September 30, 2011

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9992-IFC2,
P.O. Box 8010,
Baltimore, MD 21244-8010

Submitted Electronically Via Email
Re. File Code CMS-9992-IFC2

Dear Sir or Madam,

On August 3, 2011 the Department of Health and Human Services (HHS) issued an interim final rule for individual and group health plans related to women's preventive services coverage under the Patient Protection and Affordable Care Act (PPACA).[1] 76 Fed. Reg. 46621 (Aug. 3, 2011). In it HHS specified Health and Research Services (HRSA) guidelines that must be covered by individual and group health plans under the PPACA, including contraceptives and sterilization procedures, among other "preventive services" for women. The regulation also requested comments related to its definition for "religious employers" that may be eligible to receive an exemption from this coverage mandate.

On behalf of the Family Research Council (FRC), which represents hundred of thousands of American families, we oppose strongly the decision to include, with no cost sharing, "all Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling"[2] in the list of mandated services which all individual and group health plans will be required to cover. We oppose this mandate because: 1) contraceptives and sterilization procedures do not constitute a form of preventive medicine since they do not prevent any disease; 2) access to contraception is already widely available in

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[1] PPACA, 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). Section 2713(a)(4) of PHSA would extend 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) would include all "items or services" that are currently recommended by the USPSTF. Paragraph (4) therefore would add to that mandate coverage of items and services not recommended by the USPSTF, but which would be provided for by the Health Resources and Services Administration (HRSA).

[2] U.S. Department of Health and Human Services Health Resources Services Administration, "Women's Preventive Services: Required Health Plan Coverage Guidelines," August 1, 2011, p 1. http://www.hrsa.gov/womensguidelines/.

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the U.S. bringing into question the practical policy need of this mandate; 3) the mandate includes drugs that have abortifacient modes of action thereby forcing all health plans to cover abortion; 4) the required inclusion of contraceptives and sterilization procedures in health plans will violate the consciences of millions of Americans who object morally to "contraceptives" per se as well as drugs and devices that can act as abortifacients (*i.e.*, they can be embryocidal).

We also comment negatively on the excessively narrowly defined "religious employer" exemption to this mandate. Under the exemption as drafted, so few religious groups will be eligible for the exemption's protection that, in reality, most religious employers will be faced with either violating their consciences or dropping health coverage. We conclude by discussing how this unprecedented mandate conflicts with conscience and religious freedom protections currently in place to protect the American people from government interference.

I. Contraceptives Are Not Properly Classified as Preventive Medicines.

At a most basic level, the mandate to include the full range of FDA-approved contraceptives as necessary preventive medicine defies common sense because pregnancy is not a disease or disabling condition. Pregnancy is a beneficial, temporary condition that not only indicates a condition of good health on the part of the woman who is pregnant, but is a benefit to society in that this healthy condition is necessary for the propagation of the human race. To the contrary it is the woman who has difficulty becoming pregnant who experiences a medical complication and will likely seek medical services to reverse that medical condition. Pregnancy is a normal medical condition from which serious medical complications can arise but typically do not. Diseases or complications *related* to pregnancy are to be treated, but pregnancy itself is not a disease or illness.

Because they prevent the body from a normal healthy function, contraceptive services are by their nature elective and are not medically necessary. They should not be placed in the same category as other basic types of preventive medical care.

Additional concerns exist regarding contraceptives because FDA has approved several drugs and devices as "contraceptives" that can act destructively on the embryo after fertilization as well as post-implantation.[3] The termination of a pre-born baby through early chemical abortion obviously would "prevent" bringing a child to term. However, since pregnancy is not a disease, the provision of contraceptives that function as abortifacients should not be required as "preventive care for women." By destroying that which is both healthy and alive in a woman, abortion contradicts the very definition of a preventive service for women.

