June 8, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9968-ANPRM
P.O. Box 8016
Baltimore, MD 21244-1850

Submitted Electronically Via Email
Re. File Code CMS–9968–ANPRM

Dear Sir or Madam,

On March 21, 2012 the Department of Health and Human Services (HHS) issued an advanced notice of proposed rulemaking (ANPRM), "Certain Preventive Services Under the Affordable Care Act" requesting public comments on the purported "accommodation" related to the final rule, "Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act," published February 15, 2012, implementing section 1001 of the "Patient Protection and Affordable Care Act" (P.L. 111-148) (PPACA). That rule required all insurance plans to cover, with no cost-sharing, the full range of Food and Drug Administration-approved (FDA) contraceptives – including those with abortifacient modes of action. The requirement included only a very narrow exemption for houses of worship. The March 21 ANPRM requests public feedback on how non-exempt organizations that are religiously opposed to the HHS mandate should comply with this directive. That is, HHS is seeking suggestions on how religious organizations' health plans would cover these services for free, even if doing so conflicts with their beliefs.

Family Research Council (FRC) writes today representing the large body of Americans who oppose the HHS mandate and the significant manner in which it discriminates against people of faith. FRC believes that the ANPRM represents the latest in a series of decisions that now culminates in this grave threat to religious liberty.

Our comments have several parts. Part I summarizes the actions which have led to the latest ANPRM. In Part II we discuss the topic of conscience and religious liberty in the context of the ANPRM and various actions taken by HHS previously – as noted in Part I. Part III addresses the topic of certain FDA-approved contraceptives that have abortifacient mechanisms of action. Part IV discusses states with similar mandates. Part V addresses the recently released cost-analysis of the mandate compiled by HHS. We conclude by asking that HHS reconsider its position entirely and take seriously its obligations to protect conscience

rights and religious freedom, as required by law, in any future actions related to this regulation.

I. Summary of Events Leading to ANRPM.

To retrace the timeline, the "Patient Protection and Affordable Care Act" (P.L. 111-148) as enacted in March 2010 contains a provision on preventive health services in Section 1001. This provision created a new Section 2713 of the Public Health Service Act (PHSA) mandating 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). During the healthcare reform debate, Senator Barbara Mikulski (D-MD) offered an amendment (S.AMDT. #2791) that passed on December 3, 2009, to extend the preventive care mandate to include coverage of preventive services for women.

Specifically, Senator Mikulski's amendment created a Section 2713(a)(4) of PHSA that 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). Nowhere does this statute require HHS to include drugs or devices in a way that infringe upon the conscience laws already enacted over the past 35 years regarding "abortion" or "any item or service" to which individual Americans and organizations have conscience objections.

HHS published an interim rule in July 2010 indicating that guidelines for women's preventive services would be developed and issued by HHS no later than August 2011. The legal provision granted wide latitude to HHS, and HHS could clearly have complied with the law while protecting conscience rights of all Americans.

At the request of HHS, between November 2010 and March 2011, the Institute of Medicine (IOM) hosted three committee meetings in Washington, D.C., to discuss and make recommendations regarding specific women's preventive services that should have no cost-sharing. The IOM report "Clinical Preventive Services for Women: Closing the Gaps" was released on July 19, 2011.

On August 2, 2011, HHS issued an amendment to the interim final rule from July 2010 adopting the recommendations of the IOM report. The regulation forces all group and individual health plans to provide all FDA-approved contraceptives, sterilizing agents, and education and counseling services, with no co-pay by August 1, 2012. The HHS regulation provides an exemption only for a narrow category of "religious employers" which would essentially only include churches. The regulation limits "religious employers" to those organizations which a) have the "inculcation of religious values as its purpose," b) primarily employ persons who share its religious tenets, c) primarily serve persons who share its religious tenets, and d) is a non-profit organization that under 26 U.S.C. §§ 6003(a)(1) and 6033(a)(3)(A)(i) or (iii) is exempt from filing annual tax returns.

On January 20, 2011, after receiving over 200,000 public comments on the mandate, HHS issued a press release stating that religious groups not covered by the "religious employer" exemption would have one year to decide how to comply with the requirements to cover contraceptives and sterilizations. On February 10, after weeks of pressure from the public, President Obama announced a so-called "accommodation," but on the same day, HHS issued the final rule with *no* changes to the religious employer exemption or mandate. HHS also issued guidance solidifying the contraceptive coverage mandate.

On March 21, 2012, HHS issued the current ANPRM asking for comments on how such an accommodation might be implemented. The ANPRM does nothing to garner comments about how to expand the definition of religious employer, nor does it ask how HHS should take into account the moral objections of other entities as currently protected by law. The current rule remains discriminatory, and is in direct conflict with the conscience rights afforded to Americans and religious freedom protections under current law.

