis.⁴⁹ If HHS is willing to use Title X to help minors get contraceptives without their parents' knowledge or consent, there is no reason HHS could not also open Title X to women who work for ministries with religious objections to the mandate.

We suspect the Departments may cite to two reasons the government raised during the contraceptive mandate litigation as to why using Title X was unacceptable as a "lesser restrictive means." First, HHS is obligated by law to reserve Title X serves for "low-income families."⁵⁰ As such, "patients whose income exceeds 250% of the federal poverty level *must* pay the reasonable cost of any services."⁵¹ "[T]hus," the government contends, "Title X ... is not available to provide contraceptive coverage for employees and students of objecting organizations."⁵²

⁴⁶ Dep't of Health & Human Servs., *Title X Family Planning Program*, <u>https://opa.hhs.gov/sites/default/files/2020-</u>10/opa-title-x-family-planning-program-50th-2020.pdf.

⁴⁷ Id.

⁴⁸ It is highly ironic that HHS has denied it has authority to define who can have access to Title X funds. As part of this same litigation, Respondents have asserted that DOL has the "broad rulemaking authority" to create plan administrators when Congress specified in ERISA Section 3(16)(A), 29 U.S.C. § 1002(16)(A), that DOL may do so only for orphan plans. Here, by contrast, Congress has explicitly given HHS the power to define "low-income family," and HHS has already used this power to advance other policy objectives. ⁴⁹ 42 C.F.R. § 59.2.

⁵⁰ Memo. For Resp'ts in Opp. at 32, *Wheaton College* v. *Burwell*, 134 S. Ct. 2806 (2014) (No. 13A1284). ⁵¹ *Id*.

⁵² *Id.* at 33.

Second, the government said that using Title X would be unacceptable because it would create unacceptable "logistical and administrative obstacles" and would "[i]mpos[e] additional barriers to women receiving the intended coverage."⁵³

But the government's reasons are incomplete and misleading. HHS could unilaterally make Title X funds available to women who work for religious ministries and The Guttmacher Institute has found that Title X is better than traditional insurance at "removing obstacles" to contraceptive access.

Further, Title X is better than traditional insurance at "removing obstacles" to contraceptive access and an alternative the Departments should consider. Though the Departments have told federal courts that providing contraceptives through Title X poses unacceptable "logistical and administrative obstacles,"⁵⁴ The Guttmacher Institute disagrees. The Guttmacher Institute's views on Title X are significant because the Institute of Medicine (IOM) relied on Guttmacher's research and advice throughout its 2011 report, which served as the basis for the contraceptive mandate.⁵⁵

According to Guttmacher, Title X is *better than* traditional health insurance at "helping clients obtain—and quickly begin using—a contraceptive method best suited to them."⁵⁶ Title X excels at "removing obstacles" to contraceptive access because funded clinics are "more likely ... to provide contraceptives on-site, rather than giving women a prescription that must be filled at a pharmacy."⁵⁷ "Doing so can be critically important" because giving a woman a prescription that must be filled elsewhere "requires a woman to make two trips ... to get the contraceptives she needs."⁵⁸ This "can be a significant obstacle for a woman who is juggling the demands of school, family, or work."⁵⁹ "This emphasis on clearing obstacles to contraceptive use" is something that Guttmacher believes makes Title X clinics superior to other women's health clinics.⁶⁰

The 2019 Title X Rule defined "low-income family" to include "cases involving 'payment for contraceptive services only,' where the woman's employer 'does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage."⁶¹ This definition, consistent with *Burwell v. Hobby Lobby*, provided one of the lesser restrictive means for the government to provide contraception to women directly instead of requiring employers to violate their sincerely held religious beliefs. This win-win solution was removed in the final

⁵³ *Id.* (citations omitted).

⁵⁴ Memo. For Resp'ts in Opp. at 31, *Wheaton College* v. *Burwell*, 134 S. Ct. 2806 (2014) (No. 13A1284).
⁵⁵ IOM Report at 62, 108, 109 (2011), <u>https://nap.nationalacademies.org/catalog/13181/clinical-preventive-services-for-women-closing-the-gaps</u> (citing The Guttmacher Institute); *see also Burwell v. Hobby Lobby Stores, Inc.*, 573
U.S. 682, 742-73 (2014) (HRSA developed the contractive mandate based on recommendations made in the IOM Report). The Guttmacher Institute is the former research affiliate of Planned Parenthood and focuses on "advancing sexual and reproductive health worldwide through research, policy analysis and public education." The Guttmacher Institute, *About*, https://www.guttmacher.org/about.

⁵⁶ Rachel Benson Gold, *Going the Extra Mile: The Difference Title X Makes*, Guttmacher Policy Rev., Spring 2012, at 13-14.

⁵⁷ *Id.* at 14.

⁵⁸ Id.

⁵⁹ *Id.* at 15.

⁶⁰ Id.

⁶¹ 84 Fed. Reg. 7714, 7734.

Title X Rule issued in 2021 under the Biden administration. The 2021 Rule removed (over objections)⁶² that part of the definition of "low-income family."⁶³

This move by HHS undercuts the Departments' claim that access to contraceptives, especially for low-income women, is a compelling government interest.

III. Congress has not declared any interest, let alone a compelling interest, in mandating contraceptive and abortifacient coverage.

At the outset, it is important to correct the Departments' misstatements about Congress' interest in creating a contraceptive mandate. The Proposed Rule claims that the 2018 final rules "failed to adequately account for women's legal entitlement to access preventive care, including contraceptive services, *as Congress intended*."⁶⁴ "The Departments acknowledge that this proposal would not achieve *the Women's Health Amendment's goal* of ensuring that women have seamless cost-free coverage of contraceptives."⁶⁵

As shown below, neither the Affordable Care Act nor the Women's Health Amendment created a contraceptive mandate. When bills have been introduced to create a contraceptive mandate, Congress has consistently rejected them. Our limited research has found twenty-four contraceptive mandate bills Congress rejected before the ACA and two more that were introduced after the Supreme Court ruled against the Departments in *Hobby Lobby*.⁶⁶

This legislative history makes unmistakably clear that the Departments' contraceptive mandate reflects *their* interests—not Congress' interests. This distinction has important legal and constitutional significance. The Framers considered "structural protections of freedom," including "separation of powers," the "most important" protections of freedom.⁶⁷ "The fragmentation of power produced by the structure of our Government is central to liberty, and when we destroy it, we place liberty at peril."⁶⁸

On countless occasions, in dozens upon dozens of lawsuits, the Departments have asserted that the federal government has a "compelling governmental interest" in expanding access to contraceptive services. But an interest isn't "compelling" in the context of a First Amendment strict scrutiny challenge just because a handful of agencies want it. The strict scrutiny test is so demanding, even "important interests" usually fail.

In examining whether an interest is compelling for purpose of the strict scrutiny test, one easy threshold question is whether Congress has advanced the interest itself. After all, if the Supreme Court has said that being a *law* is not enough to establish a compelling governmental interest, then surely the fact that Congress has decided *not* to advance an interest should be conclusive. After all, under our

⁶² 86 Fed. Reg. 56,144, 56,156 ("Two comments opposed removing women who cannot receive contraception from their employer because they have a religious or moral objection from the definition of low-income."); *see, e.g.*, EPPC Scholar Comment Opposing Proposed Rule "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services," RIN 0937-AA11 (May 17, 2021), <u>https://eppc.org/wp-</u>content/uploads/2021/05/EPPC Comment Opposing Title X-Proposed Rule and f"This provision should be retained

<u>content/uploads/2021/05/EPPC-Comment-Opposing-Title-X-Proposed-Rule.pdf</u> ("This provision should be retained in the definition of 'low income family."").

⁶³ 86 Fed. Reg. 56144, 56156.

⁶⁴ *Id.* at 7243.

⁶⁵ *Id.* at 7254.

⁶⁶ 573 U.S. 682 (2014).

⁶⁷ *NFIB v. Sebelius*, 132 S. Ct. 2566, 2676-77 (2012) (joint opinion of Scalia, Kennedy, Thomas, and Alito, JJ., dissenting).

⁶⁸ Id.

"constitutional structure," it should be "Congress," not an "agency," that decides matters related to "a First Amendment issue of ... this consequence."⁶⁹

The Departments' policy preferences cannot amount to a compelling *government* interests when *Congress* will not touch them with a ten-foot pole. The Departments' mandate is "incompatible with the expressed or implied will of Congress," where the executive branch's "power is at its lowest ebb."⁷⁰ The Departments should take Congress' refusal to create a contraceptive mandate into account as it describes the mandate in the final rule, particularly where the Departments compare the public interest in a contraceptive mandate with other interests that Congress has affirmed.

A. History of the Departments' contraceptive mandate.

Some of the controversy associated with the contraceptive mandate comes from the fact that the Food and Drug Administration's (FDA) list of contraceptives includes items that do more than merely prevent conception. In HHS's own words, "[b]ecause FDA includes in the category of 'contraceptives' certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo, the IOM's recommendation included several contraceptive methods under the [ACA]," specifically the requirement that "non-grandfathered group or individual health insurance coverage [] cover certain contraceptive services without cost sharing."⁷¹ The Departments ground their mandate in Section 2713 of the Public Health Service Act ("PHS Act"), which was added to the PHS Act through the ACA. Section 2713 requires non-grandfathered group health plans and health insurance issuers to provide coverage of certain specified preventive services without cost-sharing. A separate law, the Women's Health Amendment of 2010, amended the preventive services requirement that many persons and organizations believe are abortifacient—that is, as causing early abortion.⁷²

B. Regulatory and litigation history of the contraceptive mandate.

By the Departments' own count, this Proposed Rule marks the nineteenth regulatory change the Departments have issued related to the contraceptive mandate. According to the Departments, these "several rules of rulemaking" reflect their ongoing "effort to address the claims of [] religious employers ... that object to providing coverage for contraceptive services."⁷³

The saga over the Departments' contraceptive mandate took a major turn in 2018 when the Departments issued two new regulations that took their concessions before the Supreme Court into account. The November 2018 religious exemption final rules stopped using the tax code to determine who counted as a "religious employer."⁷⁴ The revised exemption was available to any non-governmental employer with "sincerely held religious beliefs[] to []establishing, maintaining, providing, offering, or arranging for (as applicable)" coverage of or payments for some or all FDA-approved contraceptives.⁷⁵ The Departments recognized that their accommodation substantially burdened the religious exercise of many objecting religious employers, and therefore made the accommodation optional for religious employers.

⁶⁹ Tr. of Oral Argument at 56:19-57:4, Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014).

⁷⁰ *Medellin v. Texas*, 552 U.S. 491, 525 (quoting *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 637-38 (1952)).

⁷¹ 82 Fed. Reg. 47,792, 47,794.

⁷² 42 U.S.C. § 300gg-13.

⁷³ 88 Fed. Reg. 7242.

⁷⁴ 83 Fed. Reg. at 57,536.

⁷⁵ 88 Fed. Reg. 7249.

The same day the Departments issued the November 2018 moral exemption final rules, which offered a separate exemption for employers with sincerely held non-religious moral oppositions to cooperating with the mandate.⁷⁶

These new rules sparked another round of lawsuits. But whereas previously the lawsuits were brought by groups seeking to protect their civil rights, this time the lawsuits were brought by state attorneys general-including then California Attorney General and current HHS Secretary Xavier Becerra. These lawsuits argued that the Departments acted unlawfully by broadening the religious employer exemption. Obama appointed district court judges in Pennsylvania and California promptly agreed and enjoyed the 2018 rules. The Third and Ninth Circuits agreed. But in 2020, the Supreme Court in Little Sisters of the Poor v. Pennsylvania overturned the lower courts, holding that HRSA had broad authority from Congress to craft religious exemptions to the mandate.⁷⁷

С. Nothing in the ACA or WHA speaks to contraceptives.