II. Contraceptives Are Readily Available in the United States.

Arguments favoring increasing access to contraceptives as a way of reducing sexually transmitted diseases (STD), "unwanted pregnancies," or abortion are flawed. Contraceptives are widely available in the U.S. and already are heavily subsidized by the federal government; total public expenditures

[3] It is a scientifically valid belief that conception occurs at fertilization and that pregnancy begins with fertilization and not with implantation. This analysis is supported by a recent survey of the four American medical dictionaries showing that three of the four back this position to some extent. Christopher M. Gacek, "Conceiving 'Pregnancy': U.S. Medical Dictionaries and Their Definitions of 'Conception' and 'Pregnancy,'" *National Catholic Bioethics Quarterly* (Autumn 2009): 542-557.

for contraceptive services were $1.85 billion in 2006.[4] Medicaid family planning costs during that time totaled $1.3 billion[5]. States additionally contributed $241 million for family planning in fiscal year 2006. Also in the same fiscal year, Title X, an additional funding stream for family planning, contributed another $215 million of taxpayer dollars for family planning services.[6] In more recent years, Title X costs have been as high as $317 million annually.[7]

Contraceptives are also covered by most insurance plans; nine out of ten employer-based insurance health plans cover the full range of contraceptives.[8] Additionally, there is no good evidence to suggest that women who choose not to contracept are making that decision due to financial need. A survey of sexually active women conducted by the Guttmacher Institute shows only that 12 percent report "lacking access to contraceptives due to financial or other reasons."[9] This survey leaves open the possibility that the lack of access for all such women is due to other reasons, not financial.

Moreover, increased contraception does not necessarily correlate with a decrease in unintended pregnancies or sexually transmitted diseases. Recent peer reviewed studies from Sweden,[10] the United Kingdom,[11] and Spain[12] agree that increased use of contraceptives coincides with an increase in abortions and STDs. In the United States, lower contraceptive use correlates with fewer abortions. From 1995 to 2002, the rate of contraceptive use decreased from 64 percent to 62 percent[13] and abortion numbers decreased from 1,359,400 to 1,269,000.[14]

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[4] A. Sonfield, C. Alrich, and R.B. Gold, "Public Funding for Family Planning, Sterilization and Abortion Services, FY 1980–2006," *Occasional Report* 38 (Jan 2008): 28-33.

[5] Guttmacher Institute, "Facts on Contraceptive Use in the United States" (August 2011): p. 1 (http://www.guttmacher.org/pubs/fb_contraceptive_serv.html).

[6] *Ibid.*

[7] Title II of Division D of The Consolidated Appropriations Act, 2010 (P.L. 111-117), 123 STAT 3239.

[8] Guttmacher Institute, "Facts on Contraceptive Use in the United States" (June 2010): p. 1 (http://www.guttmacher.org/pubs/fb_contr_use.html).

[9] R. Jones, J. Darroch and S.K. Henshaw "Contraceptive Use Among U.S. Women Having Abortions," *Perspectives on Sexual and Reproductive Health 34* (Nov/Dec 2002): 294-303

[10] K. Edgardh, et al., "Adolescent Sexual Health in Sweden," *Sexual Transmitted Infections* 78 (2002): 352-6 (http://sti.bmjjournals.com/cgi/content/full/78/5/352).

[11] Sourafel Girma, David Paton, "The Impact of Emergency Birth Control on Teen Pregnancy and STIs," *Journal of Health Economic,* (March 2011): 373-380. *See also* A. Glasier, "Emergency Contraception," *British Medical Journal* (Sept 2006): 560-561.

[12] J.L. Duenas, et al., "Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population During 1997–2007," *Contraception* (January 2011): 82-87.

[13] Guttmacher Institute, "Facts on Contraceptive Use in the United States" (June 2010): p.1 (http://www.guttmacher.org/pubs/fb_contr_use.html). These numbers represent use among all women age 15-44, and thus, because many women in this age group would not be sexually active, the rate of use among sexually active women would be higher.

[14] R.K. Jones, M. Zolna, L.B. Finer, and S.K. Henshaw, "Abortion in the United States: Incidence and Access to Services, 2005" *Perspectives on Sexual and Reproductive Health* (2008): p. 9 (http://www.guttmacher.org/pubs/psrh/full/4000608.pdf).

A Federal mandate on a significant portion of the American population is unwarranted given the lack of need in addition to the profound implications that will arise for those who fundamentally object to covering, providing for, or paying for contraception and sterilization.

III. The Mandate Including Provision of the Full Range of FDA-approved Contraceptives Includes Abortifacient Drugs and Services.

