



# THE NATIONAL CATHOLIC BIOETHICS CENTER

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September 17, 2010

To: Whom it may concern at

DEPARTMENT OF THE TREASURY  
Internal Revenue Service  
26 CFR Part 54  
TD 9493  
RIN 1545-BJ60

DEPARTMENT OF LABOR  
Employee Security Administration  
29 CFR Part 2590  
RIN 1210-AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OCIIO-9992-IFC  
45 CFR Part 147  
RIN 0938-AQ07

**Re: File Code OCIIO-9992-IFC**

On July 19, 2010, the Department of Health and Human Services issued an interim final rule for group health plans and health insurance issuers relating to coverage of preventive services under the Patient Protection and Affordable Care Act of 2010 (PPACA). HHS invited comments on the regulation to be submitted on or before September 17, 2010.

Herein, we are providing input to the Department of HHS in its development of guidelines on “evidence-informed preventive care and screening” for women, which must be included in/by group health plans and insurance issuers under the PPACA.<sup>1</sup> These guidelines will

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<sup>1</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 131, (Mar. 23, 2010), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_public\\_laws&docid=f:publ148.111.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ148.111.pdf); Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41726, 41731 (July 19, 2010) (to be codified at 45 C.F.R. pt.147).

include coverage requirements for medical care not already required by the PPACA.<sup>2</sup>

The National Catholic Bioethics Center (Center) is a non-profit research and educational institute committed to applying moral principles to ethical issues arising in health care and the life sciences. The Center provides consultations to institutions and individuals seeking its opinion on the appropriate application of such moral principles. The Center has 2500 individual and institutional members throughout the United States, who are constituents of the members of Congress, and submits the following comments:

1. Pregnancy is not a disease and contraceptives, sterilizations, abortifacients, and abortion should not be included as mandated preventive services. Furthermore, the interim final rules, appropriately, did not include such mandates; and numerous health care providers, necessary for the health and well being of millions of women, would be unable to comply with such mandates, that exceed the requirements of the provisions of the PPACA;
2. The legislative history of PPACA indicates the intent **not** to include drugs or devices that induce the expulsion of a human embryo before or after implantation. Specifically, Section 2713(a)(4) of the PPACA does not include abortions or abortifacients in “preventive care and screenings” for women. Furthermore, the Senate floor debate over the addition of Section 2713(a)(4) to the Act indicated that they are not included;
3. It would be inappropriate to require group health plans and health insurance issuers to cover drugs or devices that induce the expulsion of a human embryo before or after implantation, including the recently-approved drug *ulipristal acetate [ella]*, and;
4. Mandating that insurance companies cover contraceptives, sterilizations and drugs or devices that induce the expulsion of a human embryo before or after implantation would violate the consciences of many Americans, and would contradict promises by the Obama Administration that the PPACA does not undermine existing conscience protections in law.

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1. **Pregnancy is not a disease and contraceptives, sterilizations, abortifacients, and abortion should not be included as mandated preventive services. Furthermore, the interim final rules, appropriately, did not include such**

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<sup>2</sup> Id.

**mandates; and numerous health care providers, necessary for the health and well being of millions of women, would be unable to comply with such mandates, that exceed the requirements of the provisions of the PPACA.**

Contraception, sterilization, abortifacients, and abortion are not comparable to the preventive services recommended in the Interim Final Rules. If they were, the federal government would be mandating coverage to "cure" pregnancy. Pregnancy, follows its own natural course 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, PPACA *prohibits* any federal mandate to cover abortion as an essential health benefit in *all* circumstances. [PPACA, §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 PPACA, at least one of these plans must exclude most abortions. [*Id.*, §1334(a)(6)].

In these provisions, the PPACA 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.

