ETHICS AND PUBLIC POLICY CENTER

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Via Federal eRulemaking Portal

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200 Independence Avenue SW
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Lisa M. Gomez
Assistant Secretary
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue, NW
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Melanie R. Krause
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Department of the Treasury
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Re: HHS/DOL/Treasury Proposed Rule, "Enhancing Coverage of Preventive Services Under the Affordable Care Act" RIN: 0928-AV57 (HHS); 1210-AC25 (DOL); 1545-BR35 (TREAS)

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, "Enhancing Coverage of Preventive Services Under the Affordable Care Act" (Proposed Rule).[1]

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[1] HHS/DOL/Treasury Proposed Rule, Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85,750 (Oct. 28, 2024).

This is not the first time that EPPC scholars have objected to the Department's contraception mandate. We renew our general objection to the Departments' mandate, including many arguments we made in April 2023. Congress did not authorize the Departments to create a contraception mandate. The mandate is and has always been an abuse of the limited authority that Congress delegated to HRSA under the Women's Health Amendment to the Affordable Care Act.

This comment also focuses on one particular aspect of the Proposed Rule, the Departments' attempt to expand the contraception mandate even further by requiring covered entities to provide free coverage to any over-the-counter (OTC) contraceptives without a doctor's visit. This requirement, particularly as it relates to any hormonal contraceptives that the FDA makes available OTC, creates significant new risks for women's health, new practical problems, new religious liberty issues, and new legal questions that the Proposed Rule does not adequately account for.

For all these reasons, the Departments should abandon and withdraw the Proposed Rule.

I. EPPC Scholars renew their April 2023 objections to the Departments' contraception mandate.

In February 2023, the Departments issued a proposed rule that would keep its contraception mandate in place, while rescinding the moral exemption and establishing a new "individual contraception arrangement."[2] On April 3, 2023, we submitted a public comment strongly opposing that proposal.[3]

The issues we raised at that time remain relevant to the Proposed Rule. As that February 2023 proposed rule is still pending, the Departments have not yet responded to the concerns we voiced in our April 2023 public comment. We renew them here to remind the Departments of these concerns and to remind the Department of these ongoing, fundamental concerns about the legality of the Departments' crusade, dating back to 2011, to impose on the American healthcare system an ever-expanding contraception mandate that Congress did not ask for and for which the Departments have no delegated authority.

A. There is no need for the Proposed Rule.

For any rulemaking, EO 12866 requires that agencies identify the problem they intend to address.[4] 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.[5] 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 caused or will cause harms or burdens necessitating the need for this rulemaking.

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[2] 88 Fed. Reg 7236.

[3] EPPC Scholars' Comment, Opposing HHS/Labor/Treasury Proposed Rule "Coverage of Certain Preventive Services Under the Affordable Care Act," RIN 0938-AU94, (Hereinafter "EPPC April 2023 Public Comment"), https://eppc.org/wp-content/uploads/2023/04/EPPC-Scholars-Comment-Opposing-Contraceptive-Mandate-Proposed-Rule.pdf.

[4] 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.").

[5] *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").

Additionally, to the extent the Departments have articulated any such harms or burdens, they have failed to show that the proposed regulations will remedy these concerns.

- **General claims of lack of access to contraceptive services do not create a need for rulemaking.**[6]

    - To begin, "pregnancy" is not a disease. Not as a general matter, and not in the context of the Women's Health Amendment (WHA). It is arbitrary and capricious for the Departments to claim otherwise. For that reason alone, Congress did not delegate authority to create a contraception mandate under the WHA.

    - Leaving this point aside, the Departments continue to try to justify both their contraceptive mandate as a whole and each successive iteration of their mandate by making speculative and unjustified claims of "harm," alleged (but not substantiated) problems with the mandate in its present form, and equally unjustified claims that each new proposal will meaningfully solve these same "access" problems. The Departments' speculations are unwarranted and do not satisfy their obligations under the Administrative Procedure Act (APA).

- ***Dobbs* dose not create a need for rulemaking.**[7]

    - In April 2023, we argued that the Departments were wrong to claim that the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* justified yet another set of regulations under their contraceptive mandate. *Dobbs* said nothing about contraception; it merely recognized that there never has been a right to abortion in the U.S. Constitution.

    - Here again, the Departments claim again and again that *Dobbs* justifies their newest proposed additions to their contraception mandate.[8]

    - We reiterate our objection to the Departments' reliance on *Dobbs* as justifying this proposed rulemaking. Nothing about *Dobbs* or various commenters' *Dobbs*-adjacent handwringing creates a need that justifies the Departments' efforts to coerce health plans into paying for non-prescription contraceptives.

B. The contraception mandate is unlawful because Congress has not declared any interest, let alone a compelling interest, in mandating contraceptive and abortifacient coverage.

We also renew here our April 2023 objections to the Departments' contraceptive mandate as a whole.[9] Contrary to the Departments' representations, Congress never intended for the Departments to create a contraception mandate and the WHA never charged the Department with ensuring women seamless access to contraceptives.

