

Comments of the Center for Reproductive Rights

Interim Final Rules on Preventive Services CMS-9992-IFC2

Submitted September 30, 2011

The Center for Reproductive Rights respectfully submits the following comments on the interim final rule on preventive services. Since 1992, the Center for Reproductive Rights has worked toward the time when the promise of reproductive freedom is enshrined in law in the United States and throughout the world. We envision a world where every woman is free to decide whether and when to have children; where every woman has access to the best reproductive healthcare available; where every woman can exercise her choices without coercion or discrimination. More simply put, we envision a world where every woman participates with full dignity as an equal member of society.

In the United States nearly half of all pregnancies are unintended. Increased use of contraception is a key means of addressing this problem. The members of Congress who authored the Women's Health Amendment to the Patient Protection and Affordable Care Act took the critical first step by incorporating this pressing public-health issue into the Affordable Care Act. The Institute of Medicine, tasked with developing a list of essential preventive services for women, took the next step by demonstrating that no-copay contraceptive coverage is essential to the well-being of women and children. The Department of Health and Human Services now has the opportunity to make access to contraception a reality for millions of women by eliminating the exemption for religious institutions.

I. The Women's Preventive-Services Mandate Was Intended to Address a Critical Health-Coverage Gap, and the Process of Developing It Was Thorough and Fair

The Women's Health Amendment ("WHA") was added to the Patient Protection and Affordable Care Act ("PPACA" or the "Act") because of lawmakers' long-running concern that

¹ For purposes of our analysis, although we analyze the issue specifically in terms of contraception, we agree with the IOM's approach in treating sterilization as, essentially, a permanent or near-permanent form of contraception.

more than half of women delay or avoid preventive healthcare due to cost,² and that women pay substantially more in out-of-pocket costs for healthcare than men pay.³

While the Act already required the preventive services recommended by the U.S. Preventive Services Task Force ("USPSTF") to be covered without cost-sharing requirements, the WHA gave the Secretary of the Department of Health and Human Services ("HHS") the authority to require plans to cover additional preventive services for women. Because comprehensive coverage of preventive services must take into account the unique health needs of women throughout their lifespan, the WHA ensures coverage of women's preventive services based on a separate set of guidelines developed by experts to meet all of women's unique preventive health needs.

In short, the mandate for women's preventive services was included in the Act because existing preventive services recommendations did not encompass the full range of preventive services that women need. The women-specific preventive services supplement and fill in the gaps in other mandated preventive services in PPACA, including those put forth by the USPSTF, the American Academy of Pediatrics (Bright Futures), and the federal Advisory Committee on Immunization Practices. HHS looked to the Institute of Medicine ("IOM") – part of the independent National Academy of Sciences – to develop these preventive service recommendations for women.

In turn, the IOM convened a panel of outside experts – the Committee on Preventive Services for Women – and tasked it with preparing the recommendations. The members of the IOM panel were exemplary; they included specialists in disease prevention, women's health issues, adolescent health issues, and the development of evidence-based guidelines. Drafts of the Committee's work were reviewed by yet another distinguished group of experts, including professors of medicine, nursing, public health, and health policy.

The process of the IOM Committee was thorough and transparent. The Committee met five times over six months, and three open meetings were held to elicit testimony from stakeholders, researchers, advocates, and the public. To develop the eventual recommendations, the Committee collected existing guidelines for women's health services, and assembled additional evidence by reviewing medical literature, federal health priority goals and objectives, federal reimbursement policies, clinical guidelines of healthcare professional organizations, and public

² Cf. Senator Tom Harkin (D-IA) ("far too many women are increasingly delaying or skipping preventive health care due to costs") (quoted in Senator Barbara Mikulski, Press Release: Senate Approves Mikulski Amendment Making Women's Preventive Care Affordable and Accessible, Dec. 3, 2009, available at http://mikulski.senate.gov/media/pressrelease/12-03-2009.cfm); Senator Barbara Mikulski (D-MD) ("Insurance companies have used every trick in the book to deny coverage to women. This amendment makes sure that the insurance companies must cover the basic