- 2. The legislative history of PPACA indicates the intent not to include drugs or devices that induce the expulsion of a human embryo before or after implantation. Specifically, Section 2713(a)(4) of the PPACA does not include abortions or abortifacients in "preventive care and screenings" for women. Furthermore, the Senate floor debate over the addition of Section 2713(a)(4) to the Act indicated that they are not included.**

The PPACA does not explicitly mandate private group health plans and health insurance issuers to cover elective abortions or abortifacients as part of "evidence-informed preventive care and screening."<sup>3</sup> In fact, Section 2713(a)(4), which requires private insurance plans to cover certain preventive services for women, was added to the PPACA

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<sup>3</sup> **"SEC. 2713. COVERAGE OF PREVENTIVE HEALTH SERVICES.** (a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for— . . . (4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." Paragraph (1) as referenced above includes "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force." This list **does not** include abortion or abortifacients.

by amendment on December 3, 2009. In offering the amendment, Senator Barbara Mikulski (D-MD) 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.<sup>4</sup>

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.<sup>5</sup>

It is evident that the legislative intent of the amendment was not to include elective abortions or abortifacients. Further, during debate over the amendment on the Senate Floor on December 3, 2009, Senator Mikulski had the following exchange with Senator Robert Casey (D-PA):

Mr. CASEY. There is one clarification I would like to ask the Senator. I know we discussed it during the HELP markup and it was not clarified at that time and thus I chose to vote against the amendment because of the possibility that it might be construed so broadly as to cover abortion. But I understand that the Senator has now clarified specifically that this amendment will not cover abortion in any way. **Specifically, abortion has never been defined as a preventive service and there is neither the legislative intent nor the language in this amendment to cover abortion as a preventive service or to mandate abortion coverage in any way.** I ask the Senator is that correct?

Ms. MIKULSKI. **Yes, that is correct. This amendment does not cover abortion. Abortion has never been defined as a preventive service. This amendment is strictly concerned with ensuring that women get the kind of preventive screenings and treatments they may need to prevent diseases particular to women such as breast cancer and cervical cancer. There is neither legislative intent nor legislative language that would cover abortion under this amendment, nor would abortion coverage be**

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<sup>4</sup> <http://mikulski.senate.gov/Newsroom/PressReleases/record.cfm?id=320304>

<sup>5</sup> Ibid.

**mandated in any way by the Secretary of Health and Human Services**  
(emphasis added).<sup>6</sup>

This exchange clarifies the clear intent of Section 2713 in the PPACA – to provide screenings and care for Americans to prevent disease, not to end pregnancies.

**3. It would be inappropriate to require group health plans and health insurance issuers to cover drugs or devices that induce the expulsion of a human embryo before or after implantation, including the recently-approved drug *ulipristal acetate [ella]*.**

Pregnancy is not a disease; therefore, it is illogical to include coverage for drugs or devices that induce the expulsion of a human embryo before or after implantation in preventive care and screenings. Because of its abortifacient potential, the newly-approved drug ***ulipristal acetate [ella]*** should not be included in the definition of preventive care. While the FDA is allowing the drug to be marketed as an “emergency contraceptive,” the agency’s prescribing instructions for the drug admit that *ulipristal acetate [ella]* may prevent implantation. As noted below, the FDA states that this drug is contraindicated in an existing pregnancy.<sup>7</sup> Furthermore, as the FDA notes, one reason for the effectiveness of *ulipristal acetate [ella]* is that it “may also work by preventing attachment (implantation) to the uterus.”<sup>8</sup> This means *ulipristal acetate [ella]* does more than prevent conception; *ulipristal acetate [ella]* can kill an embryo.

The fact that *ulipristal acetate [ella]* may kill an embryo even after implantation is unsurprising, as it has a similar chemical make-up to the abortion drug mifepristone (RU-486), which blocks natural progesterone receptors in three critical areas: destroying receptivity of the endometrial glands to embryo implantation;<sup>9</sup> destroying the capacity of

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<sup>6</sup>December 3, 2009 <http://thomas.loc.gov/cgi-bin/query/C?r111:./temp/~r111T7WGdp>. On December 1, 2009, Senator Mikulski 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.” <http://thomas.loc.gov/cgi-bin/query/C?r111:./temp/~r111R03fz5>

<sup>7</sup> [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022474s0001bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s0001bl.pdf).

<sup>8</sup> Ibid.

