

January 12, 2011

Secretary Kathleen Sebelius Department of Health and Human Services 200 Independence Ave., SW Washington, DC 20201

## Dear Secretary Sebelius:

On behalf of Family Research Council (FRC), and the thousands of families we represent, we urge you to ensure that the category of "preventive care services" for women in health plans does not include abortion, abortifacients or contraceptives. We additionally ask you to ensure that the conscience rights of issuers of health plans, as well as providers who contract with such plans, are protected so that those with moral or religious objections to covering contraceptives as a "preventive care service" do not become victims of discrimination.

As you are aware, the "Patient Protection and Affordable Care Act" (P.L. 111-148) as enacted contains a provision on preventive health services in Section 1001, which created a new section 2713 of the Public Health Service Act (PHSA) to mandate that all individual and group health plans provide coverage for preventive care in accordance with guidelines offered by the U.S. Preventive Services Task Force (USPSTF). As you are also aware, Senator Barbara Mikulski (D-MD) offered an amendment (S.AMDT. #2791) that passed on December 3, 2009, which is now current law, to extend this mandate to include coverage of preventive services for women. Specifically, the Mikulski provision created Section 2713(a)(4) of PHSA that extends the coverage mandate to include, with no cost sharing requirements, the following: "(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." Paragraph (1) includes all "items or services" that are currently recommended by the USPSTF. Paragraph (4) therefore adds a requirement that all health care plans cover additional items and services not currently recommended by the USPSTF. These additional services would be based on new recommendations by the Health Resources and Services Administration (HRSA). As you know, the Department of Health and Human Services (HHS) published an interim rule in July, 2010, indicating that the specific guidelines for women's preventive services would be developed and issued by HHS no later than August, 2011.

FRC and numerous other groups remain very concerned that HRSA, and by extension HHS, might recommend that several items or services which are medically and ethically problematic be included as "preventive care." This provision, and the recommendations required by it, does not leave the choice of coverage to the private decisions of health insurance companies, businesses or individuals. Rather, the provision, and the recommendations made by HHS based on it, will constitute a mandate with the full weight of federal law.

Therefore, FRC encourages you to oppose any recommendation to include abortion, whether medical or surgical, as a preventive care service for women. FRC rejects any suggestion that "abortion is healthcare." Pregnancy is not a sign of disease or illness; it occurs in a healthy woman. There is no circumstance in which abortion should be included as a preventive care measure, the coverage of which would be required by all individual and group health plans throughout the country. Indeed, while the statutory language of Section 2713 of the PHSA is silent on whether or not abortion should be considered "preventive care," Senator Mikulski herself claimed during Senate floor consideration that abortion would not be included by her amendment.

Further, not only should surgical abortion not be recommended as preventive care, neither should medical abortion, such as that caused by the drug RU-486. Thousands of adverse events have been casued by RU-486, including ten deaths in the United States. The termination of a preborn baby through surgical or medical abortion obviously would "prevent" or stop a pregnancy, but since pregnancy is not a disease, it should not be mandated by the federal government in the name of "preventive care for women." By destroying that which is healthy and alive in a woman, abortion, by its very nature, contradicts the definition of a preventive service for women.

Second, FRC also asks you to reject any recommendation to include contraceptives as preventive care for women. Fertility, like pregnancy, is not a disease. By their very nature, contraceptive services are elective, not medically necessary. They should not be placed in the same category as other basic types of medical care. Additional concerns exist regarding the inclusion of contraceptives because several drugs have been legally approved by the FDA as "emergency contraceptives" despite having modes of action that work post-fertilization as well as post-implantation.

Drugs such as Levonorgestrel, commonly called "Plan B", may function in various ways to prevent a pregnancy from occurring by blocking the production of ovum, or preventing fertilization from occurring in vivo. However, Plan B can also prevent a newly fertilized human embryo from implanting in the uterus. Such a mode of action necessarily causes the demise of the human embryo. Claims that Plan B cannot cause an abortion are based on a definitional sleight of hand, where "pregnancy" means the beginning of implantation. Clearly, if you adopt this definition of "pregnancy," then it logically follows that killing an embryo or causing its demise prior to implantation does not constitute the "termination of pregnancy." However, regardless of when you define the beginning of life, it is clear that Plan B can stop the implantation process, thereby causing the embryo's demise. Whether or not one believes that personhood or human rights apply to a preborn human embryo, it is a medical fact that an embryo is formed inside the woman prior to implantation, and that Plan B can cause its demise by preventing the embryo from implanting. As such, whether categorized legally as a contraceptive or not, Plan B medically can function in a way to destroy a human embryo. Therefore, we urge you to reject any inclusion of "emergency contraceptives," such as Plan B, as preventive care services that all health plans would be required to cover with no cost to the individual.

