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Submitted Electronically

March 24, 2023

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9940-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Subj: Coverage of Certain Preventive Services Under the Affordable Care Act, RIN 0938-AU94, CMS-9903-P

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (USCCB), we submit the following comments on proposed rules, published by the Departments of Treasury, Labor, and Health & Human Services (collectively, the Departments) at 88 Fed. Reg. 7236 (Feb. 2, 2023), relating to the coverage of certain preventive services under the Affordable Care Act (ACA).

Since the ACA's enactment in 2010, we have filed comments[1] each time the Departments

[1] *See* USCCB Comments on Interim Final Rules on Preventive Services (Aug. 31, 2011), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/comments-to-hhs-on-preventive-services-2011-08-2.pdf; USCCB Comments on Advance Notice of Proposed Rulemaking on Preventive Services (May 15, 2012), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/comments-on-advance-notice-of-proposed-rulemaking-on-preventive-services-12-05-15.pdf; USCCB Comments on Notice of Proposed Rulemaking on Preventive Services (Mar. 20, 2013), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2013-NPRM-Comments-3-20-final.pdf; USCCB Comments on Proposed Rules on Coverage of Certain Preventive Services Under the Affordable Care Act (Oct. 8, 2014), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2014-hhs-comments-on-proposed-rule-on-for-profits-10-8.pdf; USCCB Comments on Interim Final Rules on Coverage of Certain Preventive Services Under the Affordable Care Act (Oct. 8, 2014), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2014-hhs-comments-on-interim-final-rules-10-8.pdf; USCCB Comments on Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (Nov. 21, 2017), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/Comments-Religious-Exemptions-From-Contraceptive-Mandate.pdf; USCCB Comments on Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (Nov. 21, 2017), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/Comments-Moral-Exemptions-From-Contraceptive-Mandate.pdf. *See also* USCCB Comments on Interim Final Rules Relating to Coverage of Preventive Services (Sept. 17, 2010) (discussing why contraceptives should not be included in the then-anticipated

issued a regulatory proposal on contraceptive coverage.[2] Our earlier comments raised two overarching themes.

First, we have consistently argued that contraceptives should not be mandated as "preventive" services because, unlike genuinely preventive services, contraceptives do not prevent disease or illness. Instead, they inhibit healthy, natural body functions and are associated with an increased risk of adverse health outcomes, such as breast cancer, that other "preventive services" are designed to prevent. Even contrary to their own purposes, at a societal level, their use may increase the incidence of unplanned pregnancies. The contraceptive mandate is therefore at odds with the purpose of the preventive services provision of the ACA upon which the mandate purports to be based. In addition, insofar as it requires coverage of drugs and devices that can cause an abortion, the mandate violates ACA provisions dealing with abortion coverage and non-preemption of state law, as well as the Weldon amendment.

Second, we have consistently argued that if coverage of contraceptives were to be mandated, all stakeholders with religious or moral objections should be exempt. We concluded that a broad exemption for religious objectors was required under the Religious Freedom Restoration Act, and that an exemption for religious and moral objectors was both prudent as a matter of public policy and consistent with longstanding legal protections for conscience.

In the present proposal, the Departments do not address the first of these two overarching issues, but implicitly continue to leave it to the discretion of the Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) to decide whether to include contraceptives in the Women's Preventive Services Guidelines. Because the Guidelines themselves have never been the subject of full notice and comment rulemaking, however, and because there is no indication that they ever will be, we raise the issue here, as we have in our past rulemaking comments on contraceptive coverage, because significant questions remain whether contraceptives are an appropriate subject for inclusion the Guidelines in the first instance. For reasons set out in these comments, HHS could reasonably conclude that they are not.[3] We urge HHS, whether in this rulemaking or in some other appropriate forum, to reconsider and rescind the mandate. At a minimum, to ensure compliance with the abortion and non-preemption provisions of the ACA and the Weldon amendment, HHS should clarify that the mandate does not apply to any drug or device that can disrupt an existing pregnancy.

On the second issue, the Departments propose retaining the religious exemption but eliminating the moral exemption. We commend the Departments for, and we support, the Departments' proposed retention of the religious exemption. We respectfully submit, however, that the Departments' proposed elimination of the exemption for non-religious moral objections

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list of mandated preventive services under the ACA), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/comments-to-hhs-on-preventive-services-2010-09.pdf.