The Departments must be honest and transparent about where their contraceptive mandate didand did not-come from. Neither the ACA nor the Women's Health Amendment mention contraceptives. Section 2713 of the PHS Act, which was added to the PHS Act through the ACA, merely requires nongrandfathered group health plans and health insurance issuers to cover certain specified preventive services without cost-sharing.⁷⁸ Another law passed shortly after the ACA, the Women's Health Amendment (WHA), amended the preventive services requirement in Section 2713 to include "certain women's preventive services."⁷⁹ But Congress did not specify which women's preventive services were to be covered: it tasked HRSA, an office within HHS, with filling in the details.⁸⁰

HRSA in turn deferred to the Institute of Medicine (IOM), which then developed a Committee on Preventive Services for Women. Though the Departments describe the IOM as an "independent" organization, it is nothing of the sort. Eleven of the fifteen members on the IOM's Committee were either affiliated with major pro-abortion groups or had made substantial contributions to the campaigns of proabortion politicians. The Committee chair, Linda Rosenstock, had donated over \$40,000 to Barack Obama, Hilary Clinton, Barbara Boxer, and the Democratic National Committee.⁸¹

In July 2011, IOM's Committee issued a report, "Clinical Preventive Services for Women, that recommended that HRSA adopt guidelines that cover a range of preventive services and also "the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity."82

A few weeks later, on August 1, 2011, HRSA created the contraceptive mandate by publishing a website with their Women's Preventive Services Guidelines, which adopted the IOM's recommendations in full.⁸³ Over the past dozen years, HRSA has occasionally changed the scope of the Women's Preventive Services Mandate by updating this website, though the requirement to cover all FDA-approved

⁸² IOM, Clinical Preventive Services for Women at 10, https://nap.nationalacademies.org/catalog/13181/clinicalpreventive-services-for-women-closing-the-gaps. ⁸³ https://web.archive.org/web/20110802163110/http://www.hrsa.gov/womensguidelines/.

⁷⁶ 83 Fed. Reg. at 57,592.

⁷⁷ Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367 (2020).

⁷⁸ 42 U.S.C. § 300gg-13.

⁷⁹ *Id.* at (a)(4).

⁸⁰ Id.

⁸¹ Kathryn Jean Lopez, The Abortion-Rights Advocates Who Compiled the HHS Mandate, National Review Online, Feb. 12, 2012, https://www.nationalreview.com/corner/abortion-rights-advocates-who-compiled-hhs-mandatekathryn-jean-lopez/.

contraceptives has remained unchanged. The website presently says that its list of mandated services is reviewed "biennially, or upon the availability of new evidence."⁸⁴

Neither the initial publication of this HRSA list nor any of the updates to this website have been subject to public notice and comment. As the Supreme Court observed in *Little Sisters v. Pennsylvania*,

HRSA has altered its Guidelines multiple times since 2011, always proceeding without notice and comment.... Accordingly, if HRSA chose to exercise that discretion to remove contraception coverage from the next iteration of its Guidelines, it would arguably nullify the contraceptive mandate altogether without proceeding through notice and comment. The combination of the agency practice of proceeding without notice and comment and HRSA's discretion to alter the Guidelines ... provides yet another indication of Congress' failure to provide strong protections for contraceptive coverage.⁸⁵

D. Congress has consistently rejected legislation for a contraceptive mandate.

Though the WHA did not address whether there should be a federal contraceptive mandate, plenty of other bills introduced in Congress have. Since 1997, at least 26 bills have been introduced in Congress to mandate prescription contraception coverage in private health plans.

Most contraceptive mandate bills have been introduced in Congress under the titles "Equity in Prescription Insurance and Contraceptive Coverage Act" or "Prevention First Act." None of these bills have ever made it out of committee. These bills include:

- S. 743 (105th), Equity in Prescription Insurance and Contraceptive Coverage Act of 1997 (May 14, 1997)⁸⁶;
- S. 766 (105th), Equity in Prescription Insurance and Contraceptive Coverage Act of 1997 (May 20, 1997)⁸⁷;
- H.R. 2174 (105th), Equity in Prescription Insurance and Contraceptive Coverage Act of 1997 (July 16, 1997)⁸⁸;
- S. 1200 (106th), Equity in Prescription Insurance and Contraceptive Coverage Act of 1999 (June 10, 1999)⁸⁹;
- H.R. 2120 (106th), Equity in Prescription Insurance and Contraceptive Coverage Act of 1999 (June 10, 1999)⁹⁰;
- S. 1400 (106th), Family Planning and Choice Protection Act of 1999 (July 20, 1999)⁹¹;
- H.R. 2624 (106th), Family Planning and Choice Protection Act of 1999 (July 27, 1999)⁹²;
- S. 104 (107th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2001 (January 22, 2001)⁹³;

⁸⁴ <u>https://www.hrsa.gov/womens-guidelines.</u>

⁸⁵ Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2382 n.8 (2020).

⁸⁶ <u>https://www.govtrack.us/congress/bills/105/s743</u>.

⁸⁷ <u>https://www.govtrack.us/congress/bills/105/s766</u>.

⁸⁸ https://www.govtrack.us/congress/bills/105/hr2174.

⁸⁹ <u>https://www.govtrack.us/congress/bills/106/s1200</u>.

⁹⁰ <u>https://www.govtrack.us/congress/bills/106/hr2120</u>.

⁹¹ https://www.govtrack.us/congress/bills/106/s1400.

⁹² https://www.govtrack.us/congress/bills/106/hr2624.

⁹³ https://www.govtrack.us/congress/bills/107/s104.

- H.R. 1111 (107th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2001 (March 20, 2001)⁹⁴;
- S. 1396 (108th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2003 (July 11, 2003)⁹⁵;
- H.R. 2727 (108th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2003 (July 15, 2003)⁹⁶;
- H.R. 4192 (108th), Putting Prevention First Act (April 21, 2004)⁹⁷;
- S. 2336 (108th), Putting Prevention First Act (April 22, 2004)⁹⁸;
- S. 20 (109th), Prevention First Act (January 24, 2005)⁹⁹;
- H.R. 1709 (109th), Prevention First Act (April 19, 2005)¹⁰⁰;
- S. 844 (109th), Title X Family Planning Services Act of 2005 (April 19, 2005)¹⁰¹;
- S. 1214 (109th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2005 (June 9, 2005)¹⁰²;
- H.R. 4651 (109th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2005 (December 22, 2005)¹⁰³;
- S. 21 (110th), Prevention First Act (Jan 4, 2007)¹⁰⁴;
- H.R. 819 (110th), Prevention First Act (Feb 5, 2007)¹⁰⁵;
- H.R. 2412 (110th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2007 (May 21, 2007)¹⁰⁶;
- S. 3068 (110th), Equity in Prescription Insurance and Contraceptive Coverage Act of 2007 (May 22, 2008)¹⁰⁷;
- S. 21 (111th), Prevention First Act (Jan. 6, 2009)¹⁰⁸; and
- H.R. 463 (111th), Prevention First Act of 2009 (Jan. 13, 2009).¹⁰⁹

After passing the ACA and WHA, Congress has continued to reject proposed legislation to create a contraceptive mandate. On June 30, 2014, the Supreme Court entered its first of many decisions against the Departments' implementation of their contraceptive mandate. In *Burwell v. Hobby Lobby*, the Court held that the Departments' mandate, as applied to closely held corporations, violates the Religious Freedom Restoration Act (RFRA).¹¹⁰ The Court rejected the Departments' "main argument," that the employers' religious objections were "simply too attenuated" to support a RFRA claim.¹¹¹ It also held that the Departments failed to meet strict scrutiny. The Court agreed with the Tenth Circuit's reasoning that

⁹⁴ <u>https://www.govtrack.us/congress/bills/107/hr1111</u>.

⁹⁵ https://www.govtrack.us/congress/bills/108/s1396.

⁹⁶ https://www.govtrack.us/congress/bills/108/hr2727.

⁹⁷ https://www.govtrack.us/congress/bills/108/hr4192.

⁹⁸ https://www.govtrack.us/congress/bills/108/s2336.

⁹⁹ https://www.govtrack.us/congress/bills/109/s20.

¹⁰⁰ https://www.govtrack.us/congress/bills/109/hr1709.

¹⁰¹ https://www.govtrack.us/congress/bills/109/s844.

¹⁰² https://www.govtrack.us/congress/bills/109/s1214.

¹⁰³ https://www.govtrack.us/congress/bills/109/hr4651.

¹⁰⁴ https://www.govtrack.us/congress/bills/110/s21.

¹⁰⁵ https://www.govtrack.us/congress/bills/110/hr819.

¹⁰⁶ https://www.govtrack.us/congress/bills/110/hr2412.

¹⁰⁷ https://www.govtrack.us/congress/bills/110/s3068.

¹⁰⁸ https://www.govtrack.us/congress/bills/111/s21.

¹⁰⁹ https://www.govtrack.us/congress/bills/111/hr463.

¹¹⁰ 573 U.S. 682, 723 (2014).

¹¹¹ *Id.* at 723.

the Departments had too broadly articulated their interest to satisfy the focused inquiry RFRA requires.¹¹² It did not decide on this basis, however, as the "exceptionally demanding" least-restrictive-means test proved the lower-hanging fruit.¹¹³

Hours after the Supreme Court decided *Hobby Lobby*, the Obama Administration started pushing Congress "to take action to pass another law that would address this problem."¹¹⁴ On July 9, nearly identical legislation was introduced in the House¹¹⁵ and the Senate¹¹⁶ in order "to ensure that employers ... cannot deny any specific health benefits, including contraception coverage, to any of their employees or the covered dependents of such employees." These bills stated that "[b]irth control is a critical health service for women" and that "[i]t is imperative that Congress act to reinstate contraception coverage." Neither bill passed out of committee.

IV. The WHA and the Institute of Medicine expressed interest in reducing the *cost* of preventive services for women, *not* in providing "*seamless*" access.

The Departments are also wrong to claim that Congress expressed an interest in ensuring women had access to "seamless" preventive care services. The Defendants define this term: "received contraceptive coverage seamlessly through the same issuers or third party administrators that provided or administered the health coverage furnished by the eligible organization, and without financial, logistical, or administrative obstacles."¹¹⁷

Neither the WHA's text, nor the Senate debate over the WHA, nor the IOM's Report on which HRSA relied in creating the contraceptive mandate *ever* expressed an interest in "seamless" access. None expressed concern about the adverse effects of adding any additional steps, however minor, before a woman could access preventive care services. To the contrary, each of these authorities was focused on reducing the cost of preventive services for women, not ensuring "seamless" access.

The notion that contraceptive services coverage had to be "seamless" came later. It was a tactic concocted by the Departments' lawyers in the Department of Justice to defeat religious plaintiffs' arguments that the mandate failed strict scrutiny because the Departments had less restrictive ways of advancing their interests. Only after complaint appellate judges adopted DOJ's talking points did the Departments start asserting an interest in "seamless" access in their regulations. It is high time that the Departments acknowledge these facts and stop invoking a made-up interest in "seamless" access as a reason not to accommodate religious and moral objections to their contraceptive mandate.

A. The text of the WHA does not speak to this issue.

To begin, the WHA says nothing about "seamless" access. The law simply says that "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for ... with respect to women, such additional preventive care and screenings ... as provided for in comprehensive guidelines supported by the Health Resources and Services Administration."¹¹⁸

¹¹² *Id.* at 727.

