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September 30, 2011

VIA ELECTRONIC SUBMISSION

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

RE: CMS–9992–IFC2
Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

Dear Secretary Sebelius:

The National Health Law Program ("NHeLP") applauds your decision to adopt the recommendations from the Institute of Medicine ("IOM") to require insurance coverage of women's preventive health services without cost-sharing. We are pleased to offer these comments on the August 3, 2011 interim final rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act ("the ACA") regarding preventive health services. NHeLP is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. NHeLP provides technical support to direct legal services programs, community-based organizations, the private bar, providers, and individuals who work to preserve a health care safety net for the millions of uninsured or underinsured low-income people.

The ACA requires group health plans and health insurance issuers to cover, without cost-sharing, certain preventive services.[1] Among other things, the ACA requires new group health plans and health insurance issuers to cover such additional preventive care and screenings as provided for in guidelines supported by the Health Resources and Services Administration ("HRSA").[2] By doing so, the ACA recognizes that women have unique reproductive and gender specific health needs, disproportionately lower incomes and disproportionately higher out-of-pocket health care expenses.

[1] Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by Health Care and Education Reconciliation Act, Pub. L. No. 111-152, 124 Stat. 1029 (2010), § 2713(a), 42 U.S.C. § 300gg-13.
[2] ACA § 2713(a)(4), 42 U.S.C. § 300gg-13.

HRSA commissioned the independent IOM to conduct a scientific review and provide recommendations on specific preventive measures that meet women's unique health needs and help keep women healthy. The IOM developed eight recommendations based on scientific evidence, including the input of independent physicians, nurses, scientists, and other experts.[3] HRSA recently adopted the recommendations submitted by the IOM.[4] Adherence to the HRSA guidelines based on the IOM recommendations will ensure that women's health and well-being are adequately addressed. Requiring coverage of all eight preventive services recommended by the IOM is good medical and economic policy.

HRSA's proposed refusal clause, 45 C.F.R. § 147.130(a)(1)(iv)(A)-(B), however, contravenes the text and purpose of the ACA—which includes no such exception, and HRSA's Women's Preventive Services: Required Health Plan Coverage Guidelines. The proposed refusal clause subordinates an affected woman's health to her employer's religious beliefs—religious beliefs that the woman may not even share. NHeLP urges HRSA to withdraw its proposed refusal clause.

1. **The requirement to cover contraceptives as a component of preventive care is evidence-based.**

Family planning is an essential preventive service for the health of women and families.[5] HRSA charged the IOM with convening a committee to determine the preventive services necessary to ensure women's health and well-being.[6] To this end, the IOM convened a committee of 16 eminent researchers and practitioners to serve on the Committee on Preventive Services for Women.[7] The Committee met five times in six months.[8] The Committee reviewed existing guidelines, gathered and reviewed evidence and literature, and considered public comments.[9] With respect to women, the IOM identified gaps in the coverage for preventive services not already addressed by the ACA, including services recommended by the United States Preventive Services Task Force, the Bright Futures recommendations for adolescents from the American Academy of Pediatrics, and vaccinations specified by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices. The IOM recommended that, among other things, women receive coverage for all United States Food and Drug Administration ("FDA")-approved methods of contraception free of cost-sharing because: (1) pregnancy affects a broad population; (2) pregnancy prevention has a large potential impact on

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[3] Institute of Medicine of the National Academies, *Clinical Preventive Services for Women: Closing the Gaps* (2011), www.iom.edu/~/media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/preventiveservicesforwomenreportbrief_updated2.pdf.
[4] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Women's Preventive Services: Required Health Plan Coverage Guidelines, http://www.hrsa.gov/womensguidelines.
[5] The framework of World Health Organization's definition of health as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity, includes specific attention to reproductive health which addresses the reproductive processes, functions and systems at all stages of life. World Health Org. Const. pmbl. (1946).
[6] Institute of Medicine of the National Academies, *supra* note 3, at 1.
[7] *Id.* at 2.
[8] *Id.*
[9] *Id.*

health and well-being; and (3) the quality and strength of the evidence is supportive of the recommendation to provide contraceptive coverage free of cost-sharing.[10]