We also reject the inclusion of the recently approved drug, Ulipristal acetate, marketed as "ella" by Watson Pharmaceuticals, as a preventive care item or service. While the FDA approved the drug application of ella as an "emergency contraceptive" this drug is known to be chemically and functionally similar to the abortifacient drug, RU-486. Like Plan B, ella can prevent fertilization. However, unlike Plan B, ella also can block the progesterone receptors after implantation, and in doing, so can cause the demise of an implanted embryo by starving the growing embryo of nutrients necessary for development. Like RU-486, ella is a selected progesterone receptor modulator, and as such, it has modes of action that work to destroy a developing fetus pre- and post-implantation. Ella can cause the death of an already implanted embryo, meaning it can function as an abortifacient. We, therefore, urge you to reject any recommendation that "emergency contraceptives" be included as a preventive care service for women since such drugs can cause the demise of nascent human life.

Other contraceptives, which may or may not cause harm to a developing human embryo, at the very least prevent the creation of human embryos in various ways. While FRC has no position on whether the use of such contraceptives is ethically permissible, FRC strongly believes that the federal government should not impose any mandate on individual and group health plans to cover such drugs. Including contraceptives as preventive care under Section 2713 will guarantee that the conscience rights of many will be violated, since coverage for these drugs would then be required. No issuer of a health plan which refuses to cover contraceptives based on moral, ethical or religious objections should be forced to cover such drugs.

Moreover, participants in health plans will be required to pay for contraceptives in health plans if included as preventive care, since the Mikulski provision requires health care plans to cover preventive care items or services with no cost to the patient receiving such services. The effect of the Mikulski provision is to ensure that all participants in a health plan pay for the coverage of such services, without the individual patients paying any specific fee for such services. Participants in a health plan should not be required to pay for contraceptives if doing so violates their conscience. Including contraceptives as a preventive care item or service under this legal requirement would place the federal government, not only at odds with the right of conscience of thousands of people, but it would also violate the principles of current conscience laws, specifically the Church Amendment (42 U.S.C. 300a-7 (d)) and the Hyde-Weldon Amendment (P.L.111-117, Section 508 (d)(1). While the PPACA contains no direct conscience protection for services other than abortion (Section 1303(b)(4)), the Church Amendments still exist to protect the conscience rights of individuals (Church (d)) in programs administered by the Health and Human Services Department. Clearly, mandating that all health care plans cover contraceptives, and that participants in such plans share the burden of the cost of such items, will violate the principles of these conscience laws.

Including abortion or contraceptives as mandatory coverage also violates the spirit of the statement by President Barack Obama in Executive Order 13535, which claims that existing conscience protections would apply to the PPACA. The statutory language of the preventive care provision is clear, in that all individual and group health plans will be

required to cover any item or service HRSA recommends as preventive care for women. It necessarily follows if HRSA, and by extension HHS, recommends contraceptives to be covered as "preventive care," then all health plans will be required to cover such services with no cost-sharing requirements. This necessarily will cause many providers and participants to financially contribute to services they find objectionable. Therefore, in order to protect the conscience rights of insurers, providers and participants who object to contraceptives on moral, ethical, or religious grounds, these services should not be included in the recommendations of HHS for preventive care services for women.

FRC again urges you to reject any recommendations to include abortion, whether medical or surgical, as a preventive care service for women. FRC also urges you to reject any recommendations to include contraceptives, whether labeled "emergency" or not, as preventive care items or services to be covered by all individual or group health plans. Finally, we ask you to ensure that the conscience rights of issuers, providers and participants are protected while considering recommendations for coverage of preventive care services for women.

Sincerely,

Jeanne Monahan

Director, Center for Human Dignity