¹¹³ *Id.* at 728-32.

¹¹⁴ Zeke J. Miller & Kate Pickert, *White House Chooses Congressional Fight Over* Hobby Lobby *Decision*, Time, June 30, 2014, <u>http://time.com/2941491/hobby-lobby-white-house-politics-congress/</u>.

¹¹⁵ <u>https://www.congress.gov/bill/113th-congress/house-bill/5051?s=6&r=2303</u>.

¹¹⁶ https://www.congress.gov/bill/113th-congress/senate-bill/2578?s=6&r=2367.

¹¹⁷ 88 Fed. Reg. at 7243-43.

¹¹⁸ 42 U.S.C. § 300gg-13.

B. The WHA Senate debate shows that Congress was focused on cost, not "seamlessness."

The debate in the Senate over the WHA shows that the purpose of the amendment was to address a single problem: women were forgoing preventive care services because of their cost. Statements from senators during the debate over the WHA show this beyond any doubt, including statements from Senators Mikulski and Boxer, who co-sponsored the amendment.

Senator Milulski: "This amendment eliminates one of the major barriers to accessing care in the area of cost and preventive services. It does it by getting rid of, or minimizing, high copays and high deductibles that are often overwhelming hurdles for women to access screening programs."¹¹⁹

Senator Boxer: "By passing this amendment, we are saving the lives of countless mothers, daughters, grandmothers and sisters who would otherwise forgo preventative health care **because of high copays and expensive deductibles**."¹²⁰ "It is a fact that women are increasingly delaying or skipping altogether preventive health care, and they are doing it **because of costs**."¹²¹

Senator Baukus: "[W]e have never faced a greater need to get the job done than we do today. Why is that? Basically because health care costs are skyrocketing out of control."¹²²

Senator Reid: "[M]ore and more women are simply skipping the important preventive care they need. Why? They are skipping screenings for cervical cancer, they are skipping screenings for breast cancer, they are skipping screenings for pregnancy. They are even skipping annual checkups and doctor visits that could flag serious problems, such as postpartum depression and domestic violence. Why is this happening? Do women simply care less about their wellbeing? Of course not. Are diseases on the decline? Quite to the contrary. **The only reason women are putting off going to the doctor is because, in our broken health care system, it simply costs too much to stay healthy.**"¹²³

Senator Shaheen: "Too often, women forgo their health care needs **because they are not affordable**. We know cost plays a greater role in preventing women from accessing health care than it does men. In 2007, more than half of all women reported problems accessing needed health care **because of costs.**"¹²⁴

Senator Gillibrand: "In America today, too many women are delaying or skipping preventive care **because of the costs of copays and limited access**. In fact, more than half of women delay or avoid preventive care **because of its cost**."¹²⁵

- ¹²⁰ S12025.
- ¹²¹ Id.
- ¹²² S11988.
- ¹²³ S12019.
- ¹²⁴ S12027.
- ¹²⁵ Id.

¹¹⁹ S11987.

Senator Hagan: "This amendment tackles a serious problem: Women are increasingly skipping critical preventive health care screenings **because of costs**, even when they have health insurance."¹²⁶

Senator Murray: "We know that, in 2007, women reported delaying or skipping health care **because of the costs**. In May of 2009, a report by the Commonwealth Foundation found that more than half of women delayed or avoided preventive care **because of its cost**. This amendment will ensure that those women don't delay their preventive care **because they cannot afford it**."¹²⁷

Senator Cardin: "Mr. President, I rise today to encourage my colleagues to support the Mikulski amendment, which will ensure women have access to essential preventive services. The leading causes of death for women are heart disease, cancer, and stroke. Early screening for risk factors could prevent many of these deaths and lead to improved health and quality of life for women. But despite the benefits of early screening, many insurers do not cover them, and too often women skip them **because the costs are prohibitive**."¹²⁸ "This amendment would ensure that all of these women would have access to mammography **with no out-of-pocket cost**."¹²⁹

C. The IOM Report likewise focuses on cost, not "seamlessness."

Similarly, the Institute of Medicine's report ("IOM Report"), which HRSA used to justify its mandate, claims that women sometimes forgo contraception because of cost, but never even suggests—let alone establishes—that other incremental steps would result in reduced contraception use.

In the course of recommending cost-free access to contraceptive services, the Institute of Medicine states:

[A] review of the research on the impact of cost sharing on the use of health care services found that **cost-sharing requirements**, such as deductibles and copayments, can pose **barriers to care and result in reduced use of preventive and primary care services**, particularly for low-income populations. Even small increments in cost sharing have been shown to reduce the use of preventive services, such as mammograms. The elimination of **cost sharing** for contraception therefore could greatly increase its use, including use of the more effective and longer-acting methods, especially among poor and low-income women most at risk for unintended pregnancy. A recent study conducted by Kaiser Permanente found that when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods.¹³⁰

There are no similar statements in the IOM Report that suggest that requiring women to sign up for additional programs or policies would result in reduced contraceptive use. To the contrary, the IOM Report highlights the government's efforts to expand contraceptive access through Medicaid and Title X

¹³⁰ IOM Report 109 (2011) (emphasis added) (internal citations omitted), <u>https://nap.nationalacademies.org/catalog/13181/clinical-preventive-services-for-women-closing-the-gaps.</u>

¹²⁶ Id.

¹²⁷ S12028.

¹²⁸ S12058.

¹²⁹ S12059.

programs, both of which require enrollment and steps beyond what it would take to enroll in an employerbased or Exchange-based health plan.¹³¹

Even here, however, the Institute of Medicine failed to show that reducing cost results in higher rates of contraceptive use. This point was aptly demonstrated in an amicus brief submitted in Zubik v. Burwell:

[T]he IOM Report was unable to show any real correlation between cost and access to contraceptives. Only one paragraph in the entire report attempts to make this correlation, but the studies it relies on do not connect the dots. The first study explores the connection between cost and access to preventive care generally, but it doesn't focus on contraception and collected data only from low income populations. The second also says nothing about contraceptive access, as it studied women aged 65-69 enrolled in Medicare. Nothing in the report shows that women enrolled in an employer-sponsored health plan forgo contraception when it is not free.¹³²

Contraceptive mandate bills introduced after Hobby Lobby also focused on cost D. concerns. not "seamless" access.

As noted above, shortly after the Supreme Court held in January 2014 that the mandate violated RFRA as applied to closely-held religious for-profit employers, identical bills were introduced in the House¹³³ and Senate¹³⁴ to try to work around the Court's decision. The Senate bill was sponsored by Senators Mikulski and Boxer, the co-sponsors of the WHA, The bill's preamble cited economic concerns fifteen times, but not once did it express any concern about "seamless" access, however defined:

- "women's economic success"; •
- "paid higher wages";
- "with no cost sharing"; •
- "Affordability has long been a barrier"; •
- "worry about costs"; •
- "Women citing cost concerns"; •
- "Cost-sharing requirements"; •
- "eliminating cost-sharing"; •
- "The [ACA} sought to remove the barrier to care by requiring all new health care plans to cover recommended preventive services without cost-sharing";
- "Women have saved ... out-of-pocket costs"; •
- "without cost-sharing"; •
- "lowers health care spending";
- "no increase in costs"; •
- "it costs employers"; and •
- "employer's direct medical costs."

¹³¹ *Id.* at 108.

¹³² Amicus Curiae Brief of the Knights of Columbus in Support of Petitioners at 26-27, Zubik v. Burwell, 578 U.S. 403 (2016) (internal citations omitted), available at https://www.scotusblog.com/wpcontent/uploads/2016/01/Knights-of-Columbus-LSP-Amicus.pdf.

 ¹³³ https://www.congress.gov/bill/113th-congress/house-bill/5051?s=6&r=2303.
 ¹³⁴ https://www.congress.gov/bill/113th-congress/senate-bill/2578?s=6&r=2367.

E. The "seamless" argument came from DOJ, not Congress.

Neither Congress nor the IOM Report expressed any interest in "seamless" access. Even after the Supreme Court ruled against the mandate in January 2014, the minority of senators that were in favor of the Departments' mandate were still focused on cost-concerns, not "seamless" access. So where did this term come from?

The term "seamless" showed up first in DOJ briefing in mandate cases as the Departments' lawyers were trying to defeat religious employers' claim that the Departments had other acceptable means of getting women free contraceptives that did not require piggybacking on the plans of objecting religious employers. These alternatives did not count, the Departments' lawyers claimed, because they did not provide the "seamless" access that Congress had intended.

The first court decision in a mandate case to use the term "seamless" was the D.C. Circuit's November 2014 *Priests for Life* decision. The D.C. Circuit uncritically adopted DOJ's terminology, using "seamless" eight times in its opinion.¹³⁵

At this point the Departments had already issued eight sets of regulations concerning the mandate.¹³⁶ The word "seamless" did not appear in any of them. But the Departments started asserting that Congress wanted women to have "seamless" access in their first set of regulations after *Priests for Life*, the July 2015 final rules.¹³⁷ Becket Law President and law professor Mark Rienzi documented this development in a 2016 law review article:

[I]n July 2015—at a time when the government was undefeated in the courts of appeal and may have thought it would run the table and avoid Supreme Court review—HHS issued revised rules finalizing the "accommodation." In so doing, the agency needed to explain why other proposed solutions would not work. Commenters suggested many other ways that contraceptives could be provided to women who want them—by mail, directly from prescribing doctors, from pharmaceutical companies, or through government programs like Medicaid. In response, HHS took the position that "these alternatives raise obstacles to seamless coverage" because "plan beneficiaries and enrollees should not be required to incur additional costs—financial or otherwise—to receive access." The government then explained that the insurers and administrators of the employer's plan were actually better situated to provide "seamless" access. This is because any solution that operated outside the employer's plan would involve providers "that may not be in the insurance coverage network" of the employer's plan, and would "lack the coverage administration infrastructure to verify the identity of women in accommodated health plans and provide formatted claims data for government reimbursement."¹³⁸

The Departments' baseless claim that Congress had expressed an interest in "seamless" access to preventive services has been a regular feature of their regulatory and legal arguments in support of their contraceptive mandate ever since.

¹³⁵ Priests for Life v. U.S. Dep't of Health & Human Servs., 772 F.3d 229 (D.C. Cir. 2014).

¹³⁶ 88 Fed. Reg. at 7237-38.

¹³⁷ 80 Fed. Reg. 41318.

¹³⁸ Mark L. Rienzi, *Fool Me Twice:* Zubik v. Burwell *and the Perils of Judicial Faith in Government Claims*, 2016 Cato Sup. Ct. Rev. 123, 134-35 (quoting 80 Fed. Reg. 41328-29 (July 14, 2015)).

V. The Departments should retain the religious exemption and accommodation option.

A. The Departments should keep the religious exemption.

In the Proposed Rule, the Departments state their desire "to resolve the long-running litigation with respect to religious objections to providing contraceptive coverage."¹³⁹ Given the relative peace since the Supreme Court's latest intervention on behalf of religious employers in 2020, it appears the Departments are expressing their reticence to spark new litigation and more adverse rulings.