2. Unintended pregnancy carries adverse risks for an affected woman and her family.

Unintended pregnancy, which can effectively be prevented through contraception, can adversely impact the health and well-being of affected women and their families. A woman's ability to control her reproductive life and to become a parent when she has made an affirmative decision to become pregnant is fundamental to her ability to obtain an education and to be economically self-sufficient. In *Planned Parenthood v. Casey*, the United States Supreme Court recognized the importance of women's ability to make decisions about when and whether to have a child: "The ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives."[11]

Further, the importance of women's ability to prevent pregnancy for many health-related reasons is well established within medical guidelines across a range of practice areas. Children, for one, benefit from women's control over reproduction. Children born from wanted pregnancies tend to be healthier than those born from unwanted pregnancies.[12] Unwanted pregnancy is associated with, for example, low-birth weight babies and insufficient prenatal care.[13] The CDC/Agency for Toxic Substances and Disease Registry Preconception Care Work Group and the Select Panel on Preconception Care highlighted the numerous poor health outcomes including low birth weight, premature birth, and infant mortality which result when health conditions are not optimized prior to pregnancy.[14] In addition, in deciding whether to become pregnant, women take into account factors such as age, the presence of a partner, medical condition, mental health, and whether they are taking medications that are contra-indicated for pregnancy. For example, a number of commonly prescribed pharmaceuticals are known to cause impairments in the developing fetus or to create adverse health conditions if a woman becomes pregnant while taking them. Approximately 11.7 million prescriptions for drugs the FDA has categorized as Pregnancy Classes D (there is evidence of fetal harm, but the potential may be acceptable despite the harm) or X (contraindicated in women who are or may become pregnant) are filled by significant numbers of women of reproductive age each year.[15] Pregnancy for women taking these drugs carries risk for maternal health and/or fetal health.[16] Women taking these drugs who might be at risk for pregnancy are advised to use a reliable form of contraception to prevent pregnancy.[17]

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[10] *Id.* at 6, 151.
[11] *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 876-78 (1992).
[12] World Health Org., *The World Health Report 2005: Make every mother and child count* 50 (2005).
[13] Institute of Medicine of the National Academy of Sciences, *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families* 50, 52, 66-68 (1995).
[14] Kay Johnson, et al., *Ctrs. for Disease Control & Prevention, Recommendations to Improve Preconception Health and Health Care— United States: A Report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care*, MMWR Morbidity & Mortality Weekly Report (April 21, 2006).
[15] *Id.*
[16] David L. Eisenberg, et al., *Providing Contraception for Women Taking Potentially Teratogenic Medications: A Survey of Internal Medicine Physicians' Knowledge, Attitudes and Barriers*, 25 J. Gen. Internal Med. 291, 291 (2010).
[17] *Id.* at 291-92.

Access to family planning supplies is also essential to optimal women's health. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors. The World Health Organization recommends that pregnancies should be spaced at least two years apart.[18] Pregnancy spacing allows the woman's body to recover from the pregnancy. Further, if a woman becomes pregnant while breastfeeding, the health of both her baby and fetus may be compromised as her body shares nutrients between them. According to the American College of Obstetricians and Gynecologists, women who become pregnant less than six months after their previous pregnancy are 70 percent more likely to have membranes rupture prematurely, and are at a significantly higher risk of other complications.[19] Family planning is a focus area of the Healthy People 2010 health promotion objectives set out by the United States Department of Health and Human Services. Goal 9 of Healthy People 2010 is, "Improve pregnancy planning and spacing and prevent unintended pregnancy."[20] Specific indicators include increasing intended pregnancies from 51 percent to 70 percent; increasing pregnancy spacing to 24 months; increasing the proportion of women at risk for unintended pregnancy who use contraceptives to 100 percent, and increasing the proportion of teens that use contraceptive methods that both prevent pregnancy and prevent sexually transmitted disease.[21]