The "Food and Drug Administration-approved contraceptive methods" required by the contraceptive mandate include a variety of drugs and devices whose modes of action can be destructive rather than preventive. There is substantial evidence that some of the included drugs and devices can be destructive to a newly forming human embryo. However the Institute of Medicine (IOM) committee tasked with providing recommendations for inclusion of services in the mandate actively ignored and overlooked the available research and ethical concerns regarding this critical issue. A spokesperson for the IOM brushed aside such research as "personal opinions" during the question and answer portion of the press conference coinciding with the release of the IOM report. HHS then in turn also ignored numerous peer-reviewed research studies indicating that certain drugs have abortifacient properties. Despite the fact that the difference between the prevention and destruction of life is vast in the eyes of most Americans, rather than erring on the side of science, evidence and caution on this critical issue, HHS chose to mandate the provision of drugs that likely have embryo destructive modes of action.

The first of these drugs is Levonorgestral, or Plan B. Plan B possesses a number of mechanisms of action which can prevent a newly formed embryo from implanting in the uterine wall. One extensive review of the available literature on Levonorgestral revealed as many as seven mechanisms of action that could potentially prevent implantation of an embryo.[15] In another literature review of the mechanisms of action of Levonorgestral, the authors concluded, "The evidence to date supports the contention that use of EC does not always inhibit ovulation even if used in the preovulatory phase, and that it may unfavorably alter the endometrial lining regardless of when in the cycle it is used, with the effect persisting for days."[16] Plan B's labeling information also admits this scientific reality. "[Plan B] may inhibit implantation (by altering the endometrium)."[17]

The second problematic FDA-approved drug covered by the mandate is ulipristal acetate, marketed as Ella® by Watson Pharmaceuticals. To be clear, including Ella in the mandatory category of "preventive care service for women" means that HHS is requiring each health insurance plan to cover a drug with the ability to kill an implanted embryo. Causing the demise of an embryo post-implantation is agreed by all to be an abortion. FDA approved Ella as an "emergency contraceptive," but Ella is chemically and functionally similar to the

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[15] H. Croxatto, et al., "Mechanism of Action of Hormonal Preparations Used for Emergency Contraception: a Review of the Literature," *Contraception* 63 (2001): 111.

[16] C. Kahlenborn, et al., "Postfertilization Effect of Hormonal Emergency Contraception," *Annals of Pharmacotherapy* (2002): 468.

[17] U.S. Department of Health and Human Services Food and Drug Administration, "Plan B One Step Labeling Information" (July 2009): p. 4 http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf.

FDA-approved abortifacient, RU-486.[18] Even Ella's label states that the drug is contra-indicated for pregnancy.[19]

A recent article published in *Annals of Pharmacotherapy* stated "[t]he mechanism of action of ulipristal in human ovarian and endometrial tissue is identical to that of its parent compound, mifepristone."[20] Numerous other research studies confirm ulipristal's abortifacient mechanism of action.[21] In one such study involving ulipristal's action in macaques (monkeys), 4 out of 5 fetuses were aborted.[22]

In paperwork filed for the approval of ulipristal in Europe, the European Medicines Agency noted that "Ulipristal, mifepristone and lilopristone were approximately equipotent at the dose levels of 10 and 30 mg/day in terminating pregnancies in guinea-pigs…"[23] The authors of the *Annals* article noted: "[E]xisting studies in animals are instructive in terms of the potential abortive effects of the drug in humans."[24] Their analysis led them to conclude "it can be reasonably expected that the prescribed dose of 30 mg of ulipristal will have an abortive effect on early pregnancy in humans."[25] Thirty milligrams is the precise dose of ulipristal now provided in a single package of Ella when purchased as an emergency contraceptive in the United States.[26]

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[18] RU-486 (mifepristone; Mifeprex®) was approved in 2000 by the FDA as an "abortifacient."

[19] U.S. Department of Health and Human Services Food and Drug Administration, "Ella Labeling Information" (August 2010): p.1 (http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf).

[20] D. Harrison and J. Mitroka, "Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health," *Annals of Pharmacotherapy 45* (Jan. 2011): 115-9.