<sup>9</sup> Jerry R. Reel, Sheri Hild-Petito, and Richard P. Blye, “Antiovolatory and Postcoital Antifertility Activity of the Antiprogestin CDB-2914 When Administered as Single, Multiple, or Continuous Doses to Rats,” *Contraception* 58.2 (August 1998): 129.

the corpus luteum to produce progesterone for initial support of the implanted embryo;<sup>10</sup> and destroying the endometrial stromal tissues necessary for the survival of the embryo.<sup>11</sup>

Levonorgestrel [*Plan B*], another so-called “emergency contraceptive” should also not be included in preventive care. When the FDA approved *Plan B*, it acknowledged that the drug not only prevented fertilization but: “If fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation).”<sup>12</sup>

In approving *ulipristal acetate* [*ella*], the FDA contraindicates *ulipristal acetate* [*ella*] for “existing or suspected” pregnancy. The FDA admits, “There are no adequate and well controlled studies in pregnant women.” It cites studies in animals with high rates of pregnancy loss, and it acknowledges that the effects on a fetus that survives *ulipristal acetate* [*ella*] are unknown. Furthermore, in animal studies 40% of first trimester fetuses aborted after exposure to high doses of this drug.<sup>13</sup>

Clearly, *ulipristal acetate* [*ella*] and any other form of “emergency contraception” that may cause abortions should, like surgical and other chemical abortions, not be included in preventive care under Section 2713(a)(4).

**4. Mandating that insurance companies cover contraceptives, sterilizations and drugs or devices that induce the expulsion of a human embryo before or after implantation would violate the consciences of many Americans, and would contradict promises by President Obama Administration that the PPACA does not undermine existing conscience protections in law.**

Because any mandate for contraception, sterilization, abortifacient, and abortion coverage under the rubric of “preventive services” would apply to a wide array of group health plans and health insurance issuers, it would pose an unprecedented threat to rights of conscience for religious employers, health care providers, and others who have moral or religious objections to these procedures. Also, the promise of the Administration that Americans who like their current coverage will be able to keep it under health care reform would be a hollow pledge. Currently, such employers, as well as insurance issuers with moral and

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<sup>10</sup> Catherine A. VandeVoort et al., “Effects of Progesterone Receptor Blockers on Human Granulosa-Luteal Cell Culture Secretion of Progesterone, Estradiol, and Relaxin,” *Biology of Reproduction* 62.1 (January 2000): 200.

<sup>11</sup> Sheri Ann Hild et al., “CDB-2914: Anti-progestational/Anti-glucocorticoid Profile and Postcoital Anti-fertility Activity in Rats and Rabbits,” *Human Reproduction* 15.4 (April 2000): 824.

<sup>12</sup><http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm109795.htm>.

<sup>13</sup>[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022474s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf).

religious convictions on these matters, are completely free under federal law to purchase and offer health coverage that excludes these procedures. They would lose this freedom of conscience under a mandate which would require all plans to offer contraception, sterilization, abortifacient, and abortion coverage.

Such a mandate would contradict longstanding federal precedents on respect for conscientious objection. Specifically, the Church amendment, a provision of federal law since 1973, protects conscientious objection to abortion *and sterilization* in various contexts wherein federal funds are involved.<sup>14</sup> Furthermore, foreign assistance programs for family planning, contain a statutory requirement that has been renewed every year since 1986, which states that "no applicant shall be discriminated against because of such applicant's religious or conscientious commitment to offer only natural family planning" as opposed to contraceptive drugs or devices.<sup>15</sup>

Every year since 2000, Congress has stipulated the following in terms of any effort to mandate contraceptive coverage in the District of Columbia: "it is the intent of Congress that any legislation enacted on such issues should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions."<sup>16</sup> Similar conscience protections are contained within provisions for the United States' international program for preventing and treating HIV/AIDS. Specifically, organizations (specifically including faith-based organizations) are guaranteed the right to participate fully in the program without being required "to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection."<sup>17</sup> Also, every year since 1999, in the only federal program to require health plans to cover contraception for a subset of the U.S. population, Congress has stated that this mandate in the Federal Employees Health Benefits Program will not apply to "any existing or future plan, if the carrier for the plan objects to such coverage on the basis of religious beliefs."<sup>18</sup>

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<sup>14</sup> 42 U.S.C. §300a-7(b), (c)(1) and (e). The Church amendment also protects conscientious objection to any health service or research activity<sup>y</sup> that is contrary to the religious beliefs or moral convictions of individuals participating in programs administered or funded by HHS. *Id.*, § 300a-7(c)(2) and (d).