3. Unintended pregnancy is often a consequence of poverty; women are disproportionately low-income.

Many women, however, lack the resources to obtain these methods of contraception. Cost-sharing can pose barriers to accessing health care services and result in reduced use thereof, particularly for low-income women. Indeed, one of the major barriers to universal contraceptive access is the high out-of-pocket cost for women—who are also disproportionately low-income—whose health plans do not cover contraception. Low-income women have higher rates of unintended pregnancy, as compared to higher-income women.[22] Low-income women are the least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy.[23] On average, women generally have less income than men.[24] Women earn only 78 cents for every dollar that men earn, and the median earnings of women working full time, year round, were $35,549 in 2009, compared to $45,485 for men.[25] Women are more likely than men to forgo or postpone obtaining health care

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[18] Cicley Marston, *Report of a WHO Technical Consultation on Birth Spacing*, World Health Organization, (June 13-15, 2005).

[19] Am. Coll. of Obstetricians & Gynecologists, Statement of the Am. Coll. of Obstetricians & Gynecologists to the U.S. Senate, Comm. on Health, Educ., Labor & Pensions, Pub. Health Subcomm. on Safe Motherhood (April 25, 2002).

[20] U.S. Dep't of Health & Human Servs., *Healthy People 2010: Understanding and Improving Health* (Nov. 2000).

[21] *Id.*

[22] Lawrence B. Finer & Mia R. Zolna, Guttmacher Institute, *Unintended pregnancy in the United States: incidence and disparities, 2006* 8 (2011), http://www.guttmacher.org/pubs/journals/j.contraception.2011.07.13.pdf.

[23] Sheila D. Rustgi, Michelle M. Doty & Sara R. Collins, The Commonwealth Fund, *Women at Risk: Why Many Women are Forgoing Needed Health Care* 3-4 (2009), http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf.

[24] David M. Getz, U.S. Census Bureau, U.S. Dep't of Commerce, *Men's and Women's Earnings for States and Metropolitan Statistical Areas: 2009* (2010), http://www.census.gov/prod/2010pubs/acsbr09-3.pdf.

[25] *Id.* at 1.

and treatment for themselves because of cost.[26] Women of reproductive age spend 68 percent more in out-of-pocket costs than men, in part because of reproductive health-related needs.[27]

Further, the more effective methods of contraception also have the most up-front costs, which put them outside of the reach of many women.[28] In 2008, for example, only 5.5 percent of women using contraception chose the more effective and longer-term methods.[29] As the IOM recognized, the "elimination of cost sharing for contraception . . . could greatly increase its use, including use of the more effective and longer-acting methods, especially among poor and low-income women most at risk for unintended pregnancy."[30] In this regard, the California Kaiser Foundation Health Plan's experience is informative. The California Kaiser Foundation Health Plan eliminated copayments for the most effective contraceptive methods in 2002.[31] Prior to the change, users paid up to $300 for 5 years of use; after the change, use of these methods increased by 137 percent.[32]

4. Contraception effectively prevents unintended pregnancies, and women need to be able to select the method that is most appropriate.

Family planning services enable women to avoid unwanted pregnancies. In 2008, there were 66 million United States women of reproductive age (ages 13-44).[33] Over half of them—36 million women—were in need of contraceptive services and supplies because they were sexually active with a male, capable of becoming pregnant, and neither pregnant nor seeking to become pregnant.[34] Each year, nearly half of pregnancies in the United States are unintended—meaning they were either unwanted or mistimed.[35] By age 45, more than half of all American women will have experienced an unintended pregnancy, and three in ten will have had an abortion.[36]

Current methods for preventing pregnancy include hormonal contraceptives (such as pills, patches, rings, injectables, implants, and emergency contraception), barrier methods (such as male and female condoms, cervical caps, contraceptive sponges, and diaphragms), intrauterine contraception, and male and female sterilization. The wide range of pregnancy prevention options allows a woman to choose the most effective method for her lifestyle and health status.