[21] Reel et al., "Antiovulatory and Postcoital Antifertility Activity of the Antiprogestin CDB-2914 When Administered as Single, Multiple, or Continuous Doses to Rats," 58 *Contraception* (1998): 129-136, p. 129; VandeVoort et al., "Effects of Progesterone Receptor Blockers on Human Granulosa-Luteal Cell Culture Secretion of Progesterone, Estradiol, and Relaxin," 62 *Biology of Reproduction* (2000): 200-205, 200. In this article, ulipristal is referred to as "HRP-2000," Hild et al., "CDB-2914: Anti-progestational/antiglucocorticoid Profile and Post-coital Anti-fertility Activity in Rats and Rabbits," 15 *Human Reproduction* (2000): 822-829, 824; G. Teutsch and D. Philibert, "History and Perspectives of Antiprogestins from the Chemist's Point of View," 9 *Human Reproduction* (1994)(suppl 1):12-31; B. Attardi, J. Burgenson, S. Hild, and J. Reel, "In vitro Antiprogestational/Antiglucocorticoid Activity and Progestin and Glucocorticoid Receptor Binding of the Putative Metabolites and Synthetic Derivatives of CDB-2914, CDB-4124, and mifepristone," *Journal of Steroid Biochemistry and Molecular Biology* 88 (2004): 277-88.

[22] A.F. Tarantal, A.G. Hendrickx, S.A. Matlin, et. al., "Effects of Two Antiprogestins on Early Pregnancy in the Long-tailed Macaque (*Macaca fascicularis*)," 54 *Contraception* 1996: 107-15; European Medicines Agency, "CHMP Assessment Report for EllaOne," (Doc.Ref.: EMEA/261787/2009).

[23] European Medicines Agency, "CHMP Assessment Report for EllaOne," (Doc.Ref.: EMEA/261787/2009): p. 10.

[24] Harrison and Mitroka, *supra, n.20*.

[25] *Ibid.*

[26] Plan B and Ella are not the only FDA-approved contraceptive drugs or devices (e.g., IUDs) that are potentially embryocidal. However, we have focused on them because the medical evidence is most clear in these two cases that HHS's regulatory mandate includes embryo destructive items. Therefore, it is clear that the mandate will create a conflict with the moral and religious beliefs of individuals and organizations who will be forced to provide such coverage or participate in such plans.

Without a doubt the full range of FDA-approved contraceptives included in this mandate will involve a variety of drugs and devices with mechanisms of action that can destroy life rather than prevent life.

IV. Requiring Contraceptives in Health Plans Will Violate the Consciences of Millions of Americans.

Regardless of the Administration's position on the question of when life begins (*e.g.*, before or after implantation), it is not the role of the Secretary of Health and Human Services or any elected or appointed federal official to dictate what does or does not violate another person's conscience. Conscience is about choice. Insurance plan providers and participants should not be forced to engage in an action that they believe is the taking of a human life through the coverage of, and payment for, drugs they regard to be abortifacients, regardless of whether this or any Administration agrees.

This type of mandate is not popular with the American people. A poll published April 8, 2009 by the Polling Company showed that 87% of Americans believe that, generally, the conscience rights of health care professionals should be protected. More specifically, an August 4, 2011 Rasmussen poll showed that only 39% believe health insurance companies should be required to cover all government approved contraceptives for women, while 46% of respondents do not think they should be covered. Fifteen percent are undecided.[27] As the government agency implementing PPACA and its mandatory preventive care services provision, it is not the role of HHS to force Americans to participate in services that violate their essential right of conscience.

With this mandate, accompanied by its narrow exemption for certain religious employers (discussed in Section V), the Obama Administration will deny many Americans a most basic right: freedom from government interference in religious and moral matters. As a result many religious businesses or non-profit organizations, as well as Americans with insurance in the individual market, will be forced to violate their consciences on the issues they hold most profoundly. Employers will be forced to deny healthcare to their employees or violate their consciences. Individuals will be unable to purchase health plans without contraceptives and sterilization procedures.[28] Individuals will be forced to subsidize services to which they have ethical objections. The cost of such drugs and devices will be shifted from the patients to other plan participants' premiums. Individuals wanting to drop insurance coverage will be subject to PPACA's individual mandate requiring all individuals to purchase health insurance.[29]

V. The Definition of "Religious Employer" in the Proposed Exemption.

[27] Rasmussen Reports, "Health Insurance" August 2011. (http://www.rasmussenreports.com/public_content/politics/current_events/healthcare/august_2011/39_say_health_insurance_companies_should_be_required_to_cover_contraceptives).