When bills have been introduced to create a contraceptive mandate, Congress has said no each and every time. Our April 2023 comment detailed the history of the Departments' contraception mandate,

[6] *Id*. at 2-3.
[7] *Id*. at 3-6.
[8] 89 Fed. Reg. at 85755, 85756, 85762.
[9] EPPC April 2023 Public Comment at 10-15.

including the Departments' nineteen previous regulatory changes stretching back over a decade. This legislative history makes clear that the Departments' contraception mandate reflects *their* interests, not Congress' interests. This distinction has important legal and constitutional significance.

We also remind the Departments that while this is now at least the twentieth rulemaking related to the contraceptive mandate, *the contraception mandate itself has never been subject to notice and comment*. The mandate itself only exists as a line in a chart on a HRSA website, https://www.hrsa.gov/womens-guidelines. This website is maintained by HRSA, but HRSA does not take responsibility for the list of recommended "preventive" services. Rather, the recommendations were made by a hand-selected committee appointed by the Institute of Medicine. Eleven of the fifteen members on the original committee had strong ties with the abortion industry. Since 2016, the Women's Guidelines have been approved by unnamed people on a committee assembled by the American College of Gynecologists.

This website has been updated many times since first posted over a decade ago, always without notice and comment. If the row on this chart that includes contraceptives were deleted tomorrow, the contraceptive mandate would simply disappear. This a feeble foundation on which to build a mandate that the Departments claim the right to impose on the U.S. healthcare industry. It is high time that the Departments acknowledge the illegality of this effort.

C. The Women's Health Amendment and the Institute of Medicine expressed interest in reducing the *cost* of preventive services for women, *not* in providing "seamless" access.

We also renew here our objection to the Departments' claim that Congress authorized them to take steps to ensure "seamless" access to preventive care services.[10] As we showed in our April 2023 public comment, that claim is baseless. The text of the WHA says nothing about "seamless" access. The WHA Senate debate shows Congress was focused on cost, not "seamlessness." The Institute of Medicine's report, which HRSA used to justify its mandate, likewise never suggests—let alone establishes—that requiring women to take some steps (like seeing a doctor) would result in reduced contraception use."

As we detailed in our comment, Congress has unanimously rejected bills that have proposed contraception mandates. Yet it is worth noting that nowhere in these failed bills or the surrounding congressional debate has Congress ever claimed that a contraception mandate was needed to ensure "seamless" access to contraceptives, however defined. Our comment shows that the whole idea of "seamlessness" was something DOJ invented in an effort to protect the Departments' mandate in court. This post-hoc argument, *which came from federal litigators not legislators*, does not provide any basis for new rules under Departments' contraception mandate.

Given that the Departments' existing regulations already provide cost-free access to FDA-approved contraceptives, the only goal that Congress ever set out—reducing cost—has already been met. Given that there is no congressional warrant to ensure women have "seamless" access, nothing in the law or even the congressional record supports the Departments' newest effort to require free access to OTC contraceptives without a prescription.

[10] Id. at 15-19.

II. Recent legal developments reinforce the illegality of the Departments' contraception mandate.

A. The Departments' burden to justify their contraception mandate is now higher in light of *Loper Bright*.

Last June, the Supreme Court decided *Loper Bright Enterprises v. Raimondo*, which overturned *Chevron* deference. 144 S. Ct. 2244 (2024). The Court the that the Administrative Procedure Act requires courts to exercise "independent judgment" in determining whether an agency has acted within its statutory authority. It affirmed that the Constitution requires federal courts to independently interpret statutes and effectuate the will of Congress.

The following month, a "Post-*Chevron* Working Group" of nineteen senators wrote oversight letters to over a hundred federal agencies asking these agencies for more information on how they are taking the Supreme Court's *Loper Bright* decision into account in their rulemaking.[11] One of these letters went to HHS Secretary Xavier Becerra. However, based on our research it appears that neither Secretary Becerra nor HHS has answered this letter.

Moreover, while the Proposed Rule has a lot to say about *Dobbs* (which has nothing to do with the contraception mandate), the Departments say nothing about *Loper Bright* (which has everything to do with the Departments' tenuous claim that they have authority under the WHA to create *and expand*) a contraceptive mandate.

We call on HHS to answer these senators' important questions. More broadly, we call on each of the Departments to show the American people that they are taking *Loper Bright* into account in all their rulemakings, including any rulemaking related to the contraception mandate. As noted above, we believe the contraception mandate was unlawful under the APA before *Loper Bright*. The Departments' case is even weaker now. If the Departments believe their contraception mandate is still lawful under this heightened standard, they should explain why.

B. The Departments must justify their contraception mandate in light of the Supreme Court's major question doctrine.

Similarly, the Departments must defend their contraception mandate in light of the Supreme Court's major questions doctrine. Under the Supreme Court's major questions doctrine, the Departments must have clear statutory authority to impose this mandate. *See, e.g.*, *Biden v. Nebraska*, 143 S. Ct. 2355, 2358 (2023); *West Virginia v. EPA*, 142 S. Ct. 2587 (2022). The Departments hugely consequential contraception mandate is an "elephant" and the Women's Health Amendment is a "mousehole."

If the Departments believe their contraception mandate passes constitutional muster under the major questions doctrine, they should say so explicitly and make that case. If they can't do so, they should state that clearly and withdraw this mandate.