However, if the Departments are sincere about their desire to avoid more lawsuits over religious objection, the best thing they could do would be follow their proposal "to maintain the November 2018 final rules' religious exemption for entities with sincerely held religious objection to providing coverage for contraceptive services."¹⁴⁰

Notably, it took the Departments many years and many defeats in court before they finally adopted a proper, common-sense definition of "religious employer" in 2018. The Departments' first regulations related to the mandate, the July 2010 interim final rules, made no provision for religious employers.¹⁴¹ In their next set of regulations, the August 2011 interim final rules, the Departments issued one of the narrowest religious exemptions ever seen. The Departments defined "religious employer" to mean only organizations that met the following criteria:

- (1) The inculcation of religious values is the purpose of the organization;
- (2) The organization primarily employs persons who share the religious tenets of the organization;
- (3) The organization serves primarily persons who share the religious tenets of the organization; and
- (4) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.¹⁴²

Section 6033(a)(3)(A) of the Internal Revenue Code refers to "churches, their integrated auxiliaries, and conventions or associations of churches," and "the exclusively religious activities of any religious order."¹⁴³

Archbishop Gomez of the Archdiocese of Los Angeles said that the Departments' "religious employer" exemption was so narrow that "much of what Jesus Christ did would not qualify as a 'religious' ministry."¹⁴⁴

The following year, the Departments retreated somewhat. The July 2013 final rules dropped the first three criteria from their 2011 "religious employer" definition, but their marginally-broader definition was still hooked to Section 6033 of the Internal Revenue Code, which allows churches, their integrated auxiliaries, and religious orders to avoid filing informational tax returns.¹⁴⁵ Religious schools and ministries—clearly religious under any reckoning—were excluded. The Departments' ongoing refusal to

¹³⁹ 88 Fed. Reg. at 7243.

¹⁴⁰ *Id*.

¹⁴¹ 75 Fed. Reg. at 41,726.

¹⁴² 76 Fed. Reg. at 46,626.

¹⁴³ 26 U.S.C. § 6033(a)(3)(A)(i), (iii).

 ¹⁴⁴ LA Archbishop Calls on Catholics to Oppose HHS Mandate, Catholic News Agency, Jan. 25, 2012,
 <u>https://www.catholicnewsagency.com/news/24160/la-archbishop-calls-on-catholics-to-oppose-hhs-mandate</u>.
 ¹⁴⁵ 26 U.S.C. § 6033.

provide an adequate religious employer exemption led to an unprecedented wave of lawsuits brought by or on behalf of hundreds of non-profit and for-profit employers with religious objections to providing employees with free access to contraceptives, abortifacients, sterilization procedures, and related services.¹⁴⁶

It never made sense for the Departments to use the Internal Revenue Code to decide which religious employers were entitled to an exemption from their mandate. The history of Section 6033, set out in an amicus brief filed in *Zubik v. Burwell*, makes this abundantly clear:

Amici write to highlight the arbitrary nature of the decision by the Department of Health and Human Services (HHS) to base the availability of religious exemptions to the HHS contraceptive mandate ("mandate" or "contraceptive mandate") not on factors that go to an employer's religious character, but on its federal tax filing requirements. The HHS mandate relies on categories set forth in Internal Revenue Code § 6033 to distinguish between religious organizations. But the history and application of section 6033 show that the classification was solely intended to facilitate administration of the tax laws, not to draw a line between religious institutions whose free exercise was fully protected and those who received less consideration. In short, the availability of an exemption to the mandate should turn on an organization's claim to religious exercise rights, not its tax filing obligations.

By selecting section 6033, HHS created a discriminatory gerrymander that wanders far from its regulatory justification while utterly failing to respect the profound and immutable religious objections of the Petitioners and the religious amici. HHS's decision to gerrymander the exemption in this way was intentional; it knew that in significant cases, virtually identical religious groups would be treated differently based on nothing more than their classification under tax law.

If HHS had been serious about creating an exemption that took religious objections seriously, it could have modeled its exemption after one from employment law. Title VII of the Civil Rights Act of 1964 provides a tried-and-true mechanism for protecting both employee and employer civil rights, and includes a religious exemption much more suitable than that of section 6033. The Title VII exemption, unlike the gerrymandered one concocted by HHS, captures religious orders like amici and Petitioners. That definition has served as the model for other religious exemptions in employment statutes and regulations, and better reflects the likelihood that a religious organization may hire employees who share the tenets of its faith. It is a simple and more effective alternative to the flawed and ineffectual exemption HHS devised for the invasive contraceptive mandate.¹⁴⁷

In 2018, the Departments finally came to their senses and adopted an exemption that reflected a commonsense definition of a religious employer. The Departments recognized that denying an exemption to most religious employers and trying to coerce them using an "accommodation" that piggybacked on the objecting employer's plan was illegal. The Departments' efforts substantially burdened religious exercise when it was not necessary to serve a compelling governmental interest.¹⁴⁸ Under the 2018 rules, the religious employer exemption was extended to "a church, an integrated auxiliary of a church, a

¹⁴⁶ See Becket Law, HHS Mandate Information Central: HHS Case Database, <u>https://www.becketlaw.org/research-central/hhs-info-central/hhs-case-database/</u> (database of litigation against contraceptive mandate).

¹⁴⁷ Amici Curiae Brief of the Dominican Sisters of Mary, *et al.*, in Support of Petitioners at 3-4, *Zubik v. Burwell*, 578 U.S. 403 (2016), *available at* <u>https://www.scotusblog.com/wp-content/uploads/2016/01/Dominican-Sisters-of-Mary-Mother-of-the-Eucharist.pdf</u>.

¹⁴⁸ 83 Fed. Reg. at 57,546.

convention or association of churches, a religious order, a nonprofit organization, or other nongovernmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects ... based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for ... [c]overage or payments for some or all contraceptive services."¹⁴⁹

It was just and responsible for the Departments to expand the definition of "religious employer" for purposes of the religious exemption in 2018. Expanding the definition reflects American's commonsense understand of what counts as a religious employer. It honors the Departments' obligations—under the First Amendment and federal law—to respect religious liberty rights. It has saved taxpayers millions of dollars the Departments would have spent defending lawsuits and paying attorneys' fee awards when they lost.

Moreover, there is little reason to think that respecting religious liberty rights has harmed third parties. As the Departments noted in the 2018 religious exemption final rule, the Guttmacher Institute found that in the years before and after the mandate went into effect there was "no significant changes in the overall proportion of women who used a contraceptive method" and "no significant increase in the use of methods that would have been covered under the ACA."¹⁵⁰ The Guttmacher Institute surmised that the Departments' mandate had not moved the needle much because "[p]rior to the implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use."¹⁵¹ Moreover, these findings "may reflect broader access to affordable and/or free contraception made possible through programs such as Title X."¹⁵²

For all these reasons, it was prudent for the Departments to adopt a broader definition of "religious employer" in the 2018 rules. It is likewise prudent of the Departments to propose to maintain that definition in its Proposed Rule. This definition should be maintained in any final rule, allowing the Departments to lay this issue to rest and devote their time, attention, and budgeted taxpayer funds to other issues than trying to force religious employers to violate their religious convictions.

B. The Departments should leave any accommodation optional for exempt employers.

The Departments likewise propose to leave untouched their decision in the 2018 religious exemption final rule to make their problematic accommodation optional for objecting religious employers. This is a wise decision. Given the Departments' concessions before the Supreme Court in 2016, the Departments cannot hope to continue to mislead courts into finding that religious employers were wrong to conclude that the so-called accommodation forced them into cooperating with their efforts to expand access to contraceptive services.

The Departments unveiled the so-called "accommodation" in their July 2013 final rules, the same rules where they dropped three of the four original criteria from the "religious employer" definition. The Departments represented that, under this arrangement, objecting religious employers would not be "not

¹⁴⁹ *Id.* at 57,590.

¹⁵⁰ *Id.* at 57,548.

¹⁵¹ Id.

¹⁵² Id. (quoting M.L. Kavanaugh et al., Contraceptive Method Use in the United States: Trends and Characteristics Between 2008, 2012 and 2014, 97 Contraception 14, 14-21 (2018), available at http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf).

required to contract, arrange, pay, or refer for contraceptive coverage; however, plan participants and beneficiaries" would still have access to free mandated contraceptive services.¹⁵³

However, religious employers that were paying attention to the details saw quickly that the "accommodation" could not possibly work the way the Departments claimed. They objected because they saw that the "accommodation" still left them morally complicit in the delivery of contraceptive and abortifacient drugs and devices. The "accommodation" required them to execute paperwork that amended their health care plans to make their plan administrators liable for giving their employees free contraceptives under the religious employers' own health plan.

But the Departments did not budge. In court they called this arrangement an "opt out" and said that religious employers "need only attest to their religious beliefs and step aside." They claimed that the Department of Labor had unilateral authority to amend health plans and could also force third party administrators to provide contraceptive coverage outside of the objecting employers' plans.

As dozens of lawsuits made their way through the federal court system, nearly every court of appeals accepted the Defendants' arguments at face value. Judge Posner, writing for the Seventh Circuit, declared that under the accommodation, "new contracts are created," through "governmental plan instrument[s]," "to which [objecting employers are] not a party."¹⁵⁴ None of this was true.¹⁵⁵ ERISA plainly states that Congress did not give the Labor the power to take over private insurance contracts.

In 2016, the litigation over the accommodation reached the Supreme Court. There, the Departments made an about face and conceded that the religious employers had been right about the accommodation all along:

[A]fter years of claiming the opposite in the lower courts, the government conceded in its merits brief that contraceptive coverage provided under the "accommodation" actually was "part of the same plan as the coverage provided by the employer." This concession severely weakened the government's substantial burden argument... ¹⁵⁶

Furthermore, the Departments conceded that they did not need to hijack objecting religious employers' health plans in order to advance their interests in giving women free access to contraceptives:

[T]he government admitted for the first time in its merits brief that its interests actually did not require women to receive complete cost-free contraceptive coverage from their employers. Instead, the government acknowledged that its interests would be satisfied so long as women had access to a plan with some contraceptive coverage, which they could obtain from many sources, including "a family member's employer," "an Exchange," or "another government program." As the government told the Court, "All of these sources would include contraceptive coverage."

[Finally], when the Court asked for supplemental briefing on alternatives, the government acknowledged that its existing system was not the least restrictive means of achieving its

431/138244/20200316132502671_Little%20Sisters%20v%20Penn%20Amicus%20Brief%20for%20Knights%20of %20Columbus%20in%20support%20of%20Petitioners.pdf.

¹⁵³ 88 Fed. Reg. at 39,874.

¹⁵⁴ Wheaton College v. Burwell, 791 F.3d 792 (2015).

¹⁵⁵ See generally Amicus Curiae Brief of the Knights of Columbus in Support of Petitioners, *Little Sisters of the Poor Saints Peter v. Pennsylvania*, 140 S. Ct. 1292 (2020), *available at* https://www.supremecourt.gov/DocketPDF/19/19-

¹⁵⁶ Rienzi, *supra* note 138, at 132.

goal. Instead, after years of telling the lower courts that it was already using the least restrictive means possible, the government told the Court that the system actually "could be modified" to avoid forcing religious organizations to execute documents that violate their faith, while still getting women contraceptives.¹⁵⁷

The Departments' concession regarding how their accommodation worked and what they actually needed to advance their interest were critical. The Supreme Court unanimously overturned the lower court rulings the Departments had secured by convincing appellate courts otherwise.¹⁵⁸

The Supreme Court ordered the lower courts to give the Departments an opportunity to find a way to advance their interest in giving the Little Sisters' employees free contraceptives without involving the Little Sisters or their health plan. However, the Departments rejected this opportunity, ignored their concession (and federal law), and returned to their earlier positions that the accommodation was the least restrictive means of advancing their interests. In January 2017, the Departments issued an FAQ that said they would not be adjusting their accommodation, as "no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive ... contraceptive coverage."¹⁵⁹

The Departments took all of this history into account when they decided in 2018 that they would no longer try to convince objecting religious employers that their accommodation was an "opt out" and would no longer try to coerce them into using the accommodation. Instead, they made the religious employer exemption available to such employers. The 2018 Rule appropriately recognized that expanding the religious employer exemption entailed changing rules related to the accommodation as well:

[B]y virtue of expanding the exemptions to encompass all entities that were eligible for the accommodation process under the previous regulations, in addition to other newly exempt entities, the Religious IFC rendered the accommodation process optional. Entities could choose not just between the Mandate and the accommodation, but between the Mandate, the exemption, and the accommodation. These rules finalize the optional accommodation process.¹⁶⁰

As the Departments noted in the 2018 Rule, expanding the religious employer exemption to encompass all non-governmental employers with religious objections to the mandate necessarily entailed making the accommodation optional. For all the reasons that the Departments should maintain the 2018 definition of a religious employer, they should likewise leave the accommodation as optional.