[28] This excludes those who are covered by "grandfathered" plans that do not cover contraceptives.

[29] PPACA, Section 1501(b) as amended by Section 10106, 124 Stat. 907 (P.L. 148-111).

The new HHS regulation purports to provide a possible exemption, depending on HRSA, for "religious employers" but in fact exempts only places of worship. To summarize, the regulation limits a "religious employer" to an organization that a) has the "inculcation of religious values as its purpose," b) primarily employs persons who share its religious tenets, c) primarily serves persons who share its religious tenets, and d) is a non-profit organization which under 26 U.S.C. §§ 6003(a)(1) and 6033(a)(3)(A)(i) or (iii) is exempt from filing annual tax returns.

This narrow exemption will not cover most religious non-profit organizations which employ people of different faiths or which provide social services to people of other faiths. Additionally, this exemption will not protect religious entities providing health care services to the poor or those who perform missionary work in the United States or abroad. It will not include religious businesses, for-profit or non-profit health care insurers, hospitals, or even many institutions of higher education. Religiously affiliated health care issuers in the individual market are not exempted and the regulation does not allow HRSA the option of considering an exemption for such employers. In short, the exemption excludes most religious employers in both markets.

Many religious employers will be forced to choose between offering health insurance for employees and violating their consciences on issues as critical as the destruction of life. In the end, conscientious employers will be forced to withdraw health benefits.

While one of the much-discussed purposes for passing PPACA was to increase "access" to health care insurance for more Americans, the contraceptive mandate ultimately will do the very opposite. Religious employers will be forced to withdraw insurance so as to not violate their consciences on issues related to life and death. It can not be denied that the issue of the sanctity of unborn life was a major obstacle to the passage of PPACA. With the promulgation of this mandate the Administration demonstrates a blatant disregard for the deeply held opinions of most Americans.

VI. The Contraceptive Mandate Violates Current Conscience Laws and PPACA's Abortion Anti-mandate Provision.

The HHS contraceptive mandate violates the spirit and, in some cases, the letter of long-standing federal conscience laws meant to protect people and groups from government discrimination in health care. In the past 35 years, Congress has passed a number of laws (notably, the Church Amendments[30] and the Hyde-Weldon Amendment[31]) related to protecting the conscience rights of healthcare workers from government discrimination with regard to abortion or any service in a federally funded or administered program.[32] These laws

[30] 42 U.S.C. § 300a-7.

[31] Hyde-Weldon is currently contained in Section 508(d) of Division D of the Consolidated Appropriations Act, 2010 (P.L. 111-117), 123 Stat. 3280 (2009) which was renewed through the Department of Defense and Full Year Continuing Appropriations Act of 2011 (P.L. 112-10).

[32] The HHS contraceptive mandate also clearly violates the principle contained in the Coats Amendment (42 U.S.C. § 238N). It also violates the conscience measure in current law governing health contracts through the Federal Employee Health Benefits Program. A provision mandating coverage of contraceptives is qualified to prevent it from applying to "religious plans," or if "the carrier for the plan objects to such coverage on the

forbid discrimination in federally funded or administered programs. The HHS contraceptive mandate extends discrimination even further by mandating insurance coverage in the private market in such a way as to violate the consciences of insurers, providers, and plan participants who have moral or religious objections.

First, the contraceptive mandate violates the principles contained in the Church Amendments. The Church Amendments offer various protections in federally funded programs against discrimination on the basis that a participant objects to abortion or other services to which they have a moral or religious objection. "Church (d)" forbids the government from discriminating against an individual who objects to any service in a program funded by HHS. It states: "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."[33]

Clearly the law protects against forcing an individual to participate in any "program" or "research activity" contrary to his/her moral or religious beliefs under a program funded by the Secretary of HHS. Such protected parts of a program or activity would include the types of services included in HHS's contraceptive mandate. Church (d) might well apply to PPACA's "preventive services" mandate and the HHS contraceptive mandate regulation where a health plan is part of the state exchange program funded by HHS. However, the Church (d) provision clearly demonstrates the principle in law that the government should not require individuals to participate in health services that provide contraceptives, abortion, sterilization and other services to which individuals have moral or religious objections. The HHS contraceptive mandate openly violates this principle and may violate the letter of Church(d) as well.