III. Eliminating the prescription requirement endangers women's health.

One of the central aspects of the Proposed Rule is the Department's new requirement that "plans and issuers [] cover certain recommended over-the-counter items without requiring a prescription and

[11] GOP Senators Demand Info From Agencies After *Chevron* Defeat, TaxNotes, July 12, 2024, https://www.taxnotes.com/research/federal/legislative-documents/congressional-tax-correspondence/gop-senators-demand-info-agencies-after-chevron-defeat/7kgv3.

without imposing cost-sharing requirements."[12] To effectuate this proposal, the Departments have proposed a new paragraph (a)(6) to each Department's contraception mandate regulation. For example, HHS proposes to add 45 CFR §147.140(a)(6), which would require plans to provide coverage "without requiring a prescription and without imposing any cost-sharing requirement" for any "contraceptive items that can be lawfully obtained by a participant, beneficiary, or enrollee without a prescription and for which the applicable recommendation or guideline does not require a prescription."[13]

The proposed new (a)(6) is worded so broadly that it would seem to enable any individual, male or female, at any age to obtain all forms of OTC contraception at no cost and without a medical professional's or pharmacist's approval. This mandate would now include Opill, an oral contraceptive that the FDA recently approved for sale without a prescription. As described below, such a proposal poses serious risks to the health and well-being of women, especially young girls. Furthermore, it reinforces a health care system that prioritizes Big Pharma over women's health and well-being.

A. Giving women access to Opill without a prescription raises important health concerns, particularly for adolescent girls.

One of the methods of OTC contraception explicitly listed in the Proposed Rule is the newly-approved method of OTC oral contraception, Opill. As the Departments note in the background section of the Proposed Rule's preamble, the FDA approved the drug branded as Opill, a progestin-only birth control pill, on July 13, 2023.[14] Opill's primary active ingredient is synthetic progestin norgestrel (a synthetic hormone similar to that of emergency contraception). The FDA issued this approval without age restrictions or parental consent requirements.

The study provided by the drug manufacturer, Perrigo, leaves much to be desired, as the FDA itself acknowledged. During the drug's development and approval process, some groups pointed to the risks associated with the drugs and the lack of sufficient medical screening prior to receiving the drugs.[15] The FDA questioned whether the data provided by Perrigo was accurate and reliable, whether women with contraindications would know when to opt out of the medication, and whether the instructions were clearly outlined for patients. Indeed, initial drug studies showed that about 30% of study participants reported taking more pills than the company instructed them to take.[16] It is also noted that the study performed by Perrigo for this drug was smaller than other comparative contraceptive studies.[17]

Despite this study's limits, it acknowledged that Opill comes with significant risk factors and side effects. Opill may lead to an increased risk of breast cancer, cervical cancer, brain cancer, depression, high blood pressure, and ulcerative colitis. One study showed that progestin-only oral contraception nearly triples one's risk of glioma.[18] Opill can also lead to decreased bone density, which places women at risk of developing osteoporosis and bone fractures. Finally, progestin-only oral contraception has been

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[12] 89 Fed. Reg. at 85750.
[13] 89 Fed. Reg. at 85794.
[14] 89 Fed. Reg. at 85755.
[15] Jasmine Adams Piescik, "5 facts you haven't heard about Opill," October 10, 2024, https://naturalwomanhood.org/opill/.
[16] Matthew Perrone, Over-the-counter birth control pill faces FDA questions, May 5, 2023, https://apnews.com/article/birth-control-pills-without-prescription-3228f5d93f5b6583cdc1be9ce4557373.
[17] *Id*.
[18] Andersen L, Friis S, Hallas J, Ravn P, Kristensen BW, Gaist D. Hormonal contraceptive use and risk of glioma among younger women: a nationwide case-control study. Br J Clin Pharmacol. 2015 Apr;79(4):677-84. doi: 10.1111/bcp.12535. PMID: 25345919; PMCID: PMC4386952. https://pmc.ncbi.nlm.nih.gov/articles/PMC4386952/#:~:text=WHAT%20THIS%20STUDY%20ADDS,term%20users%20of%20hormonal%20contraceptives.

shown to alter the endometrium, increasing a woman's chances of developing uterine lining atrophy and infertility. Progesterone-only methods of oral contraception like Opill also "increase[e] the risk of an ectopic pregnancy, which can result in tubal rupture, catastrophic bleeding, and even maternal death."[19] In another study on the drug, more than half the participants withdrew because of irregular menstrual patterns and other related method reasons.

Other less severe side effects from Opill include "headache, dizziness, nausea, increased appetite, abdominal pain, cramps and bloating, fatigue, vaginal discharge, dysmenorrhea (painful menstruation), nervousness, backache, breast discomfort, and acne."[20] Yet, as the manufacturer warns in its labeling, these "are not all the possible side effects of Opill. Call your doctor for medical advice about side effects."

The manufacturer's warning raises important questions the Proposed Rule fails to address. For example, if one must talk to a medical professional to have an adequate understanding of Opill's potential side effects, is it wise and in the public's interest for the Departments to coerce plans and issuers into eliminating a prescription requirement?