[2] Unless context indicates otherwise, our use of the term "contraceptives" refers to contraceptives, sterilization, and related education and counseling, and "contraceptive coverage" refers to coverage of these items.

[3] Section 2713(a)(4) of the ACA, codified at 42 U.S.C. § 300gg-13(a)(4), grants HRSA the authority to provide guidelines with respect to preventive care for women but, as the Departments recognize, HRSA "exercises authority delegated from and subject to the control of the Secretary of HHS." 88 Fed. Reg. at 7247.

is a step backward. In 2017 and 2018—the round of rulemaking that led to adoption of the existing exemptions—and consistent with the position that we and others had long urged, the Departments, for reasons that were well articulated and persuasive, adopted exemptions that protected all stakeholders with religious or moral objections to contraceptive coverage. As the bishops noted at the time, the exemptions proposed and ultimately adopted in the 2017/2018 rulemaking cycle, were "a return to common sense"[4] and, in the Departments' own words at the time, consistent with "a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions." 82 Fed. Reg. 47792 (Oct. 13, 2017).

Those observations are as valid today as they were five years ago. The Departments, both now and in the 2017/2018 rulemaking, have admitted both the need and the ability to exempt religious objectors. It is a mistake, in our view, not to afford similar protection from the contraceptive mandate for those with non-religious moral objections, and therefore a mistake to rescind the moral exemption.

I. The Mandate

Contraceptives are inappropriate candidates for inclusion in the list of mandated "preventive services" for several reasons. First, they are not a preventive service as that term is used in the statute. Second, far from being preventive, contraceptives are associated with serious risks and side effects.

A. The Meaning and Purpose of "Preventive Services"

The underlying justification for mandating coverage for preventive services can be determined from the plain language of the statute and its legislative history. In section 2713(a)(4) of the ACA, 42 U.S.C. § 300gg-13(a)(4), Congress gave HRSA the discretion to specify that certain group health plans shall cover, "with respect to women, such additional *preventive* care and screenings … as provided for in comprehensive guidelines" supported by HRSA. The plain meaning of "preventive" is an item or service that prevents disease or illness. Naturally, congressional debate on this provision centered almost entirely on services to prevent life-threatening illness such as breast cancer.[5]

For the most part, the list of "preventive" services developed by HRSA is consistent with this meaning and with Congress's intent. HRSA has decided that covered services shall include breast cancer screening, breastfeeding services and supplies, screening for cervical cancer, screening for gestational diabetes mellitus, screening for human immunodeficiency virus infection, screening and counseling for interpersonal and domestic violence, screening for anxiety, counseling for sexually transmitted infections, screening for urinary incontinence,

[4] Statement of Cardinal Daniel N. DiNardo, Archbishop of Galveston-Houston and President of the USCCB, and Archbishop William E. Lori of Baltimore, Chairman of the USCCB's Ad Hoc Committee for Religious Liberty (Oct. 6, 2017), https://www.usccb.org/news/2017/hhs-mandate-decision-represents-return-common-sense.

[5] 111 Cong. Rec. S11986-88 (Nov. 30, 2009); 111 Cong. Rec. S12025-28, S12058-60 (Dec. 1, 2009); 111 Cong. Rec. S12113-14, S12119-23, S12126-31, S12143-44, S12151-52 (Dec. 2, 2009); 111 Cong. Rec. S12267-77 (Dec. 3, 2009).

obesity prevention, and well-woman preventive visits. HRSA, Women's Preventive Services Guidelines, https://www.hrsa.gov/womens-guidelines (accessed Jan. 31, 2023). HRSA mandates coverage of these services because they can prevent serious illnesses or life-threatening conditions that, once they occur, will demand treatment to cure or reverse or, at the very least, can provide an early warning so these conditions can be treated more quickly and with a greater likelihood of success.

This rationale does not apply to contraceptives. Contraceptives do not prevent disease, but instead disrupt the healthy functioning of the human reproductive system, temporarily or permanently creating the condition of infertility, which is commonly seen as a health problem. Most drugs and devices in this area have a significant "failure" rate for individuals, but when they do succeed, what they most often "prevent" is a healthy pregnancy in a healthy woman of childbearing age. Moreover, at a public health scale, their wide availability may even increase the occurrence of unplanned pregnancies, due to behavioral dynamics.[6] At various times, women may have serious personal reasons for wanting to avoid or delay a pregnancy. However, these personal reasons do not transform a temporary or permanent condition of infertility into a prerequisite for health, or turn a healthy pregnancy into a disease condition.