Second, the contraceptive mandate violates the Hyde-Weldon Amendment by mandating the provision of contraceptive drugs that can function as abortifacients even if they are FDA-approved under the category of "emergency contraceptives." The Hyde-Weldon Amendment in current law forbids the government under the Labor, Health and Human Services Act (LHHS Act) from discriminating against an individual on the basis of objections to abortion.[34] Hyde-Weldon specifically states that the federal government, or any state or local government funded under the LHHS Act, may not subject a "health care entity" to "discrimination" on the basis that, among other things, it does not "provide coverage of….abortions." The term "health care entity" is defined to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan."

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basis of religious beliefs." *See* Section 728, Division C, the Consolidated Appropriations Act, 2010 (P.L. 111-117) which was renewed through the Department of Defense and Full Year Continuing Appropriations Act of 2011 (P.L. 112-10).

[33] 42 U.S.C. § 238N.

[34] Hyde-Weldon is currently contained in Section 508(d) of Division D of The Consolidated Appropriations Act, 2010 (P.L. 111-117), which was renewed through the Department of Defense and Full Year Continuing Appropriations Act of 2011 (P.L. 112-10).

The Hyde-Weldon Amendment does not even qualify that those who object to abortion do so on the basis of religious or moral grounds. It categorically prohibits government discrimination for those who refuse, for whatever reason, to participate in or cover abortion. As discussed in Section III some drugs and devices approved as "contraceptives" and included in the HHS mandate can function as abortifacients. Therefore, the contraceptive mandate violates the Hyde-Weldon provision by requiring entities that do not cover these drugs to do so.

HHS does not need to adopt a specific view of the term "abortion" for the sake of interpreting various Federal laws regarding abortion, but it should extend protections for those who have various views on "abortion" as it relates to their conscience rights. Many believe that the use of "emergency contraceptives," such as Plan B and Ella, end the lives of embryos by preventing implantation or destroying those already implanted. As previously stated there is medical evidence that these drugs can harm an embryo by preventing implantation, and that Ella can cause an abortion after implantation. Since an induced abortion is a humanly caused interruption of pregnancy, an abortion can take place at any point after fertilization.[35]

The underlying question of the Administration's view on when life begins and, therefore, when a termination can appropriately be labeled an "abortion" is not at issue. Rather, the salient issue is whether the Obama Administration should, contrary to the Hyde/Weldon amendment, be able to discriminate against individuals who hold traditional and/or scientific opinions concerning the beginning of life differing from its own. In this context, HHS need only recognize that the reasonable subjective view of the individual or institution should govern any assessment of that individual's or institution's invocation of religious beliefs or moral convictions.[36] The contraceptive mandate, therefore, diminishes the conscience rights protected under Hyde/Weldon by assuming a narrow view of "abortion" and "pregnancy." Even with a narrow definition of abortion, the contraceptive mandate includes a drug that can function after implantation (*e.g.,* Ella). In doing so, the contraceptive mandate violates Hyde-Weldon.

In either case, the HHS contraceptive mandate clearly raises the possibility of conscience rights violations. Because employers under PPACA are required to offer health insurance with contraceptive coverage according to HHS regulations, there is no question that employers who have moral or religious objections to such services will be forced to violate their consciences or drop coverage despite penalties.[37] HHS clearly recognized the conscience conflict this mandate would generate by issuing an exemption for certain religious employers. As stated earlier, HHS chose only to protect the conscience of a tiny minority of "religious employers," rather than provide protection for the typical religious employer that exists in America.

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[35] Gacek, *supra*, n.2.

[36] The term "pregnancy" in the human subject protections, 45 C.F.R. § 46.202(f) defines pregnancy starting at implantation. However, this definition is relevant to "this subpart" only as it relates to research on fetuses and pregnant women. This definition does not apply to the term "abortion" in Hyde/Weldon or other federal statues.