These concerns are even greater for adolescent girls. The average age of menarche for American girls is 12 years of age. Neither the manufacturer nor the FDA give any indication whether there has been research done on the long-term consequences and side effects of girls beginning to take the synthetic progestin norgestrel at 12. The manufacturer's study suggests that women below the age of 15 were not included in trials.[21] The FDA's label, under "Pediatric Use," states that the safety of Opill has been established "in women of reproductive age, including adolescents as young as 15 years of age."[22] Yet Opill brags on its website that this drug has no age restriction.[23]

Given that the Departments are attempting to bypass any requirement that girls talk to a medical professional before taking Opill, it is likely that these girls (not to mention these girls' parents) will not be told about the limits on the manufacturer's published research. They will not be given the opportunity to be told about the known side effects for women within the age range of the limited study. They will not be given the opportunity to ask questions about these side effects. We are concerned that the Proposed Rule is not forthright about these important concerns and does not adequately wrestle with the question as to how a teenager or even a pre-teen would be able to give informed consent to such a powerful and consequential drug without the benefit of a doctor's visit or a pharmacist's consult.

B. Eliminating a prescription requirement makes it more likely that women will overdose on contraceptives.

As noted above, the manufacturer's own study showed that 30% of women on Opill are overdosing. There are serious reasons to believe that the Proposed Rule, by reducing a women's incentive to see a health care professional before starting on the drug, will only increase the number of women taking more than the recommended amounts of these hormones.

First, the Proposed Rule means fewer women will be warned by their doctors about the serious risks that come from overdosing. Second, women are more likely to overdose when they can get more

[19] "No Adverse Outcomes?" Natural Womanhood, https://naturalwomanhood.org/no-adverse-outcome/
[20] Ingrid Skop, M.D., FACOG, "Fact Sheet: Opill, the First Over-the-Counter Hormonal Contraception," October 12, 2023, https://lozierinstitute.org/fact-sheet-opill-the-first-over-the-counter-hormonal-contraception/.
[21] Natalie Dodson and Grace Emily Stark, "Biden-Harris Birth Control Proposal Is a Cheap Political Stunt," October 28, 2024, https://www.newsweek.com/biden-harris-birth-control-proposal-cheap-political-stunt-opinion-1972984
[22] *Id*.
[23] Opill, https://opillhcp.com/.

whenever they want and don't have to wait until a pharmacist agrees that the patient is due for a refill. These risks are even greater in light of reports that women (especially young women) have been stockpiling contraceptives in reaction to politically motivated fearmongering.[24]

These fears are real because the consequences of overdosing on Opill are significant. The manufacturer warns that exceeding dosage recommendations can lead to "nausea, vomiting, breast tenderness, dizziness, somnolence (drowsiness/fatigue), and withdrawal bleeding."[25]

It is also important to recall, as noted above, that Opill's active ingredient is similar to the active ingredient in emergency contraceptives. Risks associated with overdose on emergency contraception include "serious symptoms such as passing out or trouble breathing."[26] Medical groups recommended calling 911 immediately if one suspects an overdose. It does not appear that research has been done to uncover whether overdosing on Opill can lead to the same life-threatening situations.

Again, the Proposed Rule does not adequately take these downsides of removing a prescription requirement into account. The Departments must do better in any final rule.

C. Eliminating a prescription requirement makes it more likely that women will take hormonal contraceptives despite contraindications.

Before approving Opill as an OTC contraceptive, the FDA raised (but did not resolve) concerns that women would start taking Opill even though they had pre-existing medical conditions that made taking the drug dangerous. This concern was born out by the Perrigo study. Women in the study were specifically "instructed" that if they had a history of irregular bleeding, they should "talk to a doctor first," before starting Opill "because [irregular bleeding] could indicate a medical problem."[27] Indeed, norgestrel, the primary active ingredient in Opill, is "contraindicated in individuals who have a known or suspected pregnancy or undiagnosed vaginal bleeding."[28] Yet a substantial number of women, despite their history of irregular bleeding, and despite this warning, still reported that they thought it was safe for them to start taking Opill.

Given substantial evidence that written warnings alone are not as effective as direct caution from a medical professional, there is good reason to think that the Proposed Rule would result in many women taking Opill despite important medical contraindications. Without visiting a medical professional before obtaining OTC contraception, patients may not receive proper warnings about what medical conditions or symptoms may be contraindicated for these types of contraception. Removing the prescription requirement would also deprive women of the benefit of a visit with a pharmacist who could caution them about possible contraindications with other health problems, problems with being on oral contraceptives while on other drugs, or the decreased efficacy of oral contraceptives if the woman is on other drugs. These are important opportunities for women to receive important medical advice, as "there are many medications that will either reduce the effectiveness of, or generate adverse effects if used in combination with Opill."[29] One expert noted that there are 98 drugs included on a list of possible adverse effects and