Indeed, if contraception and sterilization were comparable to the other items listed as preventive by HRSA, the federal government would be mandating coverage in order to obviate the need for providing the "cure" or treatment later (or in order to ensure that such cure or treatment is provided early, to enhance the likelihood of success). But the condition prevented by contraceptives is pregnancy, which has its own natural course ending in live birth if not interrupted by medical intervention or spontaneous miscarriage. The "cure" or "treatment" to eliminate this condition would have to be an abortion. But the ACA prohibits any federal mandate to cover abortion as an essential health benefit in any circumstances.[7] Indeed, the Act not only leaves health plans free to exclude abortion, but explicitly allows each state to forbid coverage of abortion on or off its exchange.[8] Finally, with regard to the multi-state qualified health plans established under the ACA, at least one of these plans must exclude most abortions. 42 U.S.C. § 18054(a)(6). The ACA does not treat any other procedure this way.

In these provisions, the ACA treats pregnancy as a healthy condition but does not treat the existence of a preborn human life as an illness or condition requiring the "treatment" of abortion.

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[6] *See* Janet Yellen, et al., *An Analysis of Out-of-Wedlock Childbearing in the United States*, 111 Q, J. OF ECON. (May 1996), http://public.econ.duke.edu/~vjh3/e262p/readings/Akerlof_Yellen_Katz.pdf.; *see also* USCCB fact sheets, *infra* n.10.

[7] 42 U.S.C. § 18023(b)(1)(A) (stating that "nothing" in title I of the ACA, which includes the provision dealing with preventive services, "shall be construed to require a qualified health plan to provide coverage of [abortion] services … as part of its essential health benefits for any plan year"); *id*. (stating that it is the "issuer" of a plan, not the government, that "shall determine whether or not the plan provides coverage of [abortion]"); *see also* 42 U.S.C. § 18023(c)(1) (stating that nothing in the ACA preempts or has any effect on State law regarding abortion coverage).

[8] 42 U.S.C. § 18023(a)(1) (providing that "A State may elect to prohibit abortion coverage in qualified health plans offered through an Exchange in such State if such State enacts a law to provide for such prohibition"); 42 U.S.C. § 18023(c)(1) (providing that "Nothing in this Act [i.e., the ACA] shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of … coverage … [of] abortions").

It is inconsistent to *require* health plans to commit themselves to preventing this same condition.

Some may claim that contraception and sterilization are "preventive services" in the sense that they "prevent" abortion. But this is implausible for several reasons. First, abortion is not itself a disease, but a separate procedure that is performed only by agreement between a woman and a health professional. Second, most pregnancies, including unintended pregnancies, end in live birth rather than abortion, so it would be arbitrary to claim that preventing such pregnancies primarily prevents abortion rather than live birth. Third, studies have shown that the percentage of unintended pregnancies that are ended by abortion is *higher* if the pregnancy occurred during use of a contraceptive.[9] Finally, numerous studies have shown that contraceptive programs do not reliably or consistently reduce unplanned pregnancy or abortion rates.[10] For example, one review summarizing 23 separate studies found that not one of the studies could show a reduction in abortion rates from programs expanding access to so-called "emergency contraception."[11] An evidence-based approach to health care does not permit the claim that mandating contraceptive coverage will reduce abortions or even unintended pregnancies.

One particular drug approved by the Food and Drug Administration for "emergency contraception" poses an especially obvious problem in this regard. Ulipristal (trade name "Ella") is a close analogue to the abortion drug RU-486, with the same biological effect – that is, it can disrupt an established pregnancy after conception has taken place.[12] Therefore, it is contraindicated for women who are or may be pregnant. To characterize this drug as a "contraceptive" is misleading at best and deprives women of the right and opportunity for informed consent. To the extent that the contraceptive mandate requires coverage of drugs that can cause an abortion after implantation, the mandate would encompass abortion even as previous administrations have defined it. Such coverage runs afoul of the ACA provisions discussed above (see notes 7 & 8, *supra*, and accompanying text), as well as the Weldon amendment.[13]

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[9] While 40% of unintended pregnancies end in abortion, this percentage rises to 51% for women who used a contraceptive during the month they became pregnant. Guttmacher Institute, "Fact Sheet: Induced Abortion in the United States," Oct. 2017, at fb_induced_abortion.pdf (guttmacher.org).