C. We agree the religious exemption applies to institutions of higher learning and the exemption extends to student health plans.

We agree with the Departments that the exemption applies to institutions of higher education and the exemption extends to student health plans, as well as employee health plans. While we are not opposed to regulatory language stating this explicitly, we do not believe there is any need for such language and the addition of such language does not support a need for rulemaking. Indeed, the 2018 Rule states: "These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so

¹⁵⁷ *Id.* at 133.

¹⁵⁸ Zubik v. Burwell, 578 U.S. 403, 410 (2016).

 ¹⁵⁹ U.S. Department of Labor, FAQS About Affordable Care Act Implementation Part 36, January 9, 2017, https://www.supremecourt.gov/opinions/URLs_Cited/OT2019/19-431/19-431-2.pdf.
 ¹⁶⁰ 83 Fed. Reg. at 57,569.

by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process."¹⁶¹

IV. The Departments should address serious concerns about the proposed "individual contraceptive arrangement."

Though the Departments intend to leave some changes introduced in the 2018 Rule alone, they claim the 2018 Rule "did not give sufficient consideration to women's significant interests in access to contraceptive services."¹⁶² As such, they propose to create a new "independent pathway" to cost-free contraception called the "individual contraception arrangement."¹⁶³

Unlike the Departments' longstanding "accommodation," the proposed "individual contraception arrangement" will involve a *separate* "provider of contraception services"—not the religious' employers' plan and third-party administrator.¹⁶⁴ This separate provider would provide these services at no cost, and then seek reimbursement "from an issuer with whom it has a signed agreement for the cost of providing contraceptive services to women covered under these plans."¹⁶⁵

According to the Departments, "This individual contraception arrangement would be available to the participant, beneficiary, or enrollee without the plan sponsor or issuer having to take any action that would facilitate the coverage to which it objects. Simply put, the action is undertaken by the individual, for the individual."¹⁶⁶

The Departments note that this arrangement is not ideal from their perspective: It "would not achieve the Women's Health Amendment's goal of ensuring that women have seamless cost-free coverage of contraceptives."¹⁶⁷ However, this is a deceptive claim. As elaborated more below, the Supreme Court recognized in *Little Sisters v. Pennsylvania* that the Women's Health Amendment did not mention contraceptives at all. Dozens of bills have been introduced in Congress that have explicitly proposed a contraceptive mandate, but those bills all failed. In this case, Congress ducked the issue and chose to let HRSA (and HRSA chose to let IOM) decide what women's preventive services would have to be covered.

The financial part of the "individual contraceptive arrangement" is a bit complicated. Women get covered services free of charge through the "separate providers of contraception services."¹⁶⁸ Those separate providers can seek reimbursement from a participating qualified health plan issuer. The Departments will reimburse the health plan issuer in turn by adjusting the issuer's federally-facilitated exchange (FFE) or state-based exchange on the federal platform (SBE-FP) user fee. (This is essentially the same reimbursement scheme that the Departments have used for years under their accommodation.¹⁶⁹) According to the Proposed Rule, "HHS proposes a 15 percent administrative allowance for this adjustment, similar to the administrative allowance set in the 2015 Payment Notice for third party administrators."¹⁷⁰

¹⁷⁰ 88 Fed. Reg. at 7256.

¹⁶¹ *Id.* at 57,564.

¹⁶² 88 Fed. Reg. at 7240.

¹⁶³ *Id.* at 7243.

¹⁶⁴ 88 Fed. Reg. 7236.

¹⁶⁵ 88 Fed. Reg. 7243.

¹⁶⁶ *Id*.

¹⁶⁷ Id. at 7254.

¹⁶⁸ 88 Fed. Reg. 7236.

¹⁶⁹ See https://www.govinfo.gov/content/pkg/FR-2014-08-27/pdf/2014-20252.pdf.

We have several serious concerns regarding the proposed individual contraceptive arrangement. First, we are concerned that the Departments' proposal to fund third-party providers under this scheme is unlawful. We ask the Departments to clarify under what statute Congress gave the Departments authority to allocate user fees as proposed.

We also have concerns that the individual contraceptive arrangement will be another way to funnel federal dollars to Planned Parenthood and other abortion providers. Notably, Planned Parenthood has an outsized role in filling prescriptions for contraceptives.¹⁷¹ We ask the Departments to clarify how their proposal complies with the Hyde Amendment and what safeguards will be put in place to ensure that taxpayer dollars do not fund abortion. We also ask the Departments to exclude abortion providers from any administrative allowance adjustments.

If the individual contraceptive arrangement is finalized, we support the proposal to establish recordkeeping requirement with which the third-party providers must comply as a condition of participation. However, we are concerned that there are not sufficient safeguards in place to ensure reimbursement will be for eligible women only. The Proposed Rule acknowledges that women could provide "various types of representations" about their eligibility.¹⁷² We ask that the Departments create a standard form for women requesting contraception from a third-party provider where they can provide necessary insurance information and attest and sign that they are, indeed, eligible. This would streamline the representation for which providers can in good faith rely, removing any ambiguity over what is considered reasonable and good faith reliance. We also ask that the Departments explain how they plan to conduct oversight of the reimbursements to ensure that federal dollars are not being used for any unauthorized purposes.

V. The Departments should not revoke the moral exemption.

The Proposed Rule would revoke the 2018 Rule's moral exemption, which created an "exemption for entities and individuals that object to contraceptive coverage based on non-religious moral beliefs."¹⁷³ For a variety of reasons it would be a mistake for the Departments to reverse course on their earlier decision to dignify non-religious moral exemptions to their contraceptive mandate.

A. The Departments should not denigrate non-religious moral opposition to the contraceptive mandate.

The Departments proposed elimination of the moral exemption unjustly and unreasonable because it denigrates non-religious moral opposition to participating in the Defendants' mandate. While the Departments claim to "respect non-religious moral objections," they will only accept solutions that "would balance *the interests* of entities with non-religious moral objections against *the strong public interest* of ensuring women have access to contraceptive services without cost."¹⁷⁴ In other words, the Departments do not believe there is any public interest in addressing the moral convictions of non-religious Americans.

¹⁷¹ https://www.plannedparenthood.org/uploads/filer_public/33/63/3363814b-938e-4ad5-87d2-

<u>57ee98790766/190117-irreplaceable-role-pp-v01.pdf</u> (explaining that while Planned Parenthood accounts for only 6% of publicly funded health clinics, it serves 32% of all contraceptive clients).

¹⁷² 88 Fed. Reg. at 7257.

¹⁷³ 83 Fed. Reg. at 57, 592.

¹⁷⁴ 88 Fed. Reg. at 7250 (emphasis added); *see also id*. ("The Departments are of the view that non-religious moral objections to contraceptives are outweighed by *the strong public interest* in making contraception coverage as accessible to women as possible.").

This is doubly wrong. First, as documented above, on twenty-six occasions Congress has rejected bills that would have created a contraceptive mandate. The Departments certainly wanted to create a contraceptive mandate, but it appears that they thought that doing so would be so controversial they avoided the notice and comment process. The impetus for the mandate did not come from Congress but rather from a committee with the IOM stacked with people who had strong connections to pro-abortion advocacy groups. The Departments surreptitious conduct in 2011 tacitly admits that they knew the public did not have an interest, let alone a strong interest, in their mandate.

Second, the Departments' approach is wrong because it denigrates objections to the contraceptive mandate. The Departments' unstated premise seems to be that there are no legitimate reasons to being against contraceptives; therefore, it must be that people who oppose the mandate are in favor of discriminating against women. This attitude has infected the Departments' approach to enforcing their mandate since the beginning, when HHS Secretary Sebelius told the NAACP's Annual Conference that fighting against those seeking exemptions from the contraceptive mandate was like supporting "the fight against lynching."¹⁷⁵

The Departments' position seems to be that they will only honor oppositions to their policy approach when federal law, such as RFRA, and the First Amendment require them to do so. But wherever they can the Departments will coerce people into complying with their mandate because, in the end, there are not good and non-discriminatory reasons for opposing their will. This approach is first of all offensive to Catholics and other people with religious or moral opposition to facilitating contraception, sterilization, and abortion-inducing drugs. Second, it betrays substantial ignorance, as there are longstanding, philosophically rigorous reasons to oppose contraception, sterilization, and abortifacients that rest on sound, non-discriminatory presuppositions.

Philosophical objections to contraception and sterilization are often found in the natural law tradition. For example, philosopher Germain Grise contends that the conclusion that contraception is always wrong, is discernable through practical reason.

All men have certain basic drives or inclinations or orientations—call them what you like and these are what open us up to the whole possibility of human growth and development. Each of these drives has a particular object, and these objects, grasped as such by an insight of our practical intelligence, are the basic human goods. Our practical reason—reason concerned with what we ought to do—finds in these goods the starting points for working out the rules of our behavior.

The outcome of this process is what we call conscience—the conclusion we reach, by reasoning from these starting points, about what ought to be done. An action that is always wrong is one which requires that the person performing it set his will against one or more of these basic goods, and thereby also turn against one or more of the starting points of his practical reason. For this reason an immoral action of this kind is also fundamentally irrational....

If you take all the basic goods together, they represent the sum total of possible human achievement. As the fundamental principles and objects of human activity, they are absolutely indispensable in opening the door to personal growth and the advancement of die human community....

¹⁷⁵ Kathleen Sebelius, Remarks at 104th NAACP Annual Conference (July 16, 2013), *available at* <u>https://web.archive.org/web/20130718201102/http://www.hhs.gov/secretary/about/speeches/sp20130716.html</u>.

The evidence [that there are such basic goods] exists in the findings of psychology and anthropology. Although they differ among themselves in their terminology and on just what to include and exclude from the list, specialists in these disciplines have come to a remarkable degree of agreement on the existence of a number of basic human inclinations—things like the tendency to preserve life, the tendency to mate and raise children, the tendency to explore and question, and so on. These are the fundamental human drives, and their objects will be the basic human goods. And to repeat—an action is always wrong if it necessarily presupposes that the person performing it has set his will against one of these absolutely basic goods....

If contraception did anything be sides preventing conception, it might indeed be possible for a person to say that he intended *that* result instead of the prevention of procreation. But the plain fact of the matter is that contraception itself just doesn't do anything else except prevent a new life from beginning. If a person chooses contraception, he can't be choosing anything except to prevent procreation. And if he chooses to prevent procreation, he can only be setting his will against it.....