[37] The employee penalties are contained in Section 1513 and 10106 of PPACA (P.L. 111-148), as amended by Section 1003 of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

Third, the contraceptive mandate violates the supposed "abortion compromise" in Section 1303, as amended, of PPACA.[38] This section contains a provision that prevents the law from being used to mandate abortion coverage. It specifically states that "nothing in this title," which includes the section authorizing preventive care services for women, "shall be construed to require a qualified health plan to provide coverage of" abortion services. It also grants the decision over coverage of abortion to the issuer of the qualified health plan. While FRC believes that PPACA allows for federal funding for abortion, and does not accept that Section 1303 maintains the long-established Hyde Amendment, this specific provision does prevent HHS from using PPACA to mandate abortion as an essential benefit. It also clearly grants the decision about abortion coverage to the insurance issuer. Since the HHS contraceptive mandate on private insurance includes drugs such as Plan B and Ella, it violates Section 1303 of PPACA.

Indeed, the HHS contraceptive mandate also violates the statement of President Barack Obama in Executive Order 13535 (EO). In his EO, President Obama states that "long standing laws to protect conscience" such as the "Church Amendment" and the "Weldon Amendment" will "remain intact." The contraceptive mandate violates the EO which references the entire Church Amendment that, as stated above, includes conscience protections for services beyond abortion. The HHS contraceptive mandate, therefore, undermines PPACA provisions with respect to abortion coverage and contradicts the EO which claims that it covers the Church Amendment and Hyde-Weldon Amendment.

VI. The Contraceptive Mandate Violates the Religious Freedom Restoration Act.

An additional question before us is whether the HHS contraceptive mandate impinges upon or burdens a person's exercise of his or her religion. In 1993, Congress enacted the Religious Freedom Restoration Act ("RFRA").[39] Under RFRA, the federal government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability."[40] In order for a substantial burden on religious exercise to be permissible the government must be able to show that the law being enforced or observed is such that the government can "demonstrate that application of the burden to the person – (1) is in furtherance of a compelling government interest; and (2) is the least restrictive means of furthering that compelling government interest."[41]

The contraceptive mandate will require insurance plans to offer contraceptives and intra-uterine devices free of charge to the recipient. A number of religious faiths and denominations, the Catholic Church being the largest, have expressed moral objections to the use of such contraceptives for many decades. As extensively discussed above, some

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[38] PPACA, Section 1303(b)(1)(A) as amended by Section 10104(c).

[39] 107 Stat. 1488, as amended, 42 U.S.C. § 2000bb *et seq*.

[40] 42 U.S.C. § 2000bb-1(a).

[41] 42 U.S.C. § 2000bb-1(b).

organizations and individuals believe that contraceptives are embryo destructive,[42] and some also believe that even if no embryo destruction occurs contraceptives interfere with the moral integrity of sexual relations between men and women.

PPACA's contraceptive mandate will force those employers and employees with either set of beliefs or both to face a moral dilemma. Either they can purchase or participate in insurance plans that cover drugs and devices that may destroy embryonic human life or facilitate unacceptable sexual behavior, or they can decline to purchase or participate in such insurance policies. The overall point is that the contraceptive mandate will compel such employers either to violate their consciences by keeping such plans or drop coverage for their employees. In turn, that will cause employees to lose their coverage and be forced to find coverage elsewhere. Given the universality of the contraceptive mandate, individuals could be forced to refuse to obtain insurance coverage and face various penalties. Many employers who drop coverage for their employees will be forced to pay penalties under certain circumstances.

As established in RFRA and *Sherbert v. Verner*, the case that set forth the legal standard later adopted by Congress in RFRA, the contraceptive mandate places a substantial burden on the practice of religion by employers and employees.[43] In *Sherbert* the Supreme Court observed that the state's denial of benefits to the appellant in that case "derive[d] solely from the practice of her religion," and that "the pressure upon her to forego that practice [was] unmistakable."[44] The government's action "force[d] her to choose between following the precepts of her religion and forfeiting benefits, on the one hand, and abandoning one of the precepts of her religion…, on the other hand."[45] This, the court believed was tantamount to placing "the same kind of burden upon the free exercise of religion as would a fine imposed against the appellant for her Saturday worship."[46]

The HHS contraceptive mandate places a similar burden upon the free exercise rights of religious organizations and individual believers. Individuals are placed in the position either of participating in health insurance plans that cover the provision of drugs and devices that violate their consciences or dropping health insurance coverage. Religious organizations have the dilemma of either providing insurance coverage to which they object morally or not doing so and being penalized under PPACA.