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[24] Emily Shugerman, "Americans stockpile abortion pills and hormones ahead of 'reproductive apocalypse' under Trump," *The Guardian*, November 7, 2024, https://www.theguardian.com/us-news/2024/nov/07/abortion-pills-hormones-trump.
[25] Opill Tablets, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017031s035s036lbl.pdf.
[26] "Levonorgestrel Tablet Contraceptives - Uses, Side Effects, and More," *WebMd,*, https://www.webmd.com/drugs/2/drug-17833/levonorgestrel-oral/details.
[27] "No Adverse Outcomes?" Natural Womanhood, https://naturalwomanhood.org/no-adverse-outcome/.
[28] *Id*.
[29] *Id*.

decreased efficacy in addition to the other 10 medications "that are of definite concern for Opill's effectiveness."[30]

The Departments' Proposed Rule seems to be based on the simplistic naïve presumption that removing barriers will lead to better health outcomes. But this presumption is dangerously flawed. We call on the Departments to address the following questions before finalizing this Proposed Rule:

- Do the Departments believe that women can accurately screen themselves for medical conditions that can make it more dangerous for them to take OTC oral contraceptives?
- If so, on what basis?
- If so, does this confidence also extend to minors as young as 12?
- If so, on what basis do the Departments believe that a 12-year-old knows her body well enough to identify possible health conditions that would make Opill contraindicated?
- What is the Departments' estimates on how many women on the margin would decide not to take Opill if they were told about contraindications from a health care professional or a pharmacist?
- What are the long-term health consequences of taking Opill despite these contraindications?
- What are the long-term health costs associated with women taking Opill because they were not properly warned about contraindications?

D. Prescription-free access to OTC contraceptives may lead to more undiagnosed reproductive health conditions

Women's health is, surprisingly, one of the least studied areas of medicine. For many reproductive health conditions, it takes years to receive a diagnosis. For example it takes on average between 8 to 12 years for a woman to be properly diagnosed with endometriosis, a disease where tissue resembling endometrial lining tissue grows outside of the uterus. For reproductive health conditions as a whole, the average diagnosis delay for reproductive health conditions is between 4 and 12 years.

Some of these conditions, if diagnosed properly, could be identified during a woman's early teens, but instead, most women wait until their twenties or thirties before receiving a diagnosis. These delays are tragic and can lead to a loss of fertility or other long-term adverse health conditions.

There are many factors that lead to these delays in diagnoses. One is the lack of medical training and education for OB-GYNs on reproductive conditions, symptoms, and treatments. Relatedly, another factor is that OB-GYNs too often prescribe oral contraceptives to mask unpleasant symptoms instead of seeking to better understanding the underlying condition that is causing the symptoms.

Women's health needs more attention, not less. But the Proposed Rule would likely make this problem worse. For women who are on some form of contraception, getting a prescription for these drugs is one of the primary reasons that patients visit a medical professional annually. While a woman might consider it inconvenient to schedule and attend a doctor's visit *just* to get another prescription for contraceptives, these same visits place women in front of a medical professional on a routine basis. These

[30] *Id*.

visits allow doctors to ask women about their health and give women an occasion to ask questions about things they are experiencing.

As OB/GYN Dr. Kathleen Raviele remarked, "It takes the woman away from an encounter with a physician, a nurse practitioner or a PA, and she's going to be at high risk for having other problems that won't be picked up."[31] That would result in delayed diagnoses with serious potential adverse health consequences for women. In addition to concerns about delayed diagnosis and reproductive health conditions, OTC contraception may lead to fewer "preventative assessments that might be relevant to a woman's oral contraceptive use, as well as her overall health, such as blood pressure measurement, healthy weight counseling, cancer screenings, depression screening, and domestic abuse screening and referral."[32]

Before finalizing the Proposed Rule, we ask the Departments to consider these important concerns and make specific assessments about whether making OTC available without a prescription would make it more difficult for doctors to diagnose and prevent the very health conditions that the WHA was passed to address.

E. Eliminating the prescription requirement would make it easier for partners to commit reproductive coercion.

The Departments also fail to take into account concerns that eliminating the prescription requirement would make it easier for men to commit reproductive coercion on women.

"Reproductive coercion" is a broad term that involves a range of behaviors that interfere with a woman's reproductive autonomy.[33] According to The American College of Obstetricians and Gynecologists (ACOG), reproductive and sexual coercion "includes explicit attempts to . . . control outcomes of a pregnancy."[34] A man can commit reproductive coercion in one direction by poking holes in his condoms or hiding or destroying his partner's birth control pills. But a man can also commit reproductive coercion in the other direction, forcing women to take contraceptives against their will.

Reproductive coercion is extremely prevalent in the United States, including heartbreaking stories of men slipping abortion pills and emergency contraception into partners' drinks.[35] One NIH study found that 8.4% of women have experienced reproductive coercion, with rates significantly higher among black and Hispanic women.[36]

