



## ***Office of the General Counsel***

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*Submitted Electronically*

November 21, 2017

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9925-IFC  
P.O. Box 8016  
Baltimore, MD 21244-8016

**Subj: Moral Exemptions and Accommodations for Coverage of Certain  
Preventive Services Under the Affordable Care Act, RIN 0938-AT46**

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (“USCCB”), we submit the following comments on the interim final rules, published at 82 Fed. Reg. 47838 (Oct. 13, 2017), on moral exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act (“ACA”).<sup>1</sup>

### **I. The Mandate**

As set out in our comments on the companion interim final rule on religious exemptions, we believe HHS should reconsider and rescind the mandate requiring coverage of contraception or sterilization in health plans as part of “preventive services.” These drugs, devices and procedures prevent not a disease condition, but the healthy condition known as fertility, and they pose significant risks of their own to women’s life and health. For these reasons, and for reasons set out more fully in our comments on the companion interim final rule on religious exemptions, we request that the mandate be rescinded.

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<sup>1</sup> Today we have also filed comments on the companion interim final rule, published at 82 Fed Reg. 47792 (Oct. 13, 2017), concerning exemptions and accommodations for religious objections to contraceptives. The two sets of comments should be considered together, and each set of comments includes the other as an attachment which we incorporate by reference. 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. The “mandate” refers to the requirement to cover these items.

## II. The Exemptions

### A. A Moral Exemption is Appropriate.

HHS has given very thorough and persuasive reasons for adopting a moral-based exemption from the mandate. Among other things, the Department cites federal statutory protections for moral-based exemptions, including many that are applicable in the health care context generally and to contraceptives specifically; the legislative history of the Church amendment, a longstanding statute that protects moral as well as religious objectors; 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; executive orders relevant to moral exemptions; and litigation surrounding the mandate. 82 Fed. Reg. at 47844-48.

We agree with the Department that there should be exemptions for those with moral objections, and we agree with the reasons that the Department has given for adopting exemptions for stakeholders with moral objections.

### B. The List of Plan Sponsors Eligible for an Exemption on Moral Grounds Should Be at Least as Broad as the List of Plan Sponsors Eligible for an Exemption on Religious Grounds.

Currently the list of stakeholders eligible for an exemption for *moral* reasons, though commendably broad, is slightly narrower than the list of stakeholders eligible for an exemption for *religious* reasons.<sup>2</sup> The Department seeks public comment specifically on “whether the exemption ... for plan sponsors with moral objections to the Mandate should be finalized to encompass all of the types of plan sponsors covered by [the exemption for plan sponsors with religious objections]....” 82 Fed. Reg. at 47851.

The answer, in our view, is yes. That is, the range of plan sponsors eligible for an exemption if they have a moral objection should be no less broad than the range of plan sponsors eligible for an exemption on religious grounds. We take this position for five reasons.

*First*, in the preamble to the companion interim final rule on religious exemptions, HHS states that a publicly-traded company may have a religious objection to the mandate, even if such

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<sup>2</sup> For example, the companion interim final rule on religious exemptions provides a *non-exhaustive* list of plan sponsors that are exempt from the mandate if they have a religious objection. 82 Fed. Reg. at 47835 (setting out a list of plan sponsors that “include, but are not limited to,” certain specified entities). The interim final rule on moral exemptions, however, lacks the language “include, but are not limited to,” *see* 82 Fed. Reg. at 47861-62, and therefore presents what is a list that is arguably exhaustive rather than illustrative.

To take another example, the companion interim final rule states that a “for-profit entity that is not closely held” may obtain an exemption on religious grounds. 82 Fed. Reg. at 47835. But the present interim final rule states that a for-profit entity that is not closely held may obtain an exemption on moral grounds only if it is not publicly-traded. 82 Fed. Reg. at 47862.

an objection is unlikely, so HHS *allows* an exemption. 82 Fed. Reg. at 47810-11. In the preamble to the present interim final rule on moral exemptions, however, HHS states that a publicly-traded company could have a moral objection, but that such an objection is unlikely, so HHS *disallows* an exemption. 82 Fed. Reg. at 47851-52. These two arguments are inconsistent. If the possibility of a religious objection is sufficient in the case of the companion rule on religious exemptions to justify an exemption, as HHS correctly states, then the possibility of a moral objection should also be sufficient in the case of the present interim final rule to justify an exemption.