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[26] Sheila D. Rustgi, Michelle M. Doty & Sara R. Collins, *supra* note 23, at 3-4.
[30] Rachel B. Gold, *The Need for and Cost of Mandating Private Insurance Coverage of Contraception*, The Guttmacher Report on Pub. Policy 5 (Aug. 1998), http://www.guttmacher.org/pubs/tgr/01/4/gr010405.pdf.
[28] Lawrence B. Finer & Mia R. Zolna, *supra* note 22, at 8.
[29] Kelly Cleland, et al., *Family Planning as Cost-Saving Preventive Health Service*, New Eng. J. Med 1 (2011), http://healthpolicyandreform.nejm.org/?p=14266.
[30] Institute of Medicine of the National Academies, *supra* note 3, at 94.
[31] Jennifer J. Frost & Jacqueline E. Darroch, *Factors Associated with Contraceptive Choice and Inconsistent Method Use*, 40 Sexual & Reprod. Health 94 (2008).
[32] *Id.*
[33] Jennifer J. Frost, Stanley K. Henshaw & Adam Sonfield, Guttmacher Institute, *Contraceptive Needs and Services: National and State Data, 2008 Update* 3 (2010), http://www.guttmacher.org/pubs/win/contraceptive-needs-2008.pdf.
[34] *Id.*
[35] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, Perspectives on Sexual & Reprod. Health 90, 92 (2006), http://www.guttmacher.org/pubs/psrh/full/3809006.pdf; Guttmacher Institute, *Facts on Induced Abortion in the United States* (Aug. 2011), www.agi-usa.org/pubs/fb_induced_abortion.html.
[36] *Id.*

As the IOM reported, female sterilization, intrauterine contraception, and contraceptive implants have failure rates of less than one percent.[37] Injectable and oral contraceptives have failure rates of seven and nine percent, largely due to poor user compliance.[38] Failure rates for barrier methods are higher.[39] A woman has an 85 percent chance of an unintended pregnancy if she uses no method of contraception.[40] Approximately fifty percent of unintended pregnancies in the United States occur among the 11 percent of women using no contraceptive method.[41] According to the Guttmacher Institute, in the United States, publicly funded family planning services and supplies alone help avoid approximately 1.5 million unintended pregnancies each year.[42] If these services were not provided in 2008, unintended pregnancy rates would have been 47 percent higher, and the abortion rate would have been 50 percent higher.[43]

RECOMMENDATION: HRSA should clarify that insurance products must cover all forms of FDA-approved contraceptive drugs, devices, and supplies, as well as the services to deliver them, to ensure that women can use the method that best suits her particular health and life needs.

5. Allowing employers to refuse to provide contraceptive coverage will result in the provision of sub-standard health care to affected women.

Congress enacted section 2713 of the ACA, the IOM issued recommendation 5.5, and HRSA adopted the Women's Preventive Services: Required Health Plan Coverage Guidelines, to ensure women's access to necessary preventive health care, and to redress prevailing inequities in women's health care access. The proposed religious employer refusal clause, however, will result in the provision of sub-standard health care to affected women. The refusal clause also perpetuates long-standing discrimination against women in the provision of health care benefits.