II. Violation of Conscience and Religious Liberty.

The HHS 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.[1] 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*, (italics added) or any other kind of health care facility, organization, or plan."

The Hyde-Weldon Amendment does not require that those who object to abortion do so on religious or moral grounds. It categorically prohibits governmental discrimination for those who refuse, for whatever reason, to participate in or cover abortion. Given some drugs and devices included in the HHS mandate that can function as abortifacients, the contraceptive mandate violates the Hyde-Weldon provision by requiring entities that do not cover these drugs to do so.

The HHS Mandate violates the Religious Freedom Restoration Act ("RFRA") enacted by Congress in 1993.[2] 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."[3] 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

1 "Consolidated Appropriations Act, 2012", PL 112-74, Division F, Title V, Section 507(d)(1). The PL version page number is: 125 STAT. 1111.

2 107 Stat. 1488, as amended, 42 U.S.C. § 2000bb et seq.

3 42 U.S.C. § 2000bb-1(a).

compelling government interest; and (2) is the least restrictive means of furthering that compelling government interest."[4]

The contraceptive mandate will require insurance plans to offer abortifacients, contraceptives and intra-uterine devices free of charge to the plan beneficiaries. A number of religious denominations, the Catholic Church being the largest, have expressed moral objections to the use of such contraceptives for many decades. As will be discussed in Part III, some organizations and individuals believe that some FDA-approved contraceptives are embryo destructive,[5] and some also believe that even if no embryo destruction occurs, contraceptives interfere with the moral integrity of sexual relations between men and women.

Therefore, PPACA's preventive care services provision, as implemented by HHS, will force those employers and employees with either set of beliefs, or both, to face a moral dilemma. Either they can purchase and participate in insurance plans that cover drugs and devices that may destroy embryonic human life, or they can decline to purchase and 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. Many employers who drop coverage for their employees will be forced to pay penalties under certain circumstances. Given the breadth of the contraceptive mandate, individuals could be forced to refuse to obtain insurance coverage and face various penalties if they refuse to pay for insurance in the individual market.

Under RFRA and *Sherbert v. Verner*, the case that set forth the legal standard later adopted by Congress in RFRA, substantial burden on the practice of religion by employers and employees is illegal.[6] The HHS contraceptive mandate imposes such a burden. 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."[7] 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."[8] 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."[9]

The HHS contraceptive mandate places a similar substantial burden upon the free exercise rights of religious organizations and individual believers. Individuals are placed in the

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4 42 U.S.C. § 2000bb-1(b).

5 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.

6 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)

7 Sherbert, 374 U.S. at 404.

8 Sherbert, 374 U.S. at 404.

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

position either of buying health insurance plans in the individual market that cover the provision of drugs and devices that violate their consciences or dropping health insurance coverage. If the latter, they face penalties for failing to comply with PPACA's "individual mandate". Even if most plans in the individual market already cover contraceptives and abortifacients, the HHS mandate completely removes any choice in the matter. Religious organizations have the dilemma too of either purchasing or providing for their employees insurance coverage to which they object, or dropping their insurance with the threat of penalties under PPACA's employer mandates, which could cost upwards of $100 per day per employee.

Under RFRA, a law or regulation that imposes a "substantial burden" on a person's free exercise of religion is only justified when the government can demonstrate "that application of the burden" furthers "a compelling governmental interest."[10] The contraceptive mandate does not further a compelling governmental interest. It does not relate to the treatment of a serious or life-threatening disease, let alone one that is easily transmissible and could pose a widespread public health concern. Consequently, the potential burden placed on religious practice is not warranted.

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. Government mandates on vaccination for a dangerous flu or the isolation of contagious tuberculosis patients seem supportable. However, pregnancy is not a transmissible disease. Rather, it is a normal medical condition from which serious medical complications can arise, but typically do not. If mandating contraceptives to prevent pregnancy is a compelling governmental interest, then virtually any non-trivial medical condition could yield onerous policies. FRC believes that the IOM did not present a compelling governmental interest related to pregnancy prevention.

Next, RFRA requires that if there is a compelling governmental interest for substantially burdening a person's exercise of religion, then the government must select the least restrictive means of achieving its goal.[11] FRC believes that HHS's contraceptive mandate does not represent the "least restrictive means" the agency could have chosen. Contraceptive drugs and devices are widely available in the U.S. and already are heavily subsidized by the federal government. Public expenditures for contraceptive services in fiscal year 2010 totaled 2.37 billion.[12] Contraceptives are also covered by most insurance plans. Nine out of ten employer-based insurance health plans cover the full range of contraceptives.[13] HHS could have provided increased funding for existing federally funded family planning programs, or it could have created other financial incentives for the purchase of such drugs and devices through the tax code – possibly increasing employer-based provision via insurance coverage. Neither of these less-restrictive options would have created the burden on religious freedom that the HHS mandate does.

