THE NATIONAL CATHOLIC BIOETHICS CENTER

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Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
Washington, DC 20210
Attention: 1210-AC25

Subj: Enhancing Coverage of Preventive Services Under the Affordable Care Act RIN 1210-AC25

Dear Sir or Madam:

On behalf of The National Catholic Bioethics Center (NCBC), the Catholic Medical Association (CMA), and the National Association of Catholic Nurses, USA (NACN-USA) we respectfully submit the following comments on a proposed rule, published by the Departments of Treasury, Labor, and Health & Human Services (collectively, the Departments) at 89 Fed. Reg. 85750 (Oct. 28, 2024), concerning the above-captioned matter (The Rule).[1]

NCBC is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences. The Center has 2500 members throughout the United States and provides consultations to hundreds of institutions and individuals seeking its opinion on the appropriate application of Catholic moral teaching to these ethical issues.

CMA, founded in 1932, is the largest association of Catholic individuals in healthcare. Its membership includes more than 2,700 physicians, nurses, and physician assistants nationwide. CMA's mission is to inform, organize, and inspire its members to always practice consistent with the best interests of patients and their families, grounded in sound clinical science, all of which is consistent with upholding the Catholic faith in the science and practice of medicine.

NACN-USA is the national professional organization for Catholic nurses in the United States. A nonprofit association of hundreds of nurses of different clinical expertise, NACN-USA focuses on promoting patient advocacy, human dignity, and professional and spiritual development in the integration of faith and health within the Catholic context in nursing. NACN-USA supports and respects the sanctity and protection of human life from fertilization to natural death, the dignity of human sexuality and reproductive processes, and the wellbeing of its members' patients.

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[1] Re proposed rule (The Rule), published by the Departments of Treasury, Labor, and Health & Human Services (collectively, the Departments) at 89 Fed. Reg. 85750 (Oct. 28, 2024).

The mandates contained in The Rule require that all group health plans and health insurance issuers provide the full range of US Food and Drug Administration (FDA)-approved contraceptive over the counter methods (including contraceptive sponges, spermicides, and “emergency contraceptives”) as “preventive services” for women, as mandated under the *Patient Protection and Affordable Care Act* (ACA).[2] Furthermore, no co-pays are to be charged to beneficiaries. We will provide comment on the following implications of such a mandate.

NCBC, CMA, and NACN-USA have consistently advocated for health care policies which respect human life and dignity, honor conscience rights, and ensure that care is accessible to all, truly affordable, comprehensive, and of high quality, fostering the best interest of all served. However, we will present how The Rule does not accomplish such critical elements of sound public policy.

1. **The legislative history of ACA indicates the intent to cover screening and prevention of pathological conditions of women. Yet a broad and unfounded interpretation which mandates contraceptives and abortifacients has occurred.**

In a review of the ACA, specifically, Section 2713(a)(4), it is clear that the ACA never stipulates the intent to mandate the inclusion of contraceptives, abortifacients, or sterilizations, with no co-pay, within “preventive care and screenings” for women. Section 2713(a)(4), which requires private insurance plans to cover certain preventive services for women, was added to the ACA in an amendment offered by Senator Barbara Mikulski (D-MD) who issued a press release describing that amendment as follows:

> Services that would be covered under the Mikulski Amendment are likely to include cervical cancer screenings for a broad group of women; annual mammograms for women under 50; pregnancy and postpartum depression screenings; screenings for domestic violence; and annual women’s health screenings, which would include testing for diseases that are leading causes of death for women such as heart disease and diabetes.[3]

In her prepared floor statement, Senator Mikulski concluded:

> Often health care doesn’t cover basic women’s health care like mammograms and cervical cancer screenings. My amendment is about saving lives and saving money to give women access to comprehensive preventive services that are affordable and life saving.[4]

It is evident that the legislative intent of Section 2713(a)(4) was to screen for and prevent pathological conditions of women, not to cause them.

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[2] 124 Stat. 119 - *Patient Protection and Affordable Care Act* (ACA).
[3] http://mikulski.senate.gov/Newsroom/PressReleases/record.cfm?id=320304.
[4] http://mikulski.senate.gov/Newsroom/PressReleases/record.cfm?id=320304.