The proposed refusal clause, which allows employers to deny women access to effective, necessary, and desired preventive health care, contravenes federal law, including the ACA itself. Permitting employers to deny women coverage for contraceptive services is gender discrimination in violation of federal law and § 1557(a)-(b) of the ACA. Section 1557(a) of the ACA states that except as otherwise provided, no individual shall on the basis of sex "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)." Section 1557(b) of the ACA provides that, "Nothing in this title (or an amendment made by this title) shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards

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[37] Institute of Medicine of the National Academies, *supra* note 3, at 91.
[38] *Id.*
[39] *Id.*
[40] *Id.* at 91-92.
[41] Guttmacher Institute, *Fact Sheet: Facts on Induced Abortion in the United States* (Aug. 2011), http://www.guttmacher.org/pubs/fb_induced_abortion.html.
[42] Jennifer J. Frost, Stanley K. Henshaw & Adam Sonfield, Guttmacher Institute, *Contraceptive Needs and Services: National and State Data, 2008 Update* 5 (2010), http://www.guttmacher.org/pubs/win/contraceptive-needs-2008.pdf.
[43] *Id.*

available to individuals aggrieved under . . . Title VII of the Civil Rights Act of 1964 (42 U.S.C. § 2000e *et seq.*)." In 2000, the Equal Employment Opportunity Commission made clear that an employer's failure to provide insurance coverage for prescription contraceptives, in an otherwise comprehensive prescription drug plan, constitutes unlawful discrimination under Title VII.[44] The law is clear, and the proposed refusal clause is inconsistent with it.

In addition, § 1554 of the ACA prohibits the Secretary of the Department of Health and Human Services Health and Human Services from adopting any rule that:

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
> (2) impedes timely access to health care services;
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
> (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

Inclusion of a refusal clause in § 147.130(a)(1)(iv)(A)-(B) violates all six elements of § 1557. It creates a significant and unreasonable barrier for women to obtain the contraceptive services, drugs, devices, and supplies that meet their reproductive needs. In addition, the refusal clause interferes with the ability of women to obtain full and complete information about pregnancy-prevention options and long-standing principles of informed consent.

The primary criteria for determining coverage should be based on the standards of medical care recognized by the various "professional academies" of care. Delivering quality care requires that health care professionals provide care consistent with the highest standards of scientific evidence, based on individual patient need, and with the goal of maximizing wellness. Within this paradigm, the failure to provide access to specific types of health care is tantamount to the provision of substandard care. Professional policies and standards of care are designed to ensure consistent care even as professionals exercise discretion about specific treatments for specific patients. Refusals and denials of care threaten the consistency of health care by allowing health care decisions to be based on religious and moral beliefs that fall outside the purview of professional medical discretion.

Reproductive health includes the right of women (and men) to be informed of and to have access to safe, effective, affordable, and acceptable methods of fertility regulation of their choice.[45] It also includes the right to access appropriate health care services that will enable women to go

[44] U.S. Equal Emp't Opportunity Comm'n, Decision on Coverage of Contraception (Dec. 14, 2000), http://www.eeoc.gov/policy/docs/decision-contraception.htm.
[45] Global Policy Comm. of the World Health Organization, *WHO Position Paper on Health, Population, and Development* (Sept. 5-13, 1994).

safely through pregnancy and childbirth and to provide potential parents with the best chance of having a healthy infant.[46] Evidence-based practice requires that health care decision-making is based on the best available scientific research, seeking to improve the quality and decrease the cost of health care by ensuring that patients receive treatments known to be effective and do not receive those treatments proven to be ineffective or harmful.[47] Patient-centered care developed out of the institutionalization of informed consent as a means to achieve patient autonomy and address cultural variation. Evidence-based practice and patient-centered care work in tandem to ensure high quality health care.[48] In this way, care is individualized within a boundary of efficacy and safety. Complementing these approaches is the burgeoning attention to prevention which focuses on optimizing health outcomes before the onset of disease.[49]

Contrary to the trends in modern health care delivery, health care denials and prohibitions grounded in moral and religious beliefs rather than scientific evidence, negate evidence-based practice, patient-centered care, and prevention. Access to scientifically-grounded health care services related to contraception is critical to the health of women. Decisions to deny services based on personal and religious beliefs rather than scientific evidence ultimately result in poor health outcomes for women. The proposed refusal clause unreasonably impedes the ability of a woman to obtain appropriate and timely medical care, limits the availability of health care services to affected women, and violates standards of care.