[10] *See* fact sheets by the USCCB Secretariat of Pro-Life Activities, "Greater Access to Contraception Does Not Reduce Abortions," Feb. 7, 2020, https://www.usccb.org/issues-and-action/human-life-and-dignity/contraception/fact-sheets/upload/Contraception-fact-sheet.pdf, and "Emergency Contraception Fails to Reduce Unintended Pregnancy and Abortion," Apr. 1, 2020, https://www.usccb.org/resources/Fact%20Sheet%20Emergency%20Contraception%20Fails.pdf (both compiling studies); *see also* Yellen, *supra*.

[11] E.G. Raymond, et al., *Population Effect of Increased Access to Emergency Contraceptive Pills*, 109 *OBSTETRICS & GYNECOLOGY* 181 (2007), Population effect of increased access to emergency contraceptive pills: a systematic review - PubMed (nih.gov).

[12] Documentation on this and other medical aspects of the drug was cited in testimony submitted to the FDA by the American Association of Pro-Life Obstetricians and Gynecologists.

[13] Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, Div. H, § 507(d) (stating that no Labor/HHS funds may be made available to any government agency that discriminates against any health plan on the basis that the plan does not cover abortion). The Obama administration concluded that the Weldon amendment, which has been included in every Labor/HHS appropriation since 2004, "remain[s] intact" after enactment of the ACA. Executive

B. Medical Realities of Contraceptive Drugs and Devices

The non-contraceptive items listed by HRSA as preventive services share a basic medical profile: they pose little or no medical risk themselves, and they help prevent or ameliorate identifiable conditions that would pose known risks to life and health in the future. Oral contraceptives present the opposite profile, posing their own serious risks and side-effects, some of which can be life-threatening.

Oral contraceptives "fail the most important test of preventive medicine: they increase [the] risk of disease instead of decreasing it."[14] The Departments have acknowledged many of these risks in earlier rulemaking. 82 Fed. Reg. at 47804. Women who use oral contraceptives may have an increased risk of heart-related side effects such as stroke, heart attacks and blood clots, especially if they also smoke cigarettes. The publishers of the *Physicians' Desk Reference* warn women of these "[s]erious, and possibly life-threatening, side effects," adding:

> Seek medical attention immediately if you have any of the following: chest pain, coughing up blood, or shortness of breath (indicating a possible blood clot in the lung); pain in the calf (indicating a possible blood clot in the leg); crushing chest pain or heaviness (indicating a possible heart attack); sudden, severe headache or vomiting, dizziness, fainting, vision or speech problems, weakness, or numbness in an arm or leg (indicating a possible stroke); sudden partial or complete loss of vision (indicating a possible blood clot in the eye); breast lumps (indicating possible breast cancer or fibrocystic breast disease); severe pain or tenderness in the stomach (indicating a possible liver tumor); difficulty sleeping, lack of energy, fatigue, change in mood (possibly indicating depression); yellowing of the skin or whites of the eyes (jaundice), sometimes accompanied by fever, fatigue, loss of appetite, dark-colored urine, or light-colored bowel movements (indicating possible liver problems).[15]

According to other sources, oral contraceptives have been associated with—

- Increased risk of depression.[16]
- Increased risk of venous thromboembolism (VTE).[17]

Order 13535 (Mar. 24, 2010), quoted in 82 Fed. Reg. at 47793.

[14] Rebecca Peck & Charles W. Norris, *Significant Risks of Oral Contraceptives (OCPs): Why This Drug Class Should Not Be Included in a Preventive Care Mandate*, 79 LINACRE QUARTERLY 41, 42 (Feb. 2012), untitled (familyplanning.net).

[15] PDR Network, "Oral contraceptives," at *PDRhealth* (2009).

[16] Charlotte Wessel Skovlund, et al., *Association of Hormonal Contraception with Depression*, JAMA PSYCHIATRY (published online Sept. 28, 2016) ("Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use.").