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[31] "No Adverse Outcomes?" *Natural Womanhood*, https://naturalwomanhood.org/no-adverse-outcome/
[32] *Id*.
[33] *See* American College of Obstetricians and Gynecologists, Reproductive and Sexual Coercion, Feb. 2013, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/02/reproductive-and-sexual-coercion.
[34] *Id*.
[35] Julia Marsh, "Doctor accused of slipping Plan B in girlfriend's drink," *New York Post*, April 14, 2017, https://nypost.com/2017/04/14/doctor-accused-of-slipping-plan-b-in-girlfriends-drinks/; Lauren Aratani, "Texas man faces charges for allegedly slipping abortion drug in wife's drink," *The Guardian*, November 14, 2022, https://www.theguardian.com/us-news/2022/nov/14/texas-mason-herring-abortion-drug-wife-drink-criminal-charges; "Brookline man accused of slipping girlfriend abortion pills to end pregnancy" *CBS News*, May 28, 2024, https://www.cbsnews.com/boston/video/brookline-man-accused-of-slipping-girlfriend-abortion-pills-to-end-pregnancy/.
[36] K.C. Basile, et al*., Prevalence of Intimate Partner Reproductive Coercion in the United States: Racial and Ethnic Differences*, 36 J Interpers Violence 21-22, Nov. 2021, https://pubmed.ncbi.nlm.nih.gov/31808711/. *See also* Karen Trister Grace & Jocelyn C. Anderson, *Reproductive Coercion: A Systematic Review*, 19 Trauma Violence Abuse 371 (2018), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC5577387/.

The Proposed Rule is worded so broadly that would appear that anyone can use an insurance card to pay for OTC contraceptives, regardless of age and regardless of sex. Before finalizing this proposal we call on the Departments to investigate and to seek public comment on the following:

- Would giving men direct access to cost-free OTC hormonal contraceptives increase rates of reproductive coercion?

- Would giving men direct access to cost-free OTC hormonal contraceptives also lead to increased rates of sexual abuse?

- Would such increased rates of reproductive coercion and sexual abuse disproportionately affect black and Hispanic women?

F. The Proposal reinforces the medical establishment's pharmaceutical-heavy approach to women's health.

Finally, we fear that the Proposed Rule would undermine the goal of the WHA by reinforcing the unfortunate, harmful, pro-Big Pharma message that what women need is not better health care but more pharmaceuticals.

Here, it is important to recall that the WHA—ostensibly the law that authorized the Departments to develop a contraception mandate—requires "coverage of preventive health services."[37] The purpose of the preventative medicine is to prevent disease and death. However, as we mentioned in our April 2023 public comment, fertility and pregnancy are not diseases but rather natural functions of the human body.[38] "They are normal physiologic processes of the sexually mature person."[39]

OTC contraception does not prevent disease but rather prevents and suppresses the natural function of the female body. Even for those who claim it can be used to treat reproductive health conditions, OTC contraception may suppress the symptoms of those conditions, but it does not treat the conditions. In fact, it often allows reproductive health conditions to progress while suppressing the signs of the diseases.

OTC contraception "increase[s] the risk of disease instead of decreasing it."[40] OTC contraception contributes to increased risk of breast cancer, cervical cancer, brain cancer, depression, high blood pressure, and ulcerative colitis. Without visiting a medical professional, women will unlikely be unaware of these risks.

In light of these concerns, we ask the Departments to consider again how the Proposed Rule would affect a woman's ability to give full informed consent to OTC oral contraceptives without a conversation with a doctor or with a pharmacist. We also ask the Departments to consider how a pre-teen girl could give such informed consent under the Proposed Rule.

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[37] 42 U.S. Code § 300gg–13.
[38] EPPC Scholars April 2023 Public Comment at 2, 7.
[39] Peck R, Norris CW. Significant Risks of Oral Contraceptives (OCPs): Why This Drug Class Should Not Be Included in a Preventive Care Mandate. Linacre Q. 2012 Feb;79(1):41-56. doi: 10.1179/002436312803571447. Epub 2012 Feb 1. PMID: 30082959; PMCID: PMC6027089.
[40] *Id*.

IV. The Departments' Regulatory Impact Analysis is flawed.

Our analysis also revealed significant flaws and limitations in the Departments' Regulatory Impact Analysis (RIA).[41] We call on the Departments to provide better explanations for their RIA estimates or else to revise their work and provide more realistic numbers as required by the Administrative Procedure Act.

A. The Departments' analysis does not account for the likelihood that eliminating the prescription requirement will lead to more women suffering side effects from hormonal contraceptives.

One such limitation is the Departments' underlying claim that the Proposed Rule will improve the problems they have identified. The rationale for the Proposed Rule is largely based on their claim that the argument that "[r]esearch shows that many women are not using their contraceptive of choice, for reasons that include concerns about side effects, cost, lack of availability, or inability to get a provider appointment."[42] The Departments presume that increasing options will improve this match between preferences and use. However, it is unclear that the Proposed Rule will actually improve this match.

One of the studies cited by the Departments in their RIA is a study conducted by the Kaiser Family Foundation (KFF), "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage."[43] According to this study, only 30 percent of women report that they had all the information that they needed to choose a contraceptive method (Table 5), 57 percent received this information mainly from their health care provider (Figure 17), and, importantly, 74 percent prefer to receive this information from their health care provider (Figure 17). *If a provider prescription is no longer required to obtain contraception without cost sharing, it will reduce doctor visits and information transfer, resulting in increased improper use and unforeseen side effects. The RIA does not quantify these negative aspects of the Proposed Rule.*

The KFF's findings are particularly concerning given that the survey shows that "[a]lmost one-third of contraceptive users (31%) say they are experiencing side effects from their current method, and just over half (52%) say the side effects are more severe than they expected."[44] These side effects are the most commonly reported reason why women are not using their preferred method of contraception (25%), while inability to get an appointment is the least-reported surveyed reason (4%) (Table 6). Nothing in the Proposed Rule explains why it makes sense to risk worsening a common problem (side effects) to address an uncommon problem (inability to get an appointment).