6. **Employers' moral or religious beliefs should not determine which health care services are available to women.**

HRSA's proposed refusal clause would permit employers to impose their religious doctrines on women who do not share them and at the expense of affected women's health. All women should be able to make their own decisions about whether or when they want to become pregnant based on their own beliefs, not the beliefs of their employers. All women, regardless of where they work, should have access to the care they need.

An organization's religious beliefs should not stand in the way of an individual woman's decision to access the health care that she not only needs, but that she wants. And most sexually active women in the United States seek out contraception. The average American woman wants only two children.[50] She will therefore spend approximately 30 years attempting to avoid pregnancy.[51] Contraceptive use is nearly universal in women who are sexually active with a male partner.[52] Approximately 98 percent of sexually active Catholic women have used

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[46] *Id.*
[47] J.A. Muir Gray, *Evidence-based health care: How to make Health Policy and Management Decisions* (2d ed. 2001).
[48] Institute of Medicine of the National Academies, *Crossing the Quality Chasm: A New Health System for the 21st Century* 3-4 (March 2001), http://www.nap.edu/html/quality_chasm/reportbrief.pdf.
[49] U.S. Dep't of Health & Human Servs., *supra* note 20.
[50] The Alan Guttmacher Institute (AGI), *Fulfilling the Promise: Public Policy and U.S. Family Planning Clinics* 10 (2000), http://www.guttmacher.org/pubs/fulfill.pdf.
[51] *Id.*
[52] Williams D. Mosher WD & Jo Jones, *Use of Contraception in the United States: 1982–2008*, Nat'l Ctr. for Health Statistics, 23 Vital and Health Statistics, no. 29, 2010, at 5.

contraceptive methods banned by the Catholic Church.[53]

Most women are covered by health insurance offered by their employer.[54] According to a 1998 Guttmacher Institute study, while three-fourths of American women of reproductive age rely on private insurance, the extent to which they have contraceptive coverage can differ dramatically depending on their type of insurance.[55] To ensure women access to essential health care services, all employers should be required to provide no cost-sharing coverage for contraception. Requiring all employers—including religious employers—to provide contraceptive coverage does not force the employer to use, or even to condone, contraceptive use. Allowing an employer, however, to refuse to cover contraception creates substantial barriers to affected women's ability to prevent pregnancy, and subordinates an affected woman's health needs to the employer's beliefs.

RECOMMENDATION: We urge HRSA to remove § 147.130(a)(1)(iv)(A)-(B) to ensure that the IOM recommendations are properly implemented and that women can make their own conscientious decisions about whether to use contraception, and to have access without cost-sharing to the pregnancy-prevention services, drugs, devices and supplies that suit their particular health and life needs.

Conclusion

In sum, we strongly urge HRSA to protect women's health and to withdraw its proposed religious employer refusal clause. If you have any questions about these comments, please contact Mara Youdelman at (202) 289-7661 or Youdelman@healthlaw.org. Thank you for your consideration of our comments.

Sincerely,
/s/
Emily Spitzer
Executive Director

CC:

Director
Office of Health Reform, U.S. Department of Health and Human Services

[53] Rachel K. Jones & Joerg Dreweke, Guttmacher Institute, *Countering Conventional Wisdom: New Evidence on Religion and Contraceptive Use* 4 (2011), http://www.guttmacher.org/pubs/Religion-and-Contraceptive-Use.pdf.
[54] Usha Ranji & Alina Salganicoff, The Henry J. Kaiser Family Foundation, *Women's Health Care Chartbook: Key Findings from the Kaiser Women's Health Survey* 10 (2011), http://www.kff.org/womenshealth/upload/8164.pdf.
[55] Rachel B. Gold, *supra* note 30, at 5-6.