[E]ven though action toward procreation isn't always desirable, it's always wrong to act in a way that involves turning directly against it. You can compare this to the case of a person suffering from a fatal and incurable illness. It may not be desirable to take extraordinary means to prolong such a person's life, when continued life will only mean more suffering and misery for him. But that doesn't mean you can ever take measures to end his life. To put it another way, you needn't always keep a sick man alive, but you can't ever kill him. In the same way, you needn't always seek procreation, but you shouldn't ever prevent it.¹⁷⁶

The Departments are certainly aware there also non-religious moral objections to the abortifacients included in the contraceptive mandate. As noted in the Proposed Rule, they have already lost a lawsuit brought by an organization with non-religious objections to the mandate, *March for Life v. Burwell*.¹⁷⁷

Additionally, EPPC president Ryan T. Anderson and EPPC fellow Alexandra DeSanctis provide extensive secular reasons to oppose abortion in their recent book, *Tearing Us Apart: How Abortion Harms Everything and Solves Nothing*:

While it's essential to focus on the unborn child—whose death is the gravest harm of abortion—there's much more that needs to be said, because abortion harms far more than the child in the womb. The case against abortion is far more comprehensive. Abortion harms every single one of us by perpetuating deeply rooted falsehoods about what it means to be human. Abortion attacks the humanity and value of the child in the womb. Abortion strikes at the bond between mother and child, turning it into a conflict between adversaries and a justification for violence, a relationship not of love but of antagonism and mutual destruction. Abortion corrupts the relationship between man and woman and rejects the responsibilities that mothers and fathers have to their children and to one another. Abortion cuts at the fabric of marriage and of entire families, harming mothers, fathers, siblings, and grandparents.

¹⁷⁶ Germain Grisez, *Contraception ... Is It Always Wrong*? (Huntington, Ind.: Our Sunday Visitor, 1965); *see also* Germain Grisez, Joseph Boyle, John Finnis, William E. May, *Every Marital Act Ought to Be Open to New Life: Toward a Clearer Understanding*, 52 Thomist No. 3, 365 (July 1988).

¹⁷⁷ 88 Fed. Reg. at 7239.

Abortion distorts science and corrupts medicine, pretending that the child in the womb isn't a human being at all and that tools meant for healing can rightly be turned to killing. Abortion perverts what it means to live in a justly ordered political community with laws that protect all of us—and in a society where our laws say that some human beings don't deserve to live—we are all at risk. Abortion leads to a particular devaluation of unborn children diagnosed with illnesses or disorders in the womb, as well as a devaluation of girls in parts of the world where sons are more highly prized. It undermines solidarity with the poor, the week, the marginalized, people with disabilities, and anyone on the periphery of life. It allows those in power to deem certain lives expendable, allowing people to eliminate "populations that we don't want to have too many of," in the words of the ate Supreme Court justice Ruth Bater Ginsburg. Abortion has been a disaster.¹⁷⁸

Though the Departments might not agree with these secular arguments against contraception, sterilization, and abortion, these positions are intellectually rigorous, non-discriminatory, and worth honoring. It is inappropriate for the Departments to develop policy on the false presumption that there are no good non-religious reasons to oppose cooperating with the mandate.

B. Congressional intent does not justify revoking the moral exemption.

Additionally, it is arbitrary and capricious for the Departments to try to use Congress' protections (or lack thereof) for non-religious convictions in other contexts to justify rescinding the moral exemption from the 2018 Rule.

The Proposed Rule notes the 2018 Rule "referred to a number of Federal statutes demonstrating Congress' historical desire and intent to protect non-religious moral objections to abortion and other activities.¹⁷⁹ "However, the Departments now find it significant that Congress chose not to apply those statutory provisions to private entities that typically do not accept funds from or do business with the government, that is, entities that are, in that respect similar to sponsors of private group health plans."¹⁸⁰

This analysis is fundamentally flawed for several reasons. First, though Congress may not have created legislation to specifically address moral objections in this context, the Departments recognize that Congress has in many places recognized that the federal government has an important interest in protecting rights of conscience and respecting Americans' moral convictions. The same cannot be said, however, for the interests that the Departments invoke in support of their mandate. As noted above, Congress has never passed any law mandating that private employers give their employees free access to contraceptives, let alone abortifacients, and sterilization procedures. Every single time such legislation has been introduced in Congress it has died in committee. It is arbitrary and capricious for the Departments to find it "significant" that Congress did not pass a law that clearly thwarts one aspect of how they want to implement their mandate when the Departments do not find it "significant" that Congress never asked for a contraceptive mandate in the first place.

This first reason also points to another reason: Congress did not pass a law to require the Departments to respect moral conscience in this specific context *because it did not anticipate and did not ask for this specific context*. The most obvious reason that Congress has not protected the conscience rights of "private entities that typically do not accept funds from or do business with the government" is

¹⁷⁸ Ryan T. Anderson & Alexandra DeSanctis, *Tearing Us Apart: How Abortion Harms Everything and Solves Nothing*, 3-4 (Regency 2022); *see also* Ryan T. Anderson & Andrew T. Walker, *No, Overturning* Roe *Would not Establish Theocracy*, First Things, May 23, 2022, <u>https://www.firstthings.com/web-exclusives/2022/05/no-overturning-roe-would-not-establish-theocracy</u>.

 ¹⁷⁹ 88 Fed. Reg. at 7250 (citing 83 Fed. Reg. 57,592, 57,599).
 ¹⁸⁰ Id.

that Congress has never passed a law that impinges on the moral convictions of such private entities. The Departments have created this mandate on their own accord. That deprived Congress of the opportunity to think through the implications of such a mandate and debate what sort of provision should be made for private entities with moral objections to Congress' policy objections.

Given that Congress did not anticipate a contraceptive mandate at all, the Departments cannot reasonably infer anything from Congress' failure to create a non-religious moral exemption. The Departments' argument that it should eliminate the 2018 moral exemption on this basis is thus arbitrary and capricious. There are less restrictive means to ensure access to contraceptive services if that is really deemed necessary by the Departments.

Historically, leading political actors have stressed publicly the necessity of conscience protection. This Proposed Rule runs contrary to recent statements on rights of conscience by President Obama, President Biden, and the Supreme Court:

President Obama: "So here's what I would say, that ... we should foster a culture in which people's private religious beliefs, including atheists and agnostics, are respected. And that's the kind of culture that I think allows all of us, then, to believe what we want. That's freedom of conscience. That's what our Constitution guarantees."¹⁸¹

President Obama: "Our interests and our **conscience** compel us to act on behalf of those who long for freedom."¹⁸²

President Obama: "Let's honor the conscience of those who disagree with abortion."¹⁸³

President Obama: "Under our plan, no federal dollars will be used to fund abortions, and federal conscience protections will remain in place."¹⁸⁴

President Biden: When responding to a request from a constituent in 1994 stating "please don't force me to pay for abortions against my conscience," then Senator Biden wrote, "I agree with you."¹⁸⁵

Supreme Court of the United States: "The Court's suggestion that coercion must be 'direc[t]' to be cognizable under the Establishment Clause is contrary to long established precedent. The Court repeatedly has recognized that indirect coercion may raise serious establishment concerns, and that 'there are heightened concerns with protecting **freedom** of conscience from subtle coercive pressure in the elementary and secondary public schools."¹⁸⁶

¹⁸¹ Zaimov Stoyan, *Obama Admits 'Bias' Against Atheists in Bill Maher Interview, but Questions 'Active Persecution' Complaint*, The Christian Post, November 7, 2016, <u>https://www.christianpost.com/news/obama-admits-bias-against-atheists-bill-maher-interview-persecution.html</u>.

¹⁸² President Obama, Inaugural Address, The American Presidency Project, January 21, 2013, <u>https://www.presidency.ucsb.edu/documents/inaugural-address-15</u>.

 ¹⁸³ President Obama, Members of Congress urge Obama to maintain conscience protection, <u>https://www.archbalt.org/members-of-congress-urge-obama-to-maintain-conscience-protection/?print=print.</u>
 ¹⁸⁴ President Obama, <u>https://bilirakis.house.gov/media/press-releases/independent-nonpartisan-report-presidents-health-law-uses-taxpayer-dollars.
</u>

¹⁸⁵ Senator Biden, 1994 Letter, https://www.documentcloud.org/documents/6127592-biden94letter.

¹⁸⁶ Top Quotes: Supreme Court affirms free religious expression for football coach, <u>https://erlc.com/resource-library/articles/top-quotes-supreme-court-affirms-free-religious-expression-for-football-coach/</u>.

Supreme Court of the United States: "We hold that the Departments had the authority to provide exemptions from the regulatory contraceptive requirements for employers with religious and **conscientious objections**."¹⁸⁷

C. The Departments cannot claim an interest in coercing objecting employers into complying with its mandate when Congress decided to leave "tens of millions" of women outside of its mandate.

The Departments cannot plausibly claim a compelling interest in revoking the moral exemption when Congress has voluntarily left "tens of millions" without the assurance that they can receive free contraceptive services through their employer.¹⁸⁸ The numbers of people who fall under the two secular exceptions to the mandate remain massive and the number of people enrolled in grandfathered plans has remained steady since this Court decided *Hobby Lobby* in 2014.

Congress' decision to leave these tens of millions outside the reach of the ACA's preventive services mandate undercuts the Departments' ability to prove a compelling interest in imposing their contraceptive mandate on objecting employers. It further suggests that the Departments ought to be satisfied that the federal government has other means of ensuring women have access to contraceptives. Surely Congress thought through what its exemptions would mean for the women who work for small employers or firms with grandfathered plans and found the risks of their policy decisions worthwhile.

The Departments' insistence that employers with non-religious moral objections *must* be subjected to their contraceptive mandate is especially weak given its decision to leave huge swaths of employees unprotected by the mandate's basic promise. In *Hobby Lobby*, this Court noted that the contraceptive mandate does not apply to tens of millions of people.¹⁸⁹ This remains the case today.

First, the ACA's small business exception covers 96% of employer firms, which together employ about 28% of all workers, or 34 million people.¹⁹⁰ Second, while the Departments have long been downplaying the significance of the ACA's grandfathered exception, it still remains significant 13 years after ACA was first passed. In 2016, government has claimed the grandfathered plan exception is "quickly phasing down,"¹⁹¹ But according to the Kaiser Family Foundation (KFF), in 2020 16% of firms offering health benefits offer at least one grandfathered health plan, and 14% of covered workers are enrolled in a grandfathered plan.¹⁹² Given KFF's tally that "Employer-sponsored insurance covers almost 155 million nonelderly people,"¹⁹³ this means that about 21.7 million people are enrolled in grandfathered plans.

Taken together, because of the grandfathered exemption and the small employer exemption that Congress built into the ACA, well over 50 million American employees are on employer health plans that are not subject to the Department's contraceptive mandate. It beggars belief that, despite these choices

¹⁸⁷ https://www.supremecourt.gov/opinions/19pdf/19-431_5i36.pdf.

¹⁸⁸ Hobby Lobby, 134 S. Ct. at 2764 (quotation omitted).

¹⁸⁹ Id.

¹⁹⁰ Sean Lowry, *The Affordable Care Act and Small Businesses: Economic Issues*, 9 (Cong. Research Serv. Jan. 15, 2015); 26 U.S.C. § 4980H(c)(2) (firms with fewer than 50 full-time employees need not provide their employees with a health plan at all).

¹⁹¹ Br. in Opp. at 5 n.4, *Zubik* (No. 14-1418 et al.).

¹⁹² 2020 Survey https://www.kff.org/health-costs/report/2020-employer-health-benefits-survey/.

¹⁹³ Kaiser Family Foundation, 2021 Employer Health Benefits Survey (Nov. 10, 2021), <u>https://www.kff.org/report-</u> section/ehbs-2021-summary-of-findings/.

made by Congress, the Departments would cite Congress' supposed interests in support of their plan to issue new regulations in order to expand their mandate to an estimated 15 women.