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10 42 U.S.C. § 2000bb-1(b).

11 42 U.S.C. § 2000bb-1(b).

12 A. Sonfield and RB Gold, Public Funding for Family Planning, Sterilization and Abortion Services, FY 1980–2010, New York: Guttmacher Institute, 2012.

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

Additionally, there is no solid evidence suggesting that the majority of women who choose not to use contraceptives are making that decision due to financial need. A survey of sexually active women conducted by the Guttmacher Institute shows that only 12 percent report "lacking access to contraceptives due to financial or other reasons."[14] It is not clear how much the HHS mandate would increase the availability of such drugs and devices to this underserved population relative to other "less restrictive" means that were available to the government.

It should be noted that scientific studies raise questions about the overall efficacy of contraceptives in improving certain medical outcomes such as rates for unintended pregnancies, STDs, and abortion, as will be discussed in Part V.[15] Thus, the provision of contraceptives does not seem to be extremely effective in producing desirable outcomes. A "narrowly tailored" policy should only employ effective means to achieve its stated ends – especially when religious liberties hang of the balance.

The ANPRM also proposes to make the religious discrimination of the final rule worse. The final regulation mandates that insurance plans contain free contraceptive coverage to employees, whether the employer plans object or not. The rule proposes that the coverage for the employees be "offered" to the employee and their dependents.[16] That is, even though the religious employer's religious views will be violated, it nonetheless allows the option for employees to reject coverage of such drugs and devices in their plan. The ANPRM, however, proposes to cut off any choice by "automatically" providing the contraceptive coverage.[17] This means that plan participants would not have a choice themselves to refuse such coverage in their plans. The ANPRM, therefore, extends the religious freedom violation beyond the non-exempt religious employer to the employees who are plan participants that may object to the inclusion of such drugs and devices in their health coverage.

Even worse, the ANPRM extends this automatic free coverage to employees and their dependents, and will do so in a way to "protect the privacy" of beneficiaries even if they are minors.[18] This proposal guarantees that the entire contraception mandate violates parental rights as well. How can parents make decisions about their child's health care, or about what they consider to be conscionable, if children can get free contraceptives and abortifacients without being informed? The ANPRM proposes taking an already illegal and unethical violation of religious freedom and adding to that a gross violation of parental rights. The entire mandate should be rescinded to avoid any such government intrusion on parenting.

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 is divisive for American society and damaging to

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[14] 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

15 Anna Glasier, "Emergency Contraception: Is It Worth All the Fuss?" 333 British Medical Journal (2006): 560-1.

16 77 Fed. Reg. at 8728
17 77 Fed. Reg. at 16505
18 Ibid.

the effective provision of health care for many religious people, in as much as religious organizations will drop health coverage for their employees. Accordingly, the contraceptive mandate should be rescinded as a poorly tailored, coercive policy that violates the protections for religious freedom established in federal law by RFRA.

A serious question is if and how HHS considered whether religious liberties would be adequately preserved prior to issuing the mandate. In April, Secretary Sebelius testified before Congress that she received counsel from HHS General Counsel on religious liberty as it related to the mandate. She stated that she believed she struck an "appropriate balance" on the issue. However, when questioned further, the Secretary admitted that she was unfamiliar with any of the major religious liberty cases heard before the Supreme Court. She also admitted that no legal memo was written on the topic, and any counsel she received was done so through discussion. Indeed, reliance on the IOM report is insufficient, as they were never tasked to consider the impact of their recommendations on religious liberty and health coverage by conscientious objectors to a contraceptive mandate. For a federal mandate that changes the relationship between many religious practitioners, the Church, and State in America, it appears that the protection of religious liberty was, at best, given minimal consideration by HHS.

III. Abortifacients.

The FDA-approved "contraceptives" required by the contraceptive mandate include a variety of drugs and devices that have modes of action that can be destructive rather than preventive.