B. The Departments' economic impact estimates are unbelievably low.

We also have reason to question the Departments' rosy estimates about the economic impact of their proposal. The Department estimates that insurers will only have to spend about 41,800 hours responding to participant questions.[45] This estimate is based on 5 hours of work for each of 5 customer service representative (CSR) hours per issuer or third-party administrator, regardless of the number of

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[41] 89 Fed. Reg. at 85774-92.
[42] 89 Fed. Reg. at 85762.
[43] 89 Fed. Reg. at 85778 (citing Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). ''Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage,'' *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/.
[44] *Id*.
[45] 89 Fed. Reg. at 85789.

covered individuals. *The Departments' estimate results in an average CSR burden of only 0.83 seconds for each of the 181.4 million covered individuals!* These estimates are not credible.

It seems more appropriate to estimate the number of CSR hours based on the number of covered individuals, their probability of calling for support, and the average length of a call. For example, for every 1 percent of covered individuals who call their issuer or third-party administrator regarding the change, assuming each call lasts an average of 6 minutes, the burden would reach 181,400 hours. Even assuming such a tiny share of covered individuals call for assistance, the burden is more than four times the Departments' estimated figure.

Similar calculations could be made for other burden estimates and reveal that the Departments' estimates are unbelievably low. If more realistic estimates of the customer service burden are included, how much higher will the compliance costs be?

The RIA quantifies very few costs or benefits of the rule. But even still, $787.6 million per year of total "transfers," or items that previously would have been paid out of pocket but now will be paid by others, is too low an estimate. While the effects on federal revenue and premium tax credits are considered, the RIA ignores the fiscal effects on state governments, which also exclude employer-sponsored health insurance from taxable income and would likewise be affected through a reduction in tax revenue. This is perplexing, given that the Departments explicitly recognize that the Proposed Rule has federalism implications. How much greater would the increase in insurance premiums and the total transfers be if the implications for state governments were also considered? The APA requires the Departments to take these and related economic questions into account.

C. The Departments fail to assess the impact of shifting consulting responsibilities from doctors to pharmacists.

The Departments acknowledge that this proposal could result in women having fewer preventive care visits with their doctors and that pharmacies will *in some cases* assume a consultation role that would previously have been borne by doctors. However, the RIA does not estimate the value of this cost shifting. We ask the Departments to do better moving forward.

- How many women would lose an opportunity to talk to a doctor about oral contraceptives as a result of the Proposed Rule?
- What percentage of these women would take the initiative to talk to a pharmacist about any questions they have about Opill or other OTC oral contraceptives?
- How much time would pharmacists spend total on such consultations?
- Would pharmacists be allowed to bill for these consultations?
- If so, would the cost of such a consultation be required to be covered without cost sharing under the Proposed Rule?

V. The Proposed Rule would undermine religious liberty protections for Catholic employers.

The Proposed Rule note that the Departments have "previously issued rules that provide exemptions from the contraceptive coverage requirement for entities and individuals with moral or

religious objections to contraceptive coverage."[46] However, the Departments also note that these early 2023 proposed changes have not yet been finalized.[47] We remind the Departments that they must take these pending rules into account as they consider the impact of and the legality of any final rule.

Leaving aside these pending rules, we note that the Proposed Rule does not take into account the effect that eliminating the prescription requirement would have on religious employers. The Departments are of course aware of their obligation to consider their mandate's impact on religious employers, given the unprecedented litigation their that has resulted from their contraceptive mandates[48] However, the Proposed Rule does not appear to take into account that the morality of oral hormonal contraceptives for some religious employer, including under Catholic teaching, depends on the purpose for which they are taken. As one Catholic ethicist put it, "The moral doctrine of the [Catholic] Church judges human behavior but is silent on chemical compounds."[49] Catholic teaching on this matter is summarized in Pope Paul VI's 1968 encyclical *Humane Vitae*:

- On the one hand, it is immoral to take any drug "specifically intended to prevent procreation." Human Vitae ¶ 14.

- "On the other hand, the Church does not consider at all illicit the use of those therapeutic means necessary to cure bodily diseases, even if a foreseeable impediment to creation should result there from—provided such impediment is not directly intended for any motive whatsoever." *Id*. ¶ 15.

For example, an oral contraception might be prescribed to treat severe acne, to reduce hirsutism (excess body hair growth), or to treat painful periods, heavy bleeding, or endometriosis.[50]

Thus, when Catholic employers have sought religious exemptions from the Departments' contraception mandate, they have not asked for the power to deny coverage for hormonal contraceptives categorically, but only when prescribed as a contraceptive. This distinction is workable under the status quo because medical visits that accompany prescriptions for hormonal contraceptives are coded in such a way that allows the plan to distinguish between prescriptions written to prevent contraception and prescriptions written (for the exact same drug) to treat diagnosed medical conditions.