Most importantly, The Rule is creating new law in terms of mandating coverage of over-the-counter contraceptives, with no co-pay by the enrollees. This is well beyond the provisions of the ACA, and the statutory intent at the time of its adoption. On December 1, 2009, Senator Mikulski clearly stated: "There are no abortion services included in the Mikulski amendment. It [the Mikulski amendment] is screening for diseases that are the biggest killers for women—the silent killers of women. It also provides family planning--*but family planning as recognized by other acts*."[5] [Emphasis added.] No other federal act mandates the provision of contraceptives with no co-pay.

In fact, contraceptives should not be mandated as "preventive" services because, unlike genuinely preventive services, they do not prevent disease or illness. Instead, they inhibit healthy, natural bodily functions and are associated with an increased risk of adverse health outcomes, such as breast cancer, that other "preventive services" are designed to prevent. Moreover, contrary to their intended purpose and, as presented below, the use of contraceptives in actual practice may increase rather than decrease the incidence of unplanned pregnancies. The contraceptive mandate, including the current proposal to expand the mandate to include over-the-counter contraceptives, is therefore at odds with the purpose of the preventive services provision of the *Affordable Care Act*, upon which the mandate purports to be based. While it is recognized that The Rule strengthens and clarifies the requirement that each plan must have an "exemptions process," there are implications with the provision that these processes must not constitute an "unreasonable barrier to coverage." This provision raises concerns about the very religious and conscience protections that are to be protected. [89 FR 85766]

Furthermore, insofar as it requires coverage of drugs and devices that can cause an abortion (cited, below), the mandate, and the expansion of the mandate which now includes over-the-counter contraceptives, could violate ACA provisions dealing with abortion coverage and non-preemption of state law, as well as the Weldon amendment, and other legislative protections of religious freedom.[6]

Left unanswered is who is entitled to the provisions of the mandates contained in The Rule. Given that this mandate stems from Congress' *Women's Health Amendment*, it would seem that only women are entitled these provisions, but the term "woman" is not defined.[7]

2. Evidence supports that increased access to contraception does not prevent pregnancy.

Evidence increasingly is demonstrating that contraceptive use does not promote sexual responsibility or sexual health. Numerous studies have shown that contraceptive

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[5] http://thomas.loc.gov/cgi-bin/query/F?r111:1:./temp/~r111ulsMjy:e58173:.

[6] The Weldon Amendment, originally adopted as section 508(d) of the Labor-HHS Division (Division F) of the 2005 Consolidated Appropriations Act, Public Law 108-447, 118 Stat. 2809, 3163 (Dec. 8, 2004), has been readopted (or incorporated by reference) in each subsequent legislative measure appropriating funds to HHS.

[7] The *Women's Health Amendment*, also known as Section 2713(a)(4) of the Public Health Service Act, is part of the Affordable Care Act (ACA).

programs do not reliably or consistently reduce unplanned pregnancy or abortion rates.[8] 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."[9] Data from the Centers for Disease Control (CDC) indicate that the estimated unintended pregnancy rate (EUPR), while slightly declining from 2010 (43.3% EUPR) to 2019 (41.6% EUPR)[10] since the promulgation of the "Contraceptive Mandate Rule" of 2012,[11] represents less than a two percent decline after prescription contraceptives have been made virtually universally available, free of charge, to the population of women. In fact, for women 35-39 years of age, and 40 years of age and older, the rates of unintended pregnancy increased by 5% and 8%, respectively.[12] Thus, it is abundantly clear that providing contraceptive coverage, even with little or no cost (as The Rule mandates) does not appreciably decrease unintended pregnancies, and in fact provides false assurances that foster less sexual responsibility. Furthermore, as will be addressed below, the health risks from certain contraceptives now available over the counter are significant.

Also, the rates of sexually transmitted disease have escalated. According to data from the CDC, rates of sexually transmitted diseases (STDs) like chlamydia, gonorrhea, and syphilis have significantly increased in the United States from 2012. While there have been improving downward trends between 2015 to 2023, and while the annual overall increase in syphilis cases, including congenital syphilis cases, slowed in 2023, the rate of congenital syphilis is more than eight times higher than a decade ago.[13] Congenital syphilis is transmitted from mother to her unborn child, indicative of the direct relationship between sexual activity and its transmission. Thus, regardless of the slight downward trend in unintended pregnancies, there are other health risks associated with a contracepting culture that promotes non-monogamous sexual activity.