The first of these drugs is Levonorgestral, or Plan B, which was approved by the FDA as an Emergency Contraceptive (EC). 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.[19] It works by making implantation unlikely because the uterus becomes inhospitable to the embryo. 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."[20] Plan B's labeling information also admits this scientific reality. "[Plan B] may inhibit implantation (by altering the endometrium)."[21]

The second problematic FDA drug approved as an EC, and which is covered by the mandate, is ulipristal acetate. It is marketed as Ella® by Watson Pharmaceuticals. Ella is

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

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

[21] 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.

contra-indicated for pregnancy.[22] 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."[23] Numerous other research studies confirm ulipristal's abortifacient mechanism of action.[24] In one such study involving ulipristal's action in macaques (monkeys), 4 out of 5 fetuses were aborted.[25]

In filings required for ulipristal acetate's Europe approval, 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…"[26] 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."[27] 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."[28] 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.[29]

These studies provide sufficient evidence for one to reasonably conclude that Ella can kill an implanted embryo, and the induced demise of an embryo post-implantation is agreed by all, even the FDA, to be an abortion.[30] Ella's inclusion among those drugs that must be covered

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[22] 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).

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

[24] 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.

[25] 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).

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

[27] Harrison and Mitroka, *supra.*

[28] *Ibid*.

[29] 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.

[30] Christopher M. Gacek, "Conceiving 'Pregnancy': U.S. Medical Dictionaries and Their Definitions of 'Conception' and 'Pregnancy,'" *National Catholic Bioethics Quarterly* (Autumn 2009): 542-557.

by the HHS mandate went too far for those who cannot support or cooperate with the destruction of human life by chemical or pharmaceutical means.

IV. States With Contraceptive Mandates

HHS has repeatedly claimed that its narrow definition of "religious employer," which exempts churches from the contraception mandate, is identical to many current state laws. However, the HHS mandate, even with its narrow exemption, is far more expansive in its application than any state contraception mandate.

For example, California has a contraceptive mandate and a very narrow religious employer exemption that is similar to the HHS definition.[31] However, California's law applies only to health plans that have prescription drug coverage. Therefore, a religious employer that is not exempted under the narrow definition could nonetheless change its health plan to avoid the state contraceptive mandate by dropping its prescription drug coverage. Moreover, such a religious employer could also change to a self-insured health plan to avoid the state mandate, since California's contraception mandate does not apply to self-insured plans. In fact, some employers have become self-insuring to avoid the conscience problems created by the state's contraceptive mandate.

Similarly in New York, the law mandating that employers cover contraceptives also contains a narrow religious employer exemption similar to HHS's. However, here, too, the New York law differs significantly from the HHS mandate in that the NY law applies only to plans with prescription drug coverage.[32] If a religious employer drops prescription drug coverage from its policy, it would not be subject to the state contraception mandate. The employer could also choose to self-insure and, thereby, avoid the mandate as is the case in California.

In contrast, the HHS contraception mandate does not provide non-church religious groups with any avenues for exit from the mandate – as there are in California and New York. The HHS mandate applies to all group plans, even if they do not offer prescription drug coverage. Moreover, the HHS mandate applies to group plans whether they are fully insured or self-insured. With self-insured employers, the employer is the insurer. State contraception laws do not apply to self-insured plans, but the HHS mandate does. The HHS mandate, therefore, has the effect of being far more discriminatory than the state laws mandating contraception.

Furthermore, many state laws contain a broader definition of "religious employer," which means the HHS mandate and its narrow exemption will trump numerous state laws.

There is another difference between state and federal contraceptive requirements. The state laws do not require free contraceptive coverage, whereas the federal rule does. The ANPRM proposes accounting arrangements in which the health insurer, or in the case of self-insured employers, the third party administrators, will pay for contraceptive drugs and devices without charge. However, making insurers or third party administrators for religious employers pay the cost of free contraceptives, abortifacients, and sterilizations does nothing

31 CAL. INS. CODE § 10123.196.

32 N.Y. Ins. § 3221 (1)(16)(A)-(C)

to remove the religious liberty infringement. A religious employer who objects to the HHS mandate will still have to pay eventually for these products. HHS has not yet specified the accounting scheme that must be used by the insurer or third party administrator, but the costs will eventually be borne by the policy holder. It cannot be otherwise. The use of cut-outs to make the actual payment is nothing more than an accounting gimmick and a scam.

Taken together, the HHS mandate and its narrow religious exemption have a sweeping scope that produces a contraceptive directive unlike that found in any state law.