*Second*, we think the thorough, persuasive reasons HHS has offered for having a moral exemption in the first place justifies an exemption on moral grounds that is at least as broad as that provided for religious objectors.

*Third*, one can reasonably conclude that this particular mandate will generate moral as well as religious objections. That is because the locus of the objection, as evidenced by past litigation on the mandate, is very often on drugs and devices that prevent implantation and are therefore regarded by the objector as abortifacient irrespective of the objector's particular religious tradition. Indeed, in the case of a publicly-traded corporation, it is arguably *more* likely that some block of shareholders will share a common moral opposition to abortifacients than that they will share common religious traditions opposing such drugs or devices. *See Valley Hosp. Ass'n v. Mat-Su Coalition for Choice*, 948 P.2d 963 (Alaska 1997) (non-religious community hospital had moral objections to providing abortions, even though it had no religious objection); 42 U.S.C. § 300a-7 (recognizing the possibility of moral but non-religious objections to abortion, and therefore protecting such objectors). Indeed, moral objections are sometimes religiously grounded, sometimes they are not. So, the universe of moral objectors, it would seem, is almost always going to be larger than the universe of religious objectors because the former arguably includes the latter as a subset.

*Fourth*, while the current religious and moral exemptions, as written, easily pass muster under the Establishment Clause, and while the presence of a religious exemption in our view does not constitutionally *require* a parallel moral exemption, the Department, as a practical matter, may find it easier to defend against an Establishment Clause challenge a religious exemption that has a perfect parallel in a regulation providing an identical exemption for moral reasons.

*Fifth*, religious and moral exemptions that parallel each other will be easier for the public to understand and simpler for the federal government to administer.

For all these reasons, we think it would be prudent for the Department to broaden the exemption for plan sponsors with a moral objection to the mandate to include any plan sponsor that, if it had a religious objection, would be exempt under the companion rule.

**C. No Self-Certification Should be Required.**

The Department states that “exempt entities will not be required to comply with a self-certification process.” 82 Fed. Reg. at 47850. The Department asks, however, “whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption....” *Id.* at 47850.

We agree with the Department’s decision not to require exempt entities to comply with a self-certification process, and we recommend that no special form or other process be developed or required to claim the exemption, especially since these have been used in the past as a mechanism for ensuring compliance with the mandate and therefore have themselves raised religious and moral concerns for many stakeholders.

**Conclusion**

HHS should reconsider and rescind the mandate requiring coverage of contraception or sterilization in health plans as part of “preventive services.” These drugs, devices and procedures prevent not a disease condition, but the healthy condition known as fertility, and they pose significant risks of their own to women’s life and health. As long as the mandate is in place, we fully support the exemptions for those individuals and entities with religious and moral objections to the mandate. The exemptions for moral objections should apply to a list of stakeholders that is at least as broad as that for religious objections. Accordingly, we recommend that the interim final rule be adjusted so that it parallels the list of stakeholders with religious objections in the companion interim final rule.

Thank you for the opportunity to comment.

Sincerely,

Anthony R. Picarello, Jr.  
Associate General Secretary &  
General Counsel

Michael F. Moses  
Associate General Counsel

Hillary E. Byrnes  
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## Addendum



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**Subj: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, RIN 0938-AT20**

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (“USCCB”), we submit the following comments on the interim final rules, published at 82 Fed. Reg. 47792 (Oct. 13, 2017), on religious exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act (“ACA”).<sup>1</sup>

Since the ACA’s enactment in 2010, we have filed comments each time the Department has issued a regulatory proposal on contraceptive coverage.<sup>2</sup> Our earlier comments raised two overarching themes.