[17] Peck & Norris, *supra*, at 43 ("Oral contraceptives are associated with a three to five times higher risk of VTE");

- Increased risk of thrombotic stroke and myocardial infarction.[18]

- Increased risk of HIV-1 acquisition and transmission.[19]

- Increased risk of breast and cervical cancer.[20]

- Increased risk of hypertension.[21]

- Increased risk of bone fractures, Crohn's disease, ulcerative colitis, systemic lupus erythematosus, and other autoimmune diseases.[22]

It is important to recall in this context that most contraceptive drugs and devices are available only by prescription not primarily because they are medically indicated for any

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see also Yana Vinogradova, et al., *Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases*, BMJ (Mar. 19, 2015) ("Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism … compared with no exposure in the previous year."); *see also* Robert A. Hatcher et al., *Contraceptive Technology,* 18th rev. ed. (New York: Ardent Media, 2004), at 405-07. A 2018 systematic review of evidenced-based articles from the 1960s to 2018 concluded that "136-260 women die from VTE a year in the United States from hormonal contraception." William V. Williams, et al., *Hormonally Active Contraceptives Part I: Risks Acknowledged and Unacknowledged*, THE LINACRE QUARTERLY 126-48 (May 2021), citing L. Kennan, et al., *Systematic Review of Hormonal Contraception and Risk of Venous Thrombosis*, THE LINACRE QUARTERLY 470-77 (2018).

[18] Ojvind Lidegaard, et al., *Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception*, 366 N. ENGL. J. MED. 2257 (2012) (finding that risks of thrombotic stroke and myocardial infarction were "increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 mg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 mg"); Peck & Norris, *supra*, at 45 (reporting a 200 percent increase in the risk of myocardial infarction among users of low-dose oral contraceptives); *see also* Hatcher, *supra*, at 404-05, 445.

[19] Renee Heffron, et al., *Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study*, 12 THE LANCET (Jan. 2012) ("Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV-1 acquisition by women and HIV-1 transmission from women to men."); *see also Hormonal Contraception Doubles HIV Risk, Study Suggests,* SCIENCE DAILY (Oct. 4, 2011), https://www.sciencedaily.com/releases/2011/10/111003195253.htm.

[20] NIH Fact Sheet, *Oral Contraceptives and Cancer Risk* (Feb. 22, 2018), Oral Contraceptives (Birth Control Pills) and Cancer Risk - NCI. One study showed that users of oral contraceptives have a 50% higher risk of invasive breast cancer, and that users of triphasic oral contraceptives have three time the risk of breast cancer, compared to women who are not on hormonal contraceptives. Richard J. Fehring, *Nurses' Health Study Provides Risks and Benefits of Exogenous Reproductive Hormone Use*, 28 CURRENT MEDICAL RESEARCH, 9, 10 (Winter/Spring 2017), https://www.usccb.org/issues-and-action/marriage-and-family/natural-family-planning/medical-research/upload/CMR-WinterSpring-2017-FINAL.pdf. Mandating contraceptive coverage under the preventive services provision of the ACA is ironic given that sponsors of that provision cited the *prevention* of breast and cervical cancer as one of its key goals. Cong. Rec. S11986-91 (Nov. 30, 2009). *See also* Williams et al., *Hormonally Active Contraceptives*, *supra* (noting numerous studies that find an increased risk of breast and cervical cancer associated with use of contraceptives).

[21] Hatcher, *supra*, at 407, 445.

[22] Williams et al., *Hormonally Active Contraceptives*, *supra*.

particular illness, but because they pose sufficient risks that it would be irresponsible to distribute them without medical supervision. Indeed, even with a physician's oversight, use of oral contraceptives has given rise to a virtual cottage industry among the plaintiffs' bar seeking recovery, and obtaining multi-million dollar judgments, for resulting injuries.[23] In short, while media outlets and some advocates continue to talk about contraceptives as if they are an unmitigated boon to women's health, there is ample evidence that they can and do injure women, sometimes fatally.[24]

Our recommendation to rescind the mandate is also supported by the controversy and litigation that the mandate has generated. The mandate provoked the largest single wave of religious freedom litigation in the history of the United States: over 100 lawsuits, including 56 suits on behalf of more than 300 plaintiffs with various denominational commitments, extending over half a decade. On an issue as divisive as this one, and bearing in mind that public controversy over the mandate has now consumed more than a decade of government and private resources, the prudent course, in our view, and the one best in keeping with the advancement of women's health, is to rescind the mandate.

At a minimum, to avoid violation of the Weldon amendment and the abortion provisions of the ACA, HHS should not require coverage of any drug or device that disrupts an existing pregnancy.