V. Cost Assessment

Referenced in the February 10 final rule was a policy brief,[33] published on February 9, 2012, "The Cost of Covering Contraceptives through Health Insurance," compiled by the HHS Assistant Secretary for Policy and Education (ASPE). The brief included actuarial assessments of the HHS contraception mandate cost implications upon health insurance providers, all of which agreed that that mandate will increase health insurance costs. Nevertheless, the government authors concluded that "[w]hen medical costs associated with unintended pregnancies are taken into account, including costs of prenatal care, pregnancy complications, and deliveries, the net effect on premiums is close to zero." The error in this argument lies in its cost estimates, which rely on those found in the states with similar mandates and in the Federal Emergency Health Benefit program. Unfortunately for HHS, none of these programs are comparably expensive to the current HHS nation-wide mandate which has a much broader scope and no co-pays (see Section IV, *supra*). Additionally, none of the assessments relied upon by HHS consider the cost shifting changes in behavior that would occur with the free provision of contraceptives, abortifacients, sterilization surgeries, and intrauterine devices.

Additional data used to reach the "zero net effect" was taken from currently funded public family planning programs. However, populations impacted by public family planning programs are very different than populations impacted by the HHS mandate. Women affected by the federal contraceptive mandate would likely be higher income and would already have access to contraception. As such, very little or no savings would be incurred from this mandate.

The ASPE brief's conclusion also rests on certain unproven assumptions. First, it assumes that more women will contracept as a result of the mandate, and that more women contracepting necessarily equates to fewer pregnancies. However, given that studies have shown that cost is not a limiting factor for women in terms of contraception use,[34] as well as the many statistics showing the high percentage of women already contracepting, it is unlikely that the number of women contracepting will significantly increase under the mandate. Rather, the women who now purchase contraceptives with co-pays will simply do so without making that payment. Therefore, the mandate is unlikely to change overall pregnancy rates, and unlikely to provide the cost savings HHS purports.

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33 HHS ASPE Brief, "The Cost of Covering Contraceptives through Health Insurance," February 9, 2012 (http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml).

34 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

If women are not currently using contraception, there is little evidence to demonstrate that multitudes will suddenly begin to use "free" contraceptives to the extent that it will generate the claimed cost savings. A fundamental assumption of the HHS mandate is challenged by studies showing that increased contraception use does not necessarily correlate with a decrease in unintended pregnancies or sexually transmitted diseases. Recent peer reviewed studies from Sweden,[35] the United Kingdom,[36] and Spain[37] 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,[38] and abortions decreased from 1,359,400 to 1,269,000.[39]

None of the studies cited in the ASPE brief analyze contraceptive mandates in terms of actual reduced pregnancies. Costs generated by comparable mandates are not examined. More fundamentally, even if the inclusion of free contraceptives in a health plan leads to an actuarial net savings over a longer period of time, which is by no means certain, someone must pay for those in the short term. The immediate cost will be covered by the employer's premiums, which is what insurers use to pay for services. Even in the unlikely event that the employer sees a net cost savings, the employer's religious liberties are still violated because they are forced to contract for a health plan that acts as the mechanism by which objectionable drugs and services are provided to employees. Whether their dollars pay the cost of the services is ultimately irrelevant, since they are still forced to provide by contract those services to which they object. Therefore, whether there is a long term savings or not, the moral dilemma forced on religious employers remains the same.

VI. Conclusion.

In the summer and fall of 2009, while lobbying for healthcare reform, President Obama repeatedly promised that "if you like your healthcare plan you can keep your healthcare plan."[40] We now write to HHS to request that President Obama make good on his promise. We request that groups not be forced to violate their consciences by being forced to pay for

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[35] 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).

[36] 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.

[37] 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.

[38] 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.

[39] 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).

40 PolitiFact.com, "Barack Obama Promises You Can Keep Your Health Insurance, But There's No Guarantee," (August 11, 2009) http://www.politifact.com/truth-o-meter/statements/2009/aug/11/barack-obama/barack-obama-promises-you-can-keep-your-health-ins/.

health care plans through contracts that would adopt some sham-accounting procedure devised to give the appearance of shifting the costs for the purchase of objectionable drugs and devises. Therefore, we ask HHS to rescind its mandate requiring insurance plans to include coverage for all FDA-approved contraceptives and sterilization services.

The interim final rule as published by the Administration on August 1, 2011, and as finalized in law on February 10, 2012 is an unprecedented federal action that deeply violates the religious and conscience protections Americans have known for centuries. The March 21 ANPRM simply seeks advice on how to get around this problem by seeking ways to craft clever accounting tricks to supposedly shift costs to insurers and third party administrators. In reality, nothing was changed on February 10, and nothing will be changed by any accounting gimmick crafted by HHS. The mandate will still violate the religious liberty protections of Americans.

Forcing religious entities to provide and pay for health care coverage that includes objectionable drugs and services is an act of religious discrimination. If the government felt an accounting scheme were sufficient to protect religious liberties, why did it exempt churches in the first place? Therefore, we urge you to reconsider and completely rescind any requirement that health care plans include contraceptives, abortifacients and sterilizations.

Sincerely,

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