[When the Defendants came before the Supreme Court in *Zubik*, they] admitted for the first time in its merits brief that its interests actually did not require women to receive complete cost-free contraceptive coverage from their employers. Instead, the government acknowledged that its interests would be satisfied so long as women had access to a plan with some contraceptive coverage, which they could obtain from many sources, including "a family member's employer," "an Exchange," or "another government program." As the government told the Court, "All of these sources would include contraceptive coverage." These secular exceptions may show that the government cannot prove a compelling interest because it has left "appreciable damage to [its] supposedly vital interest[s] unprohibited."

The government's decision to leave "tens of millions" without guaranteed access to free contraceptive services through their employers suggests that the mandate does not advance a compelling interest. As the Supreme Court has noted, a law "cannot be regarded as protecting an interest of the highest order when it leaves appreciable damage to that supposedly vital interest unprohibited."¹⁹⁴

The existence of the grandfathered plan exception and the small employer exception suggest that the government in each case found policy interests that took precedence over its articulated interests in "public health" and "gender equality." In the small employer exception, it appears that Congress' desire to expand access to preventive health services through employer health plans yielded to the desire to promote small businesses. The grandfathered exception probably reflects the political pressure the administration felt to make good on President Obama's promise that "[i]f you like your health care plan, you can keep your health care plan." But practically it gives an out to corporations who want to "avoid[] the inconvenience of amending an existing plan."¹⁹⁵

Congress was well within its rights to make these policy choices. But these choices constrain the Departments' ability to say that the public interest in advancing access to *any preventive care services*, let alone contraceptives and abortifacients,¹⁹⁶ takes precedence over the public interest in honoring Americans' honest, reasonable moral convictions.

¹⁹⁴ Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 547 (1993).

¹⁹⁵ *Hobby Lobby*, 134 S. Ct. at 2780.

¹⁹⁶ To the extent the Departments continue to insist (against all evidence) that Congress willed a contraception mandate, the Departments would have to contend with the argument that Congress would not have minded making these enormous exceptions to the contraceptive mandate that almost all women had access to contraceptives *before* the Mandate went into effect. According to the IOM Report, 99% of women who have ever had sex and 89% of currently sexually active women use contraceptives. IOM Report at 103 (citing William D. Mosher & Jo Jones, *U.S. Dep't of Health and Human Servs., Use of Contraception in the U.S.: 1982-2008*, 5, 9 (2010)).

The IOM Report also failed to prove any correlation between cost and access to contraceptives. Only one paragraph in the entire report attempts to make this correlation, but the studies it relies on do not connect the dots. *Id.* at 109. The first study explores the connection between cost and access to preventive care generally, but it doesn't focus on contraception and collected data only from low-income populations. *Id.*; Helen V. Alvaré, *No Compelling Interest: The "Birth Control" Mandate and Religious Freedom*, 58 Vill. L. Rev. 379, 428-29 (2013) The second also says nothing about contraceptive access, as it studied women aged 65-69 enrolled in Medicare. IOM Report at 109; Alvaré at 429. Nothing in the report shows that women enrolled in an employer-sponsored health plan forgo contraception when it is not free.

D. The Departments' legal arguments for revoking the moral exemption are arbitrary and capricious.

The Proposed Rule's discussion of potential litigation that may result from revoking the moral exemption is also arbitrary and capricious. The Departments acknowledge that they have lost at least one lawsuit on this issue, citing the *March for Life* case, where a federal court issued a permanent injunction against the Departments because there was "no rational basis for the Departments to distinguish between religious and moral objections."¹⁹⁷ The Departments "respectfully disagree" with this decision vindicating the plaintiff's non-religious moral objections on the basis that "there is no analogous need to heed the possibility of successful claims to a non-religious moral exemption."¹⁹⁸ This makes no sense. If the Defendants' only reason to disagree with a court that found in favor of a plaintiff with non-religious objections to the mandate is that the Defendants do not believe they will lose another such lawsuit in the future, then the Defendants are involved in wishful thinking rather than reasoned decision making. The Departments' dismissive treatment of *March for Life* is the epitome of arbitrary and capricious reasoning.

Moreover, *March for Life* is not the only court decision upholding the moral exemption rule. In 2021, a federal court upheld the moral exemption against the Commonwealth of Massachusetts' claims that it was illegal under the Administration Procedure Act and the Equal Protection Clause.¹⁹⁹ The court held that it was proper for the Departments to consider that "additional objecting employers 'might come into existence'" and found that "the Departments adequately considered the relevant reliance interests in promulgating the Final Rules."²⁰⁰ The court furthermore found that "the Supreme Court has indicated, and the Commonwealth does not dispute, that the accommodation of sincerely held … moral beliefs is an important government interest" and that "expanding existing exemptions to cover a broader range of entities with sincere … moral objections to the contraceptive mandate is indubitably related to that goal of accommodating such objectors."²⁰¹

The Proposed Rule does not adequately engage with caselaw that upheld a non-religious employer's objections to the mandate and that found that the moral exemption furthers important governmental interests. In future rulemaking it is incumbent upon the Departments to do so.

In addition, the Departments opt not to apply its proposed individual contraceptive arrangement to women without access to contraceptive services under grandfathered plans, further undercutting the Departments' alleged interest and need for removal of the moral exemption.

E. The Departments' proposal to revoke the moral exemption is gratuitous as it affects very few women.

The Departments declare that their 2018 decision to respect non-religious moral objections to their mandate was wrong because of the "strong public interest in making contraceptive coverage as accessible to women as possible."²⁰² Yet, as discussed above, the Proposed Rule acknowledges, "The Departments are of the view that few entities make use of the moral exemption at this time."²⁰³ Indeed, the Departments acknowledge that honoring these conscientious objectors' convictions "likely affects very few individuals."²⁰⁴ For reference, in the 2018 regulations, the Departments estimated that

¹⁹⁷ 88 Fed. Reg. at 7249.

¹⁹⁸ Id.

¹⁹⁹ Massachusetts v. U.S. Dep't of Health & Human Servs., 513 F. Supp. 3d 215 (D. Mass. 2021).

²⁰⁰ *Id.* at 224 (quoting 83 Fed. Reg. 58,626).

²⁰¹ *Id.* at 229.

²⁰² 88 Fed. Reg. at 7250.

²⁰³ *Id.* at 7249.

²⁰⁴ Id.

"approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules."²⁰⁵ Because so few women are affected by the moral exemption, it is gratuitous for the Departments to remove the moral exemption. All the more, considering the Departments propose the alternative contraceptive arrangement as an option to provide access to contraceptive services.

VI. The Departments should consider alternative approaches to the Proposed Rule.

The Departments make a lot of contradictory claims in support of the Proposed Rule. On the one hand, the Departments "have determined that *it is necessary* to provide [women that work for objecting religious employers] with an *alternative pathway* [i.e. the individual contraceptive arrangement] to obtaining contraceptive services at no cost." On the other hand, the Departments claim "*it is necessary* to provide [women that work for objecting non-religious employers] with such coverage *directly through their plan*." (emphases added). Nothing in the Proposed Rule resolves this contradiction.

This contradiction makes the proposal to rescind the moral exemption arbitrary and capricious. But beyond this contradiction, the Departments' conclusion that non-"seamless" means of making contraceptive services available are now acceptable means that the Departments must now revisit a wide range of alternatives that they have dismissed as inadequate for many years in litigation and in rulemaking.

A. The Departments have no remaining objections to less restrictive alternatives proposed by mandate plaintiffs.

Over the past decade mandate plaintiffs have proposed many alternatives means of advancing the Departments' interests that would be less restrictive of religious exercise than coercing them to violate their conscience. Now that that the Departments have conceded that "seamless" access is not essential, they must revisit these alternatives before they impose new burdens on the consciences of religious and non-religious employers with sincere objections to cooperating with the Departments' scheme.

B. The Departments have not explained why alternative methods of providing access to contraceptives are not adequate here.

The Proposed Rules fails to explain why the Departments' interests here are not adequately advanced by other avenues of accessing contraceptives *that the Defendants themselves told the Supreme Court were adequate alternatives* in another context. In *Zubik v. Burwell*, the Departments told the Court that *secular* exemptions that left "tens of millions" of women outside their mandate's guarantees (the small employer and grandfathered plan exemptions) did not count against their supposed interest in coercing *religious* employers. The Departments told the Court that these secular exemptions did not count against their interests because it was likely that women that worked for employers subject to these secular exemptions still had acceptable access to contraceptives through "a family member's employer," "an Exchange," or "another government program." As the government told the Court, "All of these sources would include contraceptive coverage."²⁰⁶ Nothing in the Proposed Rule explains why these alternatives are good enough for women that work for employers that work for employers with grandfathered plans but not for employers with moral objections to the mandate. Revoking the moral exemption without explaining this contradiction is arbitrary and capricious.

²⁰⁵ 83 Fed. Reg. at 57,592, 57,627.

²⁰⁶ See Rienzi, supra note 138, at 30 (citing Brief for the Respondents at 65, Zubik v. Burwell, 136 S. Ct. 1557 (2016) (No. 14-1418), available at https://www.scotusblog.com/wp-content/uploads/2016/02/14-1418bsUnitedStates.pdf).

C. The Departments have not explained why market forces are inadequate.

The Departments should consider not regulating and allow market forces to fill the gap for any lack of access to contraception. If the Departments can identify a market failure, they should also consider how other regulations can provide access to contraception for women not through a religious or morally-objecting organization, such as through the Title X program. Another alternative the agencies should consider are educational campaigns, such as letters sent last year to insurers about the ACA's requirement to cover contraception²⁰⁷ and individual administrative or enforcement actions against any offenders.

D. The Departments should not regulate issuers as an end run of providing religious and moral exemptions.

The Departments seek comment regarding whether the exemption of an entity should exempt to the issuer or whether the issuer should be bound by the contraceptive coverage requirement.²⁰⁸ We have no objection to an issuer being required to provide contraception *so long as* the entity is still able to receive the religious or moral exemption and is not required to be complicit in assisting the issuer in providing contraception contrary to their sincerely held religious or moral beliefs. Without such safeguards, this requirement would create an end-run of the First Amendment's or RFRA's requirements by opting to instead require the insurance provider, who does not have any religious objections to contraception, to provide plans with coverage for contraception. This requirement would be suspect, a form of religious targeting, and cause direct harm.²⁰⁹

VII. The Departments should consult with religious freedom experts, including the career professionals in the (former) Conscience and Religious Freedom Division.

We ask the Departments to clarify how they will evaluate requests for religious and moral exemptions. We also ask for clarity over how complaints of violations of the contraceptive mandate will be handled, especially when it comes to an entity claiming a religious or moral exemption. Specifically, which offices be involved and will the staff in those offices have particular expertise with religious freedom obligations?

Under Secretary Becerra, the Conscience and Religious Freedom Division in the Office for Civil Rights of HHS, which was dedicated to protecting conscience and religious freedom rights, was sidelined and the career professionals with expertise in conscience protection laws were prohibited from investigating complaints under those laws or from advising on conscience and religious freedom related matters. Indeed, after this rule was proposed, HHS announced a restructuring of OCR, which officially eliminated the Conscience and Religious Freedom Division.²¹⁰ This move suggests that HHS does not take protections for conscience and religious freedom rights seriously and intends to treat them as second-class.

²⁰⁷ Letter from Secretaries of HHS, Treasury, and Labor to Group Health Plan Sponsors and Issuers (June 27, 2022), https://www.cms.gov/files/document/letter-plans-and-issuers-access-contraceptive-coverage.pdf.

²⁰⁸ 88 Fed. Reg. at 7248.