3. The Religious and Moral Exemptions Must be Respected.

The Rule's discussion of conscience protections, assuring that The Rule will not affect or modify Federal conscience protections, must be retained, and be explicit, including identifying specific religious and moral accommodations and exemptions. This has been an enduring problem since the 2012 "Contraceptive Mandate Rule" was promulgated. The "Contraceptive Mandate" has provoked the largest single wave of religious freedom

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[8] USCCB Secretariat of Pro-Life Activities, "Greater Access to Contraception Does Not Reduce Abortions" (Feb. 7, 2020) (compiling studies), and "Emergency Contraception Fails to Reduce Unintended Pregnancy and Abortion" (Apr. 1, 2020).

[9] E.G. Raymond, et al., "Population Effect of Increased Access to Emergency Contraceptive Pills," 109 *Obstetrics & Gynecology* 181 (2007).

[10] Centers for Disease Control and Prevention, National Center for Health Statistics, "Updated Methodology to Estimate Overall and Unintended Pregnancy Rates in the United States Data Evaluation and Methods Research," 2:2021 (April 2023) Abstract and Table B.

[11] Dept. Health and Human Services. "Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and *Affordable Care Act* – Final Rules", 77 *CFR* 8725 (February 10, 2012).

[12] Centers for Disease Control and Prevention, National Center for Health Statistics, "Updated Methodology to Estimate Overall and Unintended Pregnancy Rates in the United States Data Evaluation and Methods Research," 2:2021 (April 2023) Figure 7 and Table C.

[13] Centers for Disease Control and Prevention, National Center for Health Statistics, *"*Sexually Transmitted Infections Surveillance, 2023" (2023). *https://www.cdc.gov/sti-statistics/data-vis/index.html*.

litigation in the history of the United States: over one hundred lawsuits, including fifty-six suits on behalf of more than three hundred plaintiffs with various denominational commitments, extending over a decade.

This has been complicated by the fact that one of the two President Trump-era Rules addressing religious and moral objections has been enjoined. Those Rules' protections included: providing for true exemptions, not just pseudo "accommodations" to religious-sponsored entities (purportedly contraceptives not paid for by the employer, but paid for by the employer's plan, for which the employer pays premiums); exemption for religious, and/or moral objections by family owned non-profit entity; and if a publicly traded, for-profit business the objection must be a religious objection, otherwise an "accommodation" can be sought for a moral objection. The latter provision for moral objections has been enjoined,[14] while provisions for the religious exemptions[15] have been upheld by the U.S. Supreme Court.[16] Five years after the 2018 Final Rules, and three years after the U.S. Supreme Court's latest intervention upholding religious objections to the Contraceptive Mandate, the Biden administration has proposed new regulations aimed at restricting conscience protections and expanding access to contraception.[17] However, such a Rule has never been promulgated. This demonstrates the importance of clearly identifying in The Rule the legal protections that will be enforced for both religiously-based and moral-based objections: 89 Fed. Reg. at 85792, amending 26 C.F.R. § 54.9815-2713 ("Subject to § 54.9815-2713A and 45 CFR 147.132 and 147.133 …"); id. at 85793, amending 29 C.F.R. § 2590.715-2713 ("Subject to § 2590.715-2713A and 45 CFR 147.132 and 147.133 …"); id. at 85794, amending 45 C.F.R. § 147.130 ("Subject to §§ 147.131, 147.132, and 147.133 …"). Retention of this language is consistent with the Departments' repeated assurances that these proposed rules will not affect or modify Federal conscience protections, including the existing religious and moral accommodations and exemptions. However, their needs to be specific assurances concerning the protections that were contained in "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act," but enjoined.[18] This injunction was not overturned by the U.S. Supreme Court.