<sup>15</sup> Title III of Division F (Department of State, Foreign Operations, and Related Programs Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.

<sup>16</sup> Sec. 811 of Title VIII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.

<sup>17</sup> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, at 22 U.S.C. §7631 (d)

<sup>18</sup> See Sec. 728 of Title VII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act., 2010, Pub. L. No. 111-117.

These precedents reflect a longstanding commitment on the part of our federal government to respect the rights of conscience of all citizens, and to allow health care institutions and religious employers to participate fully in health programs (including programs for providing health coverage) without violating their moral or religious convictions. No federal law has yet been construed to require private health plans to provide coverage of contraception and sterilization. Instead, federal law has thus far left insurance issuers, employers and enrollees to negotiate such coverage in accord with their personal preferences and their moral and religious commitments. The federal government has no reason now to take away this freedom.

In a speech on healthcare before Congress, President Obama stated that under health care reform “federal conscience laws will remain in place.”<sup>19</sup> He repeated his promise to defend conscience rights in his executive order: “Under the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. §300a-7, and the Weldon Amendment, Pub. L. No. 111-8, §508(d)(1) (2009)) remain intact and new protections prohibit discrimination against health care facilities and health care providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.”<sup>20</sup>

The PPACA also explicitly prohibits Title I or amendments to Title I of the Act from requiring qualified health plans that participate in the new Exchanges to provide elective abortion coverage as part of their “essential health benefits.”<sup>21</sup> This prohibition, in effect, extends conscience protections to health insurers.

Therefore, it is inconsistent for HHS to issue regulations defining “preventive care,” a group of services that must be covered by all group health plans and health insurance issuers, to include contraceptives, sterilizations and drugs or devices that induce the expulsion of a human embryo before or after implantation. Such an inclusion would clearly violate the conscience rights of insurance providers and would, in the case of those health plans participating in the Exchanges, violate the PPACA.

## Conclusion

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<sup>19</sup> Press Release, The White House, Remarks by the President to a Joint Session of Congress on Health Care (Sept. 9, 2009), *available at* [www.whitehouse.gov/the\\_press\\_office/Remarks-by-the-President-to-a-Joint-Session-of-Congress-on-Health-Care/](http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-to-a-Joint-Session-of-Congress-on-Health-Care/).

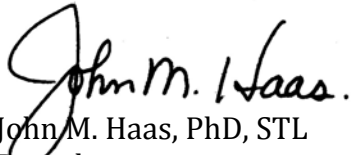
<sup>20</sup> Posting of Dan Pfeiffer to The White House Blog, <http://www.whitehouse.gov/blog/2010/03/21/one-more-step-towards-health-insurance-reform> (March 21, 2010, 16:16 EST). President Obama was referring to Section 1303(b)(4), which provides: “NO DISCRIMINATION ON BASIS OF PROVISION OF ABORTION.—No qualified health plan offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.”

<sup>21</sup> *Supranote 1 at 897.*



It would simply be inappropriate and indefensible for HHS to require group health plans and health insurance issuers to cover contraceptives, sterilizations, and drugs or devices that induce the expulsion of a human embryo before or after implantation, including the recently-approved drug *ulipristal acetate* [*ella*] or *levonorgestrel* [*Plan B*], under the pretext of “preventive care and screenings.” Section 2713(a)(4) of the PPACA does not require it, and the Senate floor debate over the addition of Section 2713(a)(4) to the Act indicated that they are not included. Further, it is clearly inappropriate for HHS to mandate such coverage given President Obama’s stated support for conscience protections and the explicit language of the PPACA.

Sincerely yours,

A handwritten signature in black ink that reads "John M. Haas." The signature is written in a cursive, flowing style.

John M. Haas, PhD, STL  
President  
The National Catholic Bioethics Center