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<sup>1</sup> Today we have also filed comments on the companion interim final rule, published at 82 Fed Reg. 47838 (Oct. 13, 2017), concerning exemptions and accommodations for moral objections to contraceptives. The two sets of comments should be considered together, and each set of comments includes the other as an attachment which we incorporate by reference. 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.

<sup>2</sup> See USCCB Comments on Interim Final Rules on Preventive Services (Aug. 31, 2011), <http://www.usccb.org/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), <http://www.usccb.org/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), <http://www.usccb.org/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), <http://www.usccb.org/about/general->

*First*, we argued that contraceptives should not be mandated as “preventive” services because, unlike genuinely preventive services, they do not prevent disease or illness. Instead, they are associated with an increased risk of adverse health outcomes, such as breast cancer, that other “preventive services” are designed to prevent. 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 argued that if coverage of contraceptives were to be mandated, all stakeholders with religious or moral objections should be exempt. We argued that the previous exemption from the mandate for churches was too narrow, and that the device HHS had created for the purpose of “accommodating” non-exempt entities was insufficient to relieve non-exempt entities of the substantial burden that the mandate placed upon them. We argued that a broad exemption for religious objectors was required under the Religious Freedom Restoration Act (“RFRA”), and that an exemption for religious and moral objectors was both prudent as a matter of public policy and consistent with longstanding traditions protecting conscience in this country.

In the present interim final rule and companion rule regarding moral convictions, HHS does not address the first of these two overarching issues, but instead leaves it to the discretion of its Health Resources and Services Administration (“HRSA”) “to decide whether to include contraceptives in the women’s preventive services Guidelines...”<sup>3</sup> Because the Guidelines themselves have never been the subject of 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 all our past rulemaking comments on contraceptive coverage, because significant questions remain whether contraceptives are an appropriate subject for inclusion in a list of preventive services in the first instance. For reasons set out in these comments, HHS could reasonably conclude that they are not. 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 with 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, HHS is to be commended. Consistent with the position that we and others have long urged, the Department, in these two interim final rules, has crafted exemptions that together protect all stakeholders with religious or moral objections to contraceptive

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[counsel/rulemaking/upload/2014-hhs-comments-on-proposed-rule-on-for-profits-10-8.pdf](http://www.usccb.org/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), <http://www.usccb.org/about/general-counsel/rulemaking/upload/2014-hhs-comments-on-interim-final-rules-10-8.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 list of mandated preventive services under the ACA), <http://www.usccb.org/about/general-counsel/rulemaking/upload/comments-to-hhs-on-preventive-services-2010-09.pdf>.

<sup>3</sup> See, e.g., 82 Fed. Reg. at 47799 (“These interim final rules leave unchanged HRSA’s authority to decide whether to include contraceptives in the women’s preventive services Guidelines for entities that are not exempted by law, regulation, or the guidelines.”).

coverage, for reasons that are well articulated and persuasive. The exemptions are, as the bishops noted when first apprised of them, “a return to common sense”<sup>4</sup> and, in the Department’s words, 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. at 47792.

## **I. The Mandate**

Contraceptives are inappropriate candidates for inclusion under mandated “preventive services” for several reasons.

### **A. The Meaning and Purpose of “Preventive Services”**

The 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. 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).

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 for interpersonal and domestic violence, counseling for sexually transmitted infections, and well-woman preventive visits. HRSA, Women’s Preventive Services Guidelines (Dec. 20, 2016), <https://www.hrsa.gov/womens-guidelines-2016/index.html>. Coverage of these services is mandated 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, but when they do succeed, what they most often “prevent” is a healthy pregnancy in a healthy woman of childbearing age. 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

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<sup>4</sup> 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), <http://www.usccb.org/news/2017/17-180z.cfm>.



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.<sup>5</sup> 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.<sup>6</sup> 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 and does not treat the existence of an unborn human life as an illness or condition requiring the “treatment” of abortion. 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.<sup>7</sup> Finally, numerous studies have shown that contraceptive programs do not reliably or consistently reduce abortion rates.<sup>8</sup> For example, one

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<sup>5</sup> 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).

<sup>6</sup> 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”).