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[23] *See, e.g.*, Drug Watch, *Yaz Settlements*, https://www.drugwatch.com/yaz/settlements/ ("Bayer has settled more than 18,000 lawsuits that alleged its birth-control pills with drospirenone, Yaz and Yasmin, caused potentially life-threatening blood clots, gallbladder problems, heart attacks and strokes. By early 2016, Bayer signed off on $2 billion in settlements in the U.S., with more claims pending internationally."); Randi Kaye & Shawna Shepherd, *Families, Lawsuits, Raise Questions About NuvaRing*, CNN (Apr. 7, 2015), Families, lawsuits, raise questions about NuvaRing | CNN; Julie Deardorff, *Lawsuits Pile Up Over Popular Birth Control Pill*, CHICAGO TRIB. (Sept. 15, 2013), Lawsuits pile up over popular birth control pill – Chicago Tribune; Natasha Singer, *Health Concerns Over Popular Contraceptives*, N.Y. TIMES (Sept. 25, 2009), Health Concerns Are Raised Over Use of Popular Contraceptives - The New York Times (nytimes.com).

[24] There is some evidence (and HHS in the past has alluded to it) that the recommendation to list contraceptives as a preventive service did not seriously evaluate these risks. *See* 82 Fed. Reg. at 47795 (noting that the IOM's committee's recommendation, which formed the basis of HRSA's decision to list contraceptives as a preventive service, was not based on "high quality, systematic evidence," as recounted by one dissenting IOM member, and that the process that led to its recommendation was, in his words, "filtered through a lens of advocacy"). Fertility-based means of spacing births—means that are both morally licit and, if practiced, as effective as artificial contraceptives—are, of course, free of these health risks because they do not rely for their mode of action upon introducing prescribed substances into a woman's body. Michael D. Manhart, et al., *Fertility Awareness-Based Methods of Family Planning: A Review of Effectiveness for Avoiding Pregnancy Using SORT*, 5 OSTEOPATHIC FAMILY PHYSICIAN 2 (2013) (finding that fertility-based means of spacing births show an unintended pregnancy rate "comparable to those of commonly used contraceptives"); Richard J. Fehring, et al., *Randomized Comparison of Two Internet-Supported Fertility-Awareness-Based Methods of Family Planning*, 88 CONTRACEPTION 24-30 (2013) (noting that, unlike contraceptive methods, which are discontinued often due to side effects, fertility-based methods of family planning are "free of side effects").

II. The Exemptions

A. The Religious Exemption

We agree with the position taken by the Departments in the 2017/2018 round of rulemaking that the contraceptive mandate and accommodations, as imposed upon religious objectors, violated the Religious Freedom Restoration Act (RFRA).[25] For these and other reasons, we support the Departments' current proposal to retain the religious exemption.

RFRA has three components. It forbids the government to take an action that (a) substantially burdens free exercise unless (b) the action serves a compelling government interest (c) by the means least restrictive of free exercise. In 2017/2018, to their credit, the Departments correctly conceded that, as imposed upon religious objectors, the mandate and accommodation substantially burdened free exercise, did not serve a compelling government interest, and were not the least restrictive means.[26] For this reason, as the Departments then acknowledged (82 Fed. Reg. at 47800), the government was required by law to alleviate the substantial burden that the mandate and the accommodation created.

There are several reasons, as the government correctly pointed out, why the mandate and accommodation violated RFRA.

First, it is settled that the mandate imposed a substantial burden on religious objectors. *Burwell v. Hobby Lobby Stores*, 134 S. Ct. 2751, 2775-79 (2014). HHS had developed an alternative means for objecting religious entities to comply with the mandate, which it characterized as an "accommodation," but the Departments correctly conceded, 82 Fed. Reg. at 47800, as the court of appeals in *Sharpe Holdings v. U.S. Dep't of Health & Human Services*. 801 F.3d 927 (8th Cir. 2015), agreed, that this alternative means of complying with the mandate, like the mandate itself, substantially burdened the free exercise of religious objectors.

Second, the mandate and accommodation were neither supported by a compelling government interest, nor were they the means least restrictive of free exercise. Among other

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[25] "The Departments [of Treasury, Labor, and HHS] have … determined that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance violates their rights under RFRA." 82 Fed. Reg. at 47800. *See also id*. at 47806 ("[R]equiring … compliance [with the mandate or accommodation] led to the violation of RFRA in many instances").