Under RFRA a law or regulation that imposes a "substantial burden" on a person's free exercise of religion is only allowed when the government can demonstrate "that application

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[42] Whatever one's position on contraceptives, in general, there is no denying that Ella, a drug covered by the contraceptive mandate has the capability to destroy embryonic life implanted in the uterus. As such, Ella is properly classified as an abortifacient.

[43] In *Sherbert*, the Court actually used the term "substantial infringement," but "substantial burden" is the commonly used term in such analysis. *Sherbert v. Verner*, 374 U.S. 398, 406 (1963)

[44] *Sherbert*, 374 U.S. at 404.

[45] *Sherbert*, 374 U.S. at 404.

[46] *Sherbert*, 374 U.S. at 404 (the appellant was a Seventh Day Adventist and attended church on Saturday not Sunday).

of the burden" furthers "a compelling governmental interest."[47] The contraceptive mandate does not further a compelling governmental interest. It does not relate to the treatment of a serious or life-threatening disease – or, indeed, to any disease - and certainly does not involve a medical threat that is easily transmissible and could pose a widespread public health concern.

For example, one could imagine that a compelling governmental interest would exist for policies needed to contain the outbreak of a virulent airborne disease like the 1918 flu pandemic. However, as stated in Section I, pregnancy is not a transmissible disease. Rather, it is a normal medical condition from which serious medical complications can arise but typically do not. The Institute of Medicine's recommendations did not present a compelling governmental interest related to pregnancy prevention that can justify the burdens on religious freedom produced by this contraceptive mandate.

Next, the contraceptive mandate does not provide the "least restrictive means of furthering" the government's putative compelling interest.[48] As noted above in Section II, scientific studies have questioned the efficacy of contraceptives in improving certain medical outcomes like rates for STDs and abortion, and even for reducing the rate of unintended pregnancies. Even if the reduction of these conditions warranted urgent governmental action, the provision of contraceptives does not seem to be effective in producing desirable outcomes, and the mandatory provision of contraceptives has even less justification. It seems logical to conclude that a "narrowly tailored" policy would only employ effective means to achieve its ends.

For decades, employers and employees have been able to address the ethical concerns raised by contraceptives with minimal disruption to the provision of health care in America. The contraceptive mandate under consideration will be divisive for American society and damaging to the effective provision of health care for many religious people. Accordingly, the contraceptive mandate should be rescinded as a poorly conceived, coercive policy that violates the protections for religious freedom established in federal law by RFRA.

VII. Conclusion.

The interim final rule as published by the Administration on August 1, 2011 is an unprecedented mandate which deeply conflicts with religious and conscience freedom protections the American people currently receive. We reiterate that in a democratic society it is not the role of the Administration to dictate what does or does not violate another person's conscience on matters as critical as life and death. Family Research Council strongly opposes the contraceptive mandate for the many reasons outlined above and asks that HHS fully rescind this rule.

In the event that HHS does not rescind the contraceptive mandate, FRC asks that an adequate "religious employer" definition for exemption to this mandate be developed. As drafted, so few religious groups will be eligible for the protection from the mandate that as previously stated, most religious employers will be faced with either violating their

[47] 42 U.S.C. § 2000bb-1(b).

[48] 42 U.S.C. § 2000bb-1(b).

consciences or dropping health coverage, which undermines the primary goal of the PPACA. Regarding the extreme narrowness of the exemption offered by HHS, we agree with Daniel Cardinal DiNardo who recently stated, "Jesus himself, or the Good Samaritan of his famous parable, would not qualify as 'religious enough' for the exemption, since they insisted on helping people who did not share their view of God."[49]

Sincerely,

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[49] "Statement for Respect Life Month," Cardinal Daniel N. DiNardo, Chairman, Committee on Pro-Life Activities United States Conference of Catholic Bishops (Sept. 26, 2011).