As indicated earlier, on December 1, 2009, Senator Mikulski clearly stated: "There are no abortion services included in the Mikulski amendment. It is screening for diseases that are the biggest killers for women—the silent killers of women. It also provides family planning--*but family planning as recognized by other acts*."[19] [Emphasis added.] No other federal act mandates the provision of contraceptives, abortifacients, and surgical sterilizations, with no co-pay. This expansion to mandates including over-the-counter contraception represents another novelty. Thus, there is great need for specificity in terms of the religious and moral exemptions and accommodations that will be protected.

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[14] Department of Health and Human Services, "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" 45 *CFR* Part 147 [CMS–9925–F] RIN 0938–AT46.
[15] Department of Health and Human Services, "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" 45 *CFR* Part 147 [CMS–9940–F2] RIN 0938–AT54.
[16] *Little Sisters of the Poor v. Pennsylvania*, 591 U.S. (2020).
[17] Department of Health and Human Services, "Coverage of Certain Preventive Services Under the Affordable Care Act," 45 *CFR* Parts 147 and 156 [CMS-9903-P] RIN 0938-AU94.
[18] *Pennsylvania v. President US*, (3d Cir. (July 12, 2019).
[19] http://thomas.loc.gov/cgi-bin/query/F?r111:1:./temp/~r111ulsMjy:e58173:.

A variety of items that have been categorized as contraceptives have been demonstrated in reputable research to be abortifacient, preventing the implantation of an engendered (fertilized) human embryo. These contraceptives include those which are available over-the-counter: Emergency contraception, such as Plan B[20] and the daily oral contraceptive, Opill, which was approved by the FDA for access without a prescription in June 2023.[21] As a result, people may be using or providing insurance coverage for the drug—including people who themselves object to the destruction of a human embryo—without fully realizing that in some cases it may have the effect of preventing the implantation of an embryo.

One particular drug, ulipristal, approved by the FDA for "emergency contraception," although not available without a prescription, 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.[22] To characterize this drug as a "contraceptive" is misleading at best and deprives women of the right and opportunity for informed consent. If the goal is patient autonomy, then that goal is undermined rather than advanced in such an information vacuum. While it is understood that Ella drug requires a prescription, and not subject to The Rule, as stated herein, there is reputable research indicating that other "emergency contraception," and oral contraceptives can impede the implantation of a conceived human being (abortifacient).[23] To the extent that the contraceptive mandate requires coverage of such drugs this runs afoul of the ACA provisions. ACA also prohibits any federal mandate to cover abortion as an essential health benefit in any circumstances;[24] and with federal cost-sharing for such coverage there can be a violation of the *Hyde Amendment*.[25] Furthermore, all employers, including those with a religious objection, but particularly those who have less conscience protection because of a non-faith based, but deeply held moral objection, must be respected consistent with numerous federal statutes: The *Church Amendments*, Section 245 of the *Public Health Service Act*, and the *Weldon Amendment*.[26]

One particular problem relates to the moral distinctions of treating a pathology with hormones versus creating sterility, even temporarily, with contraceptives. Removing the prescription requirement may make important moral distinctions more difficult for Catholic health plan sponsors. The same drugs are prescribed for both purposes. At

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[20] Gabriela Noé, *et al.,* "Contraceptive efficacy of emergency contraception with levonorgestrel given before or after ovulation Contraception," *Contraception* 81:5 (2010 May) 414-20. 1

[21] "How does Opill work? •Opill prevents pregnancy in several ways. Opill thickens mucus in your cervix, and this change may keep sperm from reaching the egg. Opill stops the release of an egg from your ovary. *Opill also thins the lining of your uterus.*" (Emphasis added) From https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017031s035s036lbl.pdf.

[22] See Donna J. Harrison & James G. Mitroka, "Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health," 45 *The Annuals of Pharmacotherapy* (Jan. 2011).

[23] *Id., Op cit.,* Noé, *et al.,* and FDA https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017031s035s036lbl.pdf.

[24] ACA, §1303.

[25] S.142 - *Hyde Amendment Codification Act* 113th Congress (2013-2014).

[26] U.S. Department of Health and Human Services, Office for Civil Rights, "Fact Sheet: Your rights under the Federal Health Care Provider Conscience Protection Laws" (May 2012).

present, Catholic plan sponsors can discern why hormonal contraceptives are being prescribed based on coding. Thus, it is unclear how this proposed change would affect actualizing the religious exemption that Catholic plan sponsors need from the contraception mandate.