<sup>7</sup> 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 [https://www.guttmacher.org/sites/default/files/factsheet/fb\\_induced\\_abortion.pdf](https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf).

<sup>8</sup> See fact sheets by the USCCB Secretariat of Pro-Life Activities, “Greater Access to Contraception Does Not Reduce Abortions,” <http://www.usccb.org/issues-and-action/human-life-and-dignity/contraception/fact-sheets/greater-access-to-contraception-does-not-reduce-abortions.cfm>, and “Emergency Contraception Fails to

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.”<sup>9</sup> 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 (“FDA”) 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.<sup>10</sup> 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 opportunity for genuine 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 5 & 6, *supra*, and accompanying text), as well as the Weldon amendment.<sup>11</sup>

## **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. *See* HRSA, Women’s Preventive Services Guidelines, [www.hrsa.gov/womens-guidelines/index.html](http://www.hrsa.gov/womens-guidelines/index.html).

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.”<sup>12</sup> HHS acknowledges many of these risks. 82 Fed.

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Reduce Unintended Pregnancy and Abortion,” June 5, 2014, at <http://www.usccb.org/issues-and-action/human-life-and-dignity/contraception/fact-sheets/emergency-contraception-fails-to-reduce-unintended-pregnancy-abortion.cfm>.

<sup>9</sup> E.G. Raymond, et al., *Population Effect of Increased Access to Emergency Contraceptive Pills*, 109 *OBSTETRICS & GYNECOLOGY* 181 (2007), <https://www.ncbi.nlm.nih.gov/pubmed/17197603>.

<sup>10</sup> Documentation on this and other medical aspects of the drug is cited in testimony submitted to the FDA by the American Association of Pro-Life Obstetricians and Gynecologists, available at <http://aaplog.org/aaplog-testimony-to-fdas-advisory-committee-for-reproductive-health-drugs-regarding-the-emergency-contraceptive-ella/>.

<sup>11</sup> Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, 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 provide abortion coverage). The previous administration concluded that the Weldon amendment “remain[s] intact” after enactment of the ACA. Executive Order 13535 (Mar. 24, 2010), quoted in 82 Fed. Reg. at 47793 (preamble).

<sup>12</sup> 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), <https://familyplanning.net/sites/default/files/Significan-Risks-of-Oral-Contraceptives-OCPs-Why-This-Drug-Should-Not-Be-Included-In-a-Preventive-Care-Mandate.pdf>.

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).<sup>13</sup>

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

- Increased risk of depression.<sup>14</sup>
- Increased risk of venous thromboembolism.<sup>15</sup>
- Increased risk of thrombotic stroke and myocardial infarction.<sup>16</sup>

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<sup>13</sup> PDR Network, “Oral contraceptives,” at *PDRhealth* (2009).

<sup>14</sup> 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.”).

<sup>15</sup> Peck & Norris, *supra*, at 43 (“Oral contraceptives are associated with a three to five times higher risk of VTE”); 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*, 18<sup>th</sup> rev. ed. (New York: Ardent Media, 2004), at 405-07.

<sup>16</sup> 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.

- Increased risk of HIV-1 acquisition and transmission.<sup>17</sup>
- Increased risk of breast, cervical, and liver cancer.<sup>18</sup>
- Increased risk of hypertension.<sup>19</sup>

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 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.<sup>20</sup> 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.<sup>21</sup>

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<sup>17</sup> 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>.

<sup>18</sup> NIH Fact Sheet, *Oral Contraceptives and Cancer Risk* (Mar. 21, 2012), <https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet>. 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), <http://www.usccb.org/issues-and-action/marriage-and-family/natural-family-planning/medical-research/upload/CMR-WinterSpring-2017-FINAL.pdf>. Mandating contraceptive cover 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).

<sup>19</sup> Hatcher, *supra*, at 407, 445.