²⁰⁹ Cf. Cedar Park Assembly of God of Kirkland, Washington v. Kreidler, f. Cedar Park Assembly of God of Kirkland, Washington v. Kreidler, No. 20-35507, *1 (9th Cir. Jul. 22, 2021) (Church "plausibly alleged that, due to the enactment of [state law requiring insurance coverage for abortion], its health insurer (Kaiser Permanente) stopped offering a plan with abortion coverage restrictions and [the church] could not procure comparable replacement coverage. This is sufficient to state an injury in fact that is fairly traceable to [the state law].").
²¹⁰ 88 Fed. Reg. 12,955 (Feb. 25, 2023) (Statement of Organization),

https://www.federalregister.gov/documents/2023/03/01/2023-03892/statement-of-organization.

Unfortunately, there has been a concerning trend by HHS to cut the career CRFD professionals out of the review process for proposed rules that implicate conscience and religious freedom rights. Indeed, HHS has only made it more difficult across the board for the agency to enforce vital conscience and religious protections in healthcare. For example, Secretary Becerra removed from the HHS Office for Civil Rights (of which the CRFD is part) the delegation of authority to enforce RFRA. Further, HHS and specifically Secretary Becerra have shown a distain for conscience and religious rights even going so far as to not enforce statutory protections for those who have conscience and religious objections to providing abortion.²¹¹

We urge HHS to utilize the expertise of the career professionals of the former Conscience and Religious Freedom Division in not just evaluating this proposal, but also in investigating complaints alleging violations of the contraceptive mandate against an entity claiming a religious or moral exemption.

VIII. The Departments fail to consider the harms of the Proposed Rule.

A. The Departments use an incorrect baseline for analysis.

When analyzing benefits for the Proposed Rule, the Departments use an incorrect baseline for analysis. The Departments claim that the 2018 rules left "many women without coverage."²¹² Yet it fails to provide any specifics such as to how many women are of childbearing age and how many were unable to obtain contraception through other means. The Departments claim a general benefit of "increased access" to contraceptive services, but that is not a benefit provided by the Proposed Rule. The Departments can only claim benefits for those who (a) do not currently have access to contraception because of the 2018 rules, (b) desire access to contraception and are unable to obtain it, and (c) would be able to obtain access because of the Proposed Rule.

B. The Departments fail to consider the costs of hormonal contraceptives.

This whole enterprise presumes hormonal contraceptives are a good thing. The Departments claim that "access to contraception is an essential component of women's health care" and "is a national public health imperative."²¹³ The Proposed Rule repeatedly claims that contraception access is "critical" to women, especially in light of the *Dobbs* decision.²¹⁴ The Departments list a myriad of reasons or "harms of depriving" women of contraceptives.²¹⁵ Among these reasons, the Departments cite "prevent[ing] unintended pregnancies and … provid[ing] better health and economic outcomes for women."²¹⁶ The Departments focus on the consequences of actions rather than the health effects of the very medication they plan mandate. The Departments' proposal presumes the benefits of contraception outweigh the harms of contraception. These harms are not some radical right-wing conspiracies, but rather, mainstream acknowledged negative impacts. The Departments fail to consider the adverse effects of contraceptive use.

²¹¹ See, e.g., Rachel N. Morrison, In Its First Year, Biden's HHS Relentlessly Attacked Christians and Unborn Babies, Federalist (Mar. 18, 2022), <u>https://thefederalist.com/2022/03/18/in-its-first-year-bidens-hhs-relentlessly-attacked-christians-and-unborn-babies/</u>.

²¹² 88 Fed. Reg. at 7242.

²¹³ *Id.* at 7240.

²¹⁴ Id. at 7246 and 7250.

²¹⁵ *Id.* at 7240.

²¹⁶ Id.

The Proposed Rule cites a 2013 study "report[ing] that 99 percent of sexually-active women have used at least one method of contraception at some point during their lifetime."²¹⁷ While many women use hormonal contraceptives, the tide is changing. Increasingly, younger generations of women are becoming aware of the severe effects of hormonal contraceptives can have on their mental and physical well-being and are taking more holistic approaches to their fertility.²¹⁸

A study, published on March 21, 2023, showed that "current or recent use of combined oral contraceptives (containing oestrogen+progestagen) has been associated with" a 20% to 30% "higher chance" of being diagnosed with breast cancer.²¹⁹ Just like pregnancy, fertility is not a disease. Breast cancer is a serious and, in some cases, a terminal illness. The Departments must consider the impact increased access to contraceptive services will have on the health and well-being of women.

In fact, the Departments have touted the few times that supporters of the WHA actually mentioned terms that could be construed to support creation of a contraceptive mandate.²²⁰ But the stated purpose of the WHA was to help women access "preventive health services." Indeed, senators expressed much more interest in the WHA being used to increase access to screenings that would prevent women from having cancer:

- Cervical cancer (33 mentions);
- Breast cancer (86 mentions);
- Mammogram (99 mentions);
- Pap smear (15 mentions);
- Colon cancer (21 mentions); and
- Ovarian cancer (7 mentions).

Relatedly, women's reproductive health diagnoses are becoming more prevalent. For example, "1 in 10 women have been diagnosed with endometrioses," with the average diagnosis period being around 7 to 10 years.²²¹ One suggestion for the gap in reproductive medical diagnoses is that most young women are immediately instructed to begin hormonal contraception during their teen years. Rather than cure or treat any reproductive illnesses, birth control functions to mask serious symptoms while reproductive and other similar diseases continue to progress.

In addition to the purely outward physical side effects, contraception can have detrimental impacts on mental health, especially for younger women. A 2019 study found that "16-year-old girls reported higher depressive symptom scores when using oral contraceptives" and "may affect their quality

https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1004188; Bendix Aria,

²¹⁷ Id.

 ²¹⁸ Schlott Rikki, Why More Women, Like Me, Are Abandoning the Pill over Emerging Health Concerns, N.Y. Post, January 30, 2023, <u>https://nypost.com/2023/01/30/young-women-abandoning-birth-control-pills-for-mental-health/</u>.
 ²¹⁹ Fitzpatrick et al., Combined and Progestagen-Only Hormonal Contraceptives and Breast Cancer Risk: A UK Nested Case-Control Study and Meta-Analysis, PLOS Medicine, March 21, 2023,

Birth Control Methods that Use One Hormone Raise Breast Cancer Risk as Much as Those with a Combo, Study Finds, NBC News, March 21, 2023, <u>https://www.nbcnews.com/health/womens-health/hormonal-birth-control-</u>raises-breast-cancer-risk-rcna75286.

²²⁰ 88 Fed. Reg. 7254.

²²¹ Endometriosis Affects 1 in 10 Women: How We Diagnose and Treat This Condition, Texas Children's Blog, <u>https://www.texaschildrens.org/blog/2013/08/endometriosis-affects-1-10-women-how-we-diagnose-and-treat-condition</u>.

of life and put them at risk for nonadherence."²²² In fact, "teenage girls who use birth control pills are more likely to cry, sleep too much and experience eating issues than their peers who don't use oral contraceptives."²²³ These symptoms may not be short term or easily mitigated when women decide to stop taking oral contraceptives. "Research has shown that adolescents who use birth control pills are more prone to be at risk for depression in adulthood—regardless of whether they continue taking the pills when they get older."²²⁴ Another 2019 study found that "long-term association between adolescent OC use and depression risk in adulthood regardless of current OC use" and the "findings suggest that adolescence may be a sensitive period during which OC use could increase women's risk for depression, years after first exposure."225

The Proposed Rule stresses the "critical" nature of access to contraception for the very few women affected but does not acknowledge the harms and dangers of these medical interventions. The Proposed Rule emphasizes "the government's interest in protecting women's health" but sidesteps exploring whether contraception actually improves "women's health."226 It is unreasonable for the Departments to defend their mandate on the basis that it advances their interest in "reduc[ing] unplanned pregnancies" on a flimsy scientific record, while ignoring the substantial evidence that incentivizing women to take hormonal contraceptives will increase the rates of cancer that Women's Health Amendment was intended to combat.²²⁷

C. The Departments' requests for comments indicate a solution in search of a problem and a distain for entities claiming religious or moral exemptions.

The Departments' requests for comments indicate that they have prejudged the rule by requesting evidence to support the need for rulemaking, information which it should have acquired prior to making its proposal. For example, the following requests for comments demonstrate that the Departments do not have the specific evidence of need or harm to justify its rulemaking:

- "The Departments seek comment on the number of eligible individuals without access to contraceptive services without cost sharing under their existing plan or coverage or living in contraception deserts and the potential search costs of these proposed rules on such individuals."228
- "The Departments seek comment on adequate ways to ensure individuals are aware of the individual contraceptive arrangement, can learn if they are eligible, and can find participating providers to access contraceptive services at no cost."229

- ²²⁷ Id. at 7562.
- ²²⁸ Id. at 7263.

²²² De Wit AE, Booij SH, Giltay EJ, Joffe H, Schoevers RA, Oldehinkel AJ, Association of Use of Oral Contraceptives with Depressive Symptoms Among Adolescents and Young Women, 77 JAMA Psychiatry 52 (2020), doi:10.1001/jamapsychiatry.2019.2838.

²²³ Kaur Harmeet, Teen Girls on Birth Control Pills Report Crying More, Sleeping Too Much and Eating Issues, Study Says, CNN Health, October 30, 2019, https://www.cnn.com/2019/10/30/health/teens-birth-control-pillsdepressive-symptoms-trnd/index.html.

²²⁵ Anderl, C., Li, G. and Chen, F.S., Oral Contraceptive Use in Adolescence Predicts Lasting Vulnerability to Depression in Adulthood, 61 J Child Psychol Psychiatr 148 (2020), https://doi.org/10.1111/jcpp.13115. ²²⁶ 88 Fed. Reg. at 7242.

²²⁹ Id. at 7254.

- "The Departments seek comment on ways to mitigate search costs for eligible individuals and how access to the individual contraceptive arrangement can best be promoted."²³⁰
- "The Departments seek comment on potential barriers that might prevent providers, issuers, and eligible individuals from participating in the individual contraceptive arrangement."²³¹

Further, other requests for comments seek support for the conclusions in the Proposed Rule, rather than any relevant evidence supporting or opposing the Proposed Rule. For example, the Departments seek comments in support of their proposal to eliminate the moral exemption:

- "The Departments seek comment on how many women lost contraceptive coverage without cost sharing based on the moral exemption rule, and how many would regain access to such coverage by rescinding the availability of the moral exemption."²³²
- "The Departments seek evidence of the quantitative harms from the moral exemption rule."²³³
- "It is now the Departments' view that the potential harm to these individuals was not adequately considered when the Departments adopted the November 2018 moral exemption final rules. The Departments seek comment on the potential impact to these individuals."²³⁴

In contrast, there are no requests for comments about the benefits of the moral exemption to those entities and the harms that would result to those entities upon removal of the moral exemption. Additionally, the Departments should consider the cost of any loss of free exercise of religion rights which results in irreparable harm.

We recognize that the Departments gave the public 60 days to provide meaningful public comment on such a major and significant Proposed Rule. This has unfortunately not been the norm for HHS and other agencies under the current administration²³⁵ and we applaud the Departments for not following that trend for this Proposed Rule.

CONCLUSION

We urge the Departments to abandon and withdraw the Proposed Rule.

Sincerely,

Rachel N. Morrison, J.D. Fellow and Director HHS Accountability Project Ethics & Public Policy Center

²³⁰ *Id.* at 7263.

²³¹ *Id.* at 7264.

²³² *Id.* at 7249.

²³³ Id.

²³⁴ *Id.* at 7249, 7250.

²³⁵ For example, HHS's Centers for Medicare & Medicaid Services (CMS) published a 145-page, triple-columned notice of proposed rulemaking on January 5 with a public comment deadline on January 27—a mere 22 days to provide input on a complex, major, and economically significant proposed rule.

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