4. **Pregnancy is not a disease to be prevented, nor is the embryo an enemy who once conceived has no right of access to the nurturing womb of his or her mother.**

In section 2713(a)(4) of the ACA, 42 U.S.C. § 300gg-13(a)(4), Congress gave HHS's Health Resources and Services Administration (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. HRSA has decided that covered services shall include contraception, 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, obesity prevention, and well-woman preventive visits. HRSA, Women's Preventive Services Guidelines were promulgated in 2011 and most recently updated in 2024, effective 2025.[27] HRSA mandates coverage of contraception and these identified services as methods to 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.

Pregnancy is a normal physiological process in human beings and animals, alike; and designating contraceptives as "preventive services" negates sound science since "preventive services" prevent serious disease, dysfunction and/or injury which would require treatment to restore health or function. Fertility is a natural quality of human nature, and pregnancy is a natural human condition. If they were not, the federal government would be mandating coverage to "cure" pregnancy. Pregnancy follows its own natural course which ends in the live birth of a baby, if not interrupted by medical intervention or miscarriage. The "cure" or "treatment" to eliminate this condition would have to be an abortion. But as a matter of clear statutory policy, ACA prohibits any federal mandate to cover abortion as an essential health benefit in *all* circumstances. [Emphasis added; ACA, §1303(b)(1)(A)]. Indeed, the Act not only leaves health plans free to exclude abortion, but explicitly allows each state to forbid coverage of abortion throughout its exchange. [*Id.,* §1303(a)(1)]. Finally, with regard to the multi-state qualified health plans established under ACA, at least one of these plans must exclude most abortions. [*Id.,* §1334(a)(6)]. 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 would be inconsistent to *require* all health plans to commit themselves to preventing this same condition.

[27] HRSA, "Women's Preventative Service Guidelines (2024). https://www.hrsa.gov/womens-guidelines.

Furthermore, designating contraceptives as "preventive services" does not constitute good clinical medicine. An extensive body of evidence shows hormonal contraceptives pose substantial threats to women, including myocardial infarction, cerebrovascular accidents, deep venous thrombosis, pulmonary emboli,[28] as well as breast and cervical cancer.[29] 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* (PDR) 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).[30]

The relationship between hormonal contraception use and breast cancer—and in particular, the disturbing connection between oral contraception use and triple-negative breast cancer (for which oral. Contraceptives raise the risk by 2.5 to 4.2 times)—should cause caution and concern.[31] The Departments acknowledge that this proposal could result in women having fewer preventive care visits with their doctors and that pharmacies will have to deal with conversations with people that doctors would have dealt with previously. Numerous risks to women and girls can ensue:

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[28] For specific cautions and risks see: "Ortho Tri-Cyclen / Ortho-Cyclen," *RxList: The Internet Drug Index.* Available at https://www.rxlist.com/ortho-tri-cyclen-drug.htm.

[29] NIH Fact Sheet, Oral Contraceptives and Cancer Risk (Feb. 22, 2018). 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 MED. RESEARCH 9, 10 (Winter/Spring 2017); see also Danielle Fitzpatrick, et al., Combined and Progestagen-Only Hormonal Contraceptives and Breast Cancer: A UK Nested Case-Control Study and MetaAnalysis, PLOS MED. (20)3 (Mar. 21, 2023) (finding a relative increase of around 20 to 30 percent in breast cancer risk associated with current or recent use of either combined oral or progestogen-only contraceptives); see also Williams, Hormonally Active Contraceptives, supra (citing numerous studies that find an increased risk of breast and cervical cancer associated with use of contraceptives). Mandating contraceptive coverage under the preventive services provision of the ACA is especially ironic given that sponsors of that provision cited the prevention of breast and cervical cancer as one of its key goals. 111 Cong. Rec. S11986-91 (Nov. 30, 2009).

[30] PDR Network, "Oral contraceptives," at *PDR* health (2009).