<sup>20</sup> *See, e.g., Bayer Says It’s Paid \$142M Over Birth Control Lawsuits*, CHICAGO TRIB. (Apr. 26, 2012) (“Bayer says settlements of U.S. lawsuits over its Yasmin birth control pill have risen to \$142 million. Bayer says it has resolved more than 600 suits claiming that Yaz causes blood clots, some of which were fatal.”), [http://articles.chicagotribune.com/2012-04-26/business/chi-bayer-says-its-paid-142m-over-birth-control-lawsuits--20120426\\_1\\_bayer-lawsuits-yaz](http://articles.chicagotribune.com/2012-04-26/business/chi-bayer-says-its-paid-142m-over-birth-control-lawsuits--20120426_1_bayer-lawsuits-yaz); Randi Kaye & Shawna Shepherd, *Families, Lawsuits, Raise Questions About NuvaRing*, CNN (Apr. 7, 2015) [www.cnn.com/2015/04/06/us/families-lawsuits-raise-questions-about-nuvaring/](http://www.cnn.com/2015/04/06/us/families-lawsuits-raise-questions-about-nuvaring/); Julie Deardorff, *Lawsuits Pile Up Over Popular Birth Control Pill*, CHICAGO TRIB. (Sept. 15, 2013), [articles.chicagotribune.com/2013-09-15/health/ct-met-birth-control-risks-20130915\\_1\\_drospirenone-clots-pills/](http://articles.chicagotribune.com/2013-09-15/health/ct-met-birth-control-risks-20130915_1_drospirenone-clots-pills/); Natasha Singer, *Health Concerns Over Popular Contraceptives*, N.Y. TIMES (Sept. 25, 2009), <http://www.nytimes.com/2009/09/26/health/26contracept.html>.

<sup>21</sup> There is some evidence (and HHS alludes 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

Our recommendation to rescind the mandate is also supported by the controversy and the litigation that the mandate has generated and continues to generate. 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. It appears that a second generation of litigation will be pursued by those opposed to the exemptions that the new rules create.<sup>22</sup> Thus, having devoted substantial time and resources defending an unprecedented volume of litigation seeking exemptions, the government now finds itself in the position of having to expend yet *more* time and resources to defend the exemptions—time and resources that could be directed to other ends if HHS would take the simple step of rescinding the mandate. On an issue as divisive as this one, the prudent course, in our view, and the one that is best in keeping with the advancement of women’s health, would be to rescind the mandate. Rescission would also be consistent with HHS’s expressed intention to protect human life from conception,<sup>23</sup> as at least some purported “contraceptives” can work post-conception.

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.

## II. The Exemptions

We agree with HHS that the contraceptive mandate and accommodations, as applied to religious objectors, violated the Religious Freedom Restoration Act (“RFRA”), and we

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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”).

<sup>22</sup> *ACLU v. Wright*, No. 4:17-cv-5772 (N.D. Cal.) (complaint filed Oct. 6, 2017); *Commonwealth of Massachusetts v. U.S. Dep’t of Health and Human Servs.*, No. 1:17-cv-11930 (D. Mass.) (complaint filed Oct. 6, 2017); *State of California v. Wright*, No. 3:17-cv-05783 (N.D. Cal.) (complaint filed Oct. 6, 2017); *State of Washington v. Trump*, No. 2:17-cv-01510 (W.D. Wash.) (complaint filed Oct. 9, 2017); *Med. Students for Choice v. Wright*, No. 1:17-cv-02096 (D. D.C.) (complaint filed Oct. 10, 2017); *Commonwealth of Pennsylvania v. Trump*, No. 2:17-cv-04540 (E.D. Pa.) (complaint filed Oct. 11, 2017); *Campbell v. Trump*, No. 1:17-cv-02455 (D. Colo.) (complaint filed Oct. 13, 2017); *Sharaef v. Hargan*, No. 3:17-cv-0081 (N.D. Ind.) (complaint filed Oct. 31, 2017).

<sup>23</sup> See proposed HHS Strategic Plan, FY 2018-22, lines 60-61 (stating that HHS programs and initiatives serve and protect Americans “at every stage of life, beginning at conception”); *id.* at lines 846-48 (stating as a core component of HHS’s missions its dedication “to serve all Americans from conception to natural death”); *id.* at lines 830-31 (promoting measures that will advance global health by “respecting the inherent dignity of persons from conception to natural death”); *id.* at lines 1143-44 (supporting the protection of human subjects in research “from conception to natural death”). The draft Strategic Plan is posted at <https://cmda.org/library/doclib/hhs-strategic-plan-fy2018-2022.pdf>.

commend HHS and the other Departments for their concession of this point,<sup>24</sup> and for the exemptions that the interim final rules provide to avoid further violations of RFRA.