This system allows Catholic employers to comply with both their religious obligation to provide health coverage for employees and their religious objection to avoid paying for their employees' contraceptives. However, the Proposed Rule would complicate matters considerably. While it is unknown whether doctors are currently recommending available non-prescription oral contraceptives to treat medical conditions, the Proposed Rule is written in such a way that it would apply to all contraceptive drugs that are in the future made available over the counter.

Before finalizing the Proposed Rule, we ask the Departments to take this distinction into account and consider how, in the absence of medical codes that accompany a prescription, it might adjust existing religious exemptions to its contraception mandate in light of the Departments' legal obligations to respect religious liberty. Given the Departments' stated goal of "resolv[ing] the long-running litigation with

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[46] 89 Fed. Reg. at 85752.
[47] *Id*. (citing 88 Fed. Reg. 7236).
[48] *See*, Becket, HHS Mandate Information Central, https://www.becketlaw.org/research-central/hhs-info-central/ (summarizing litigation from 2011 to the present brought by religious employers against the Departments' mandate).
[49] Braian Clowes, PhD., Can a Catholic Use Birth Control for Health Reasons? "Human Life International, Mar. 11, 2022, https://www.hli.org/resources/can-a-catholic-use-birth-control-for-health-reasons/.
[50] Clowes, *supra*.

respect to religious obligations to providing contraceptive coverage,"[51] we ask the Departments to reopen public comments and specifically seek public comment on how changing the Departments' contraception mandate to eliminate the prescription requirement would impact religious liberty for Catholic employers and any other religious or non-religious employers that make similar moral distinctions based on the reason why someone wishes to use hormonal contraceptives. At the same time, the Departments should seek public comment regarding proposals on how it should change existing religious exemptions if the Departments decide to eliminate a prescription requirement.

VI. The Departments' purported "incremental approach" raises additional concerns.

We also raise concerns regarding the Departments' decision to characterize this Proposed Rule as part of an "incremental approach" to expanding preventive service mandates:

> The Departments also recognize that the proposals described in this section II.A.2 of this preamble, if finalized, ***could require significant changes to current plan and issuer operations***. Therefore, the Departments propose ***an incremental approach*** in this rulemaking with respect to the types of recommended services addressed that is focused initially on expanding coverage of contraception. ***This incremental approach would facilitate implementation for plans, issuers, and other interested parties and allow the Departments to gather additional feedback on challenges and benefits of adopting these proposed policies before considering whether and how to propose similar requirements with respect to other recommended preventive services.***[52]

This is an important claim, yet the Departments say very little about this "incremental approach," including what they are considering as its outer limits. We call on the Departments to say more in any future rule and in any future proposals related to this "incremental approach":

- Do the Departments believe Congress authorized them to create mandates "without cost-sharing" for OTC products related to other items covered under the WHA? If so, which ones?

- Are there any preventive services covered by the WHA that are categorically excluded from this "incremental approach"? If so, which ones? And why?

- Does this "incremental approach" also extend to the ACA's general preventive services mandate? If so, why? And what are its limits?

VII. Other Questions

We also call on the Departments to consider and answer the following questions before finalizing the Proposed Rule:

- It appears that the Proposed Rule would require plans to give beneficiaries unlimited free access to all FDA-approved OTC contraceptives. Such OTC contraceptives appear to include male condoms, female condoms, spermicides (gels, foams, creams, films, and suppositories), contraceptive sponges, emergency contraceptives, and hormonal contraceptives (currently only Opill). We ask the Department to clarify: is it really their intent to provide beneficiaries to unlimited free access to all such contraceptive products?

[51] 88 Fed. Reg. at 7243.
[52] 89 Fed. Reg. at 85763.

- Relatedly, do the Departments actually claim that Congress, when it passed the WHA, delegated the Departments' authority to create and manage a requirement that health insurance plans provide men with free access to condoms? If so, how?

- It would appear that the Proposed Rule allows anyone to purchase as many OTC contraceptives as he or she wants, regardless of age, regardless of whether the sex of the purchaser matches the sex of the intended user. Is that right? If there are any limits to the mandate in this regard, please explain what limits there are.

- Using basic economic principles, it would seem that making OTC contraceptives free would increase the demand for such products. Do the Departments believe that their Proposed Rule adequately anticipates what this would do to the demand for such products? If so, why?

- Using basic economic principles, it would seem that increasing the demand for OTC contraceptives would increase the price of these products. Yet the Proposed Rule would pass 100% of these costs on to third parties. Do the Departments believe that their Proposed Rule adequately anticipates what their proposal would do to the cost of OTC contraceptives? If so, why?

- Using basic economic principles, it would seem that making OTC contraceptives free would result in health insurance plans passing along these costs to plan sponsors. Do the Departments believe that their Proposed Rule adequately anticipates what their proposal would do to the cost of health care plans? If so, why?

- For example, what would stop someone on a qualifying health plan from stocking piling free contraceptives and reselling them to people who are not on such a plan?

- Are pharmacies and retail stores expected to figure out how to bill insurance companies directly for these items, or are individuals expected to pay out of pocket and then seek reimbursement for covered items, as they might do for their HSA or FSA?

Conclusion

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

Sincerely,

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