[31] Jessica M. Dolle, Janet R. Daling, Emily White, et al., "Risk Factors for Triple-Negative Breast Cancer in Women Under the Age of 45 Years," Cancer Epidemiol Biomarkers Prev. 2009;18:1157-1166.

Women/girls would be less inclined to see their obstetrician/gynecologist if they don't have to visit to discuss contraceptives. Furthermore, they would be less able to give informed consent without a conversation with a doctor or with a pharmacist.

Women/girls would be more inclined to self-prescribe for birth control to treat symptoms instead of seeking out medical advice as to the cause of these symptoms. That would result in delayed diagnoses with serious potential adverse health consequences. Some reproductive health conditions, such as endometriosis, can take up to 6-12 years to diagnose.

There are numerous risks, especially to minors unaddressed by The Rule:

There are public health consequences of allowing a 12-year-old girl starting hormonal contraceptives on her own, without any consultation with a doctor or pharmacist, for any reason. There are known risks of depression making an adolescent girl even more vulnerable, especially in the absence of parental involvement.[32]

There is the possibility of a boyfriend/abuser purchasing emergency contraceptives (i.e., early chemical abortions) purportedly on a woman's behalf.

Designating contraceptives as "preventive services" would give the false impression that these are safe and standard medications. This risk is only heightened when contraceptives are made available over-the-counter without oversight and monitoring by, and discussion with, a physician. And, since the expanded mandate to require coverage of contraceptives has no age limit, the proposed regulations, if adopted, would allow access to contraceptives with neither parental nor physician oversight or involvement, thus creating even greater health risks for minors.

Conclusion

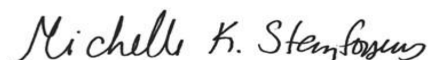
In summary, these drugs, devices, and procedures do not prevent a disease condition, but the healthy condition known as fertility, and pose significant risks of their own to women's lives and health. At the same time The Rule is treating pregnancy as a disease that should be prevented. This is medically, socially, and anthropologically inaccurate and sexually biased. Therefore, The Rule is acting against the very provisions in the ACA and its legislative history. Furthermore, The Rule clearly mandates coverage at no cost for contraceptives to prevent the "disease" of pregnancy, and abortifacients which cause the termination of the newly conceived human being. These and other contraceptives are presented inaccurately as a deterrent to unplanned pregnancies, when the very data presented by the CDC belie these claims. Empowering women to know and act with their bodies to manage their fertility in a responsible manner is the real answer to the physiological, social, and psychological problems

[32] Eveline Mu and Jayashri Kulkarni, "Hormonal contraception and mood disorders," *Aust Prescr*. 45:3 2022 Jun 1) 75–79.

created by a culture encouraging women to engage in unhealthy lifestyles. Then, forcing employers to participate in and to pay for the choices of others, which clearly and demonstrably have been detrimental, is the utmost violation of the United States *Constitution*. The legislative intent was never to mandate that all insurance plans be required to provide, with no co-pay, contraceptives, and abortifacients. This Rule not only creates new law but violates the *Constitutional* protections of religious freedom in the process.

At a minimum, to ensure compliance with the abortion and non-preemption provisions of the ACA and Weldon amendment, the Departments should clarify that the mandate, including the proposed expansion of the mandate contemplated in the present proposed regulations, does not apply to any drug or device that can disrupt an existing pregnancy, from the moment of fertilization. Furthermore, robust protection of religious freedom is needed for all, whether religiously sponsored or not, including a strong provision for an exemption based on a moral objection. This is essential to protect the very foundation upon which this country was based. Of great importance to the wellbeing of this country is the recognition that The Rule is merely going to replicate and maximize the failed initiatives to address the problem of unplanned pregnancies, sexually transmitted disease, and sexual irresponsibility. Thus, we urge the Departments, either in this or another rulemaking, to reconsider and rescind the contraceptive mandate. Furthermore, we urge the Departments, even if they reject these recommendations, not to adopt the current proposal to expand the contraceptive mandate to include over-the-counter contraceptives because doing so will exacerbate the problems noted here.

Sincerely yours,



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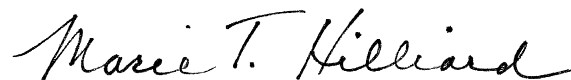

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