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. To its credit, the Department concedes that, as applied to religious objectors, the mandate and accommodation substantially burden free exercise, do not serve a compelling government interest, and are not the least restrictive means.<sup>25</sup> For this reason, as HHS acknowledges (82 Fed. Reg. at 47800), the government is required by law to alleviate the substantial burden that the mandate and the accommodation create.

There are several reasons, as the government is correct to point out, why the mandate and accommodation violate RFRA.

First, it is settled that the mandate imposes 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 Department now correctly concedes, 82 Fed. Reg. at 47800, as the court of appeals held in *Sharpe Holdings v. U.S. Dep’t of Health & Human Services*. 801 F.3d 927 (8th Cir. 2015), that this alternative means of complying with the mandate, like the mandate itself, substantially burdens the free exercise of religious objectors.

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

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<sup>24</sup> “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”).

<sup>25</sup> *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”).

As HHS also concedes, 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 have always been exempt from the contraceptive mandate, regardless of the type of plan they offer. That the mandate leaves such appreciable damage to the previously claimed interest in ensuring contraceptive coverage is “strong evidence” (82 Fed. Reg. at 47801) that the mandate does 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 now acknowledges, 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 acknowledges (*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 causing 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 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 (about \$50 per month on average). 82 Fed. Reg. at 47803. These facts “significantly diminish[] 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 exemptions created by the interim final rule are, in HHS’s 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 HHS estimates 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 enrolled in grandfathered plans.

RFRA is, of course, a requirement that the government has no discretion to ignore, as HHS has acknowledged. 82 Fed. Reg. at 47800. Having concluded that RFRA has been violated, as it has, the government is required to take action to ensure compliance with the statute. But even if the mandate and accommodation did not violate RFRA, HHS, as it points out (*id.* at 47806), would still have the discretion to create exemptions. We agree with HHS’s decision to exercise that discretion in favor of the expanded exemptions that this interim final rule creates, even if RFRA did not require it. And we agree with the decision to exempt a broad range of stakeholders with religious objections, including churches, nonprofit organizations, closely held for-profit entities, for-profit entities that are not closely held, and any other non-governmental employer, as well as institutions of higher education, health insurance issuers, and individuals.<sup>26</sup>

The Department indicates “exempt entities will not be required to comply with a self-certification process.” 82 Fed. Reg. at 47808. The Department asks, however, “whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption...” *Id.* at 47809. We agree with the Department’s decision not to require exempt entities to comply with a self-certification process, and we recommend that no special form or other process be developed or required to claim the exemption, especially since these have been used in the past as a mechanism for ensuring compliance with the mandate and therefore have themselves raised religious and moral concerns for many stakeholders.

### **Conclusion**

HHS should reconsider and rescind the mandate requiring coverage of contraception or sterilization in health plans as part of “preventive services.” These drugs, devices and procedures prevent not a disease condition, but the healthy condition known as fertility, and they pose significant risks of their own to women’s life and health. At a minimum, consistent with the abortion and non-preemption provisions of the ACA and with 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 fully support the exemptions that this rule and the companion rule together provide to stakeholders with religious and moral objections, and we commend HHS for adopting these exemptions.

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<sup>26</sup> We raise one technical matter. The preamble to the regulation suggests that the exemption “will no longer ‘be determined on an employer by employer basis,’ but will be determined on a plan basis,” yet the language in 45 C.F.R. § 147.132(a) does not, on its face, protect an objecting organization which is an employer that *adopts* (rather than sponsors or maintains) a plan sponsored or maintained by an objecting organization. Such organizations should be protected. A similar issue may affect objecting entities under the moral exemption.



Thank you for the opportunity to comment.

Sincerely,

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