[26] *See*, *e.g*., 82 Fed. Reg. at 47800 ("We have concluded that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA."); *id*. ("Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not."); *id*. ("the Departments have concluded that the application of the Mandate to entities with sincerely held religious objections to it does not serve a compelling governmental interest."); *id*. at 47806 ("[W]e have concluded that requiring … compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many … entities or individuals, and … requiring such compliance did not serve a compelling interest, and was not the least restrictive means of serving a compelling interest").

things—

• Congress did not require, and has not required, coverage of contraceptives.

• Congress did not require, and has not required, across-the-board coverage of preventive services generally. As HHS previously noted, over 25 million grandfathered plans are exempt from the requirement to cover preventive services, 82 Fed. Reg. at 47794, and "there is no legal requirement" that these plans "ever be phased out." *Hobby Lobby Stores*, 134 S. Ct. at 2764 n.10, quoted in 82 Fed. Reg. at 47794. As HHS also conceded, the government lacks the authority to compel self-insured church plans to cover preventive services. 82 Fed. Reg. at 47801. And under the prior regulations, churches themselves had always been exempt from the contraceptive mandate, regardless of the type of plan they offer. That the mandate left such appreciable damage to the previously claimed interest in ensuring contraceptive coverage was "strong evidence" (82 Fed. Reg. at 47801) that the mandate did not serve an interest of the highest order, as would be required to comply with RFRA. *Church of Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 535 (1993).

• HHS's earlier decision to exempt churches but not church-affiliated charities from the contraceptive mandate was based on the supposition that employees of the latter were less inclined than employees of the former to support their church's position on contraceptives. HHS later acknowledged, however, that this supposition was "not supported by any specific data or other source." 82 Fed. Reg. at 47802. In addition, earlier attempts to gerrymander religious organizations, as HHS rightly acknowledged (*id*.), were in conflict with the right of such organizations to employ persons who will "advance the organization's goals and … be respectful of [its] beliefs even if they do not share all of those beliefs."

• The ACA was intended to *expand* health coverage, but the mandate has the perverse effect of pressuring or coercing some entities and individuals to *drop* health coverage. 82 Fed. Reg. at 47802-03 (noting that "some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or be subject to the accommodation"); *id*. at 47812 (noting that the individual exemption "will reduce the incidence of certain individuals choosing to forego [sic] health coverage because the only coverage available would violate their sincerely held religious beliefs").

• There are "multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women," and for those who do not qualify for these programs, the cost of contraceptives is relatively low. 82 Fed. Reg. at 47803. These facts "significantly diminish[ed] the Government's interest in applying the Mandate to employers over their sincerely held religious objections." *Id*.

• Even if contraceptives were a benefit to women's health, which we dispute, the existing exemptions were, in the Departments' best estimate, likely to affect the contraceptive costs of approximately 31,700 women, which is "less than 0.1 percent of the 55.6 million women in private plans" that the Departments estimated receive preventive services coverage under the preventive services requirement. 82 Fed. Reg. at 47821. This number is remarkably small when compared with the 25 million persons that were enrolled in grandfathered plans that do not require such coverage.

RFRA is, of course, a requirement that the government has no discretion to ignore, as the Departments have previously acknowledged. 82 Fed. Reg. at 47800. Having concluded that RFRA had been violated, the government is required to take action to ensure compliance with RFRA. But even if the mandate and accommodation did not violate RFRA, the Departments, as they themselves previously pointed out (*id*. at 47806), still have the discretion to create exemptions. We agree with and support HHS's decision, if contraceptives continue to be a mandated item of coverage, to exercise discretion now in favor of retaining the religious exemption whether RFRA is violated or not.

Nonetheless, the Departments suggest, though without details, that they may be open to mandating something like the much-contested religious accommodation.[27] In our view, this would be a huge mistake because it would lead to litigation similar to that brought to challenge the mandate and accommodation. That litigation has consumed nearly a decade. At some point, and we think the point is now, the Departments need to stop tinkering with these rules as each new innovation simply generates another round of litigation. One solution, as we have consistently recommended, is for the HRSA to exercise its discretion to remove contraceptives as a mandated item of coverage given the enormous controversy it has generated and the consequent drain on government and private resources.

B. The Moral Exemption

The "plain language of the statute [section 2713(a)(4) of the ACA] clearly allows the Departments to create … religious *and moral* exemptions" to the contraceptive mandate. *Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2382 (2020) (emphasis added), quoted in 88 Fed. Reg. at 7247.

Nonetheless, the Departments propose to eliminate the non-religious moral exemption from the regulations. In support of the proposal, the Departments argue that (a) a non-religious moral

[27] See 88 Fed. Reg. at 7249 ("The Departments also seek comment on whether and how the health insurance issuer, in instances in which it does not have its own religious objection to covering contraceptive services, should be required to provide the contraceptive coverage, and what guardrails should be in place to separate the issuer's coverage of contraceptive services from the coverage provided under the insured group health plan or student health insurance coverage."); *id*. at 7265 ("The Departments also considered an approach under which, if an objecting entity designs or contracts for a health plan without contraceptive coverage, the contraceptive coverage requirement would apply directly to the issuer").

exemption is "not legally required," (b) such an exemption likely affects very few individuals, (c) few entities make use of the moral exemption, and (d) non-religious objections "are outweighed by the strong public interest in making contraceptive overage as accessible to women as possible." 88 Fed. Reg. at 7249-50.

These rationales, in our view, are unpersuasive.

Assuming for argument's sake that a moral exemption is not legally required,[28] federal agency rulemaking is not limited to what is *already* required by law. Otherwise, federal rulemaking would be superfluous because it would only restate or mirror what the law already provides. Indeed, the underlying contraceptive mandate is not legally required. That few individuals are affected by a moral exemption, and that few entities make use of one—even assuming that to be true—would seem to weigh in *favor* of such an exemption because it would tend to minimize any claimed harm. *See also* note 28, *supra* (establishing that there are at least some non-moral religious objectors). In any event, lack of popularity is no reason to refuse a moral exemption. Traditionally conscience laws in this country protect those whose views are unpopular. Lastly, the Departments' asserted interest in making contraceptive coverage accessible, in our view, does not justify refusal to honor a moral objection to such coverage. The Departments, after all, have created a mechanism for providing contraceptive coverage in the case of *religious* objectors and could easily make the same mechanism available in the case of non-religious *moral* objectors.

In the 2017/2018 cycle of rulemaking, the Departments provided ample and persuasive reasons for adopting a non-religious moral exemption from the mandate when they proposed and adopted such an exemption. Among other things, the Departments cited federal statutory protections for moral-based exemptions, including many that are applicable in the health care context generally and to contraceptives specifically[29]; court precedents relevant to moral exemptions; conscience protections in regulations and among the states; broadly-framed principles of freedom of conscience embraced by the Founders; and litigation surrounding the mandate. 82 Fed. Reg. 47838, 47844-48 (Oct. 13, 2017); 83 Fed. Reg. 57592 (Nov. 15, 2018). Indeed, it would seem that rescission of the moral exemption will lead to another round of litigation, one that is entirely avoidable if the Departments simply retain the exemption.

The Departments in 2018 "concluded that it is appropriate to provide moral exemptions" from the contraceptive mandate. *Id*. at 57603. The Departments were right. The correctness of that view has not changed in the intervening years.

[28] But see *March for Life v. Burwell*, 128 F. Supp. 3d 1116 (D. D.C. 2015) (holding that refusal to provide an exemption for moral objectors is unlawful).

[29] The Departments correctly noted, for example, that Congress has stated its intent that any legislation enacted in the District of Columbia on the provision of contraceptive coverage "should include a 'conscience clause' which provides exceptions for religious beliefs *and moral convictions*," has protected individuals with religious *or moral objections* to prescribing contraceptives, and has protected applicants for family planning funds with a "religious *or conscientious* commitment" to offer only natural family planning. 83 Fed. Reg. at 57594 n.1 (emphasis added).

Conclusion

We urge HHS through HRSA to reconsider and rescind the mandate requiring coverage of contraception or sterilization in health plans as part of "preventive services." These drugs, devices and procedures do not prevent a disease condition, but the healthy condition known as fertility, and pose significant risks of their own to women's lives and health. At a minimum, consistent with the abortion and non-preemption provisions of the ACA and the Weldon amendment, HHS should not mandate coverage of any drug or device that can disrupt an existing pregnancy.

As long as the mandate, or any portion of the mandate, remains in place, we support an exemption for all stakeholders with religious or moral objections. For these reasons, we support the Departments' proposal to retain the existing religious exemption, and we urge the Departments to retain the existing moral exemption.

Thank you for the opportunity to comment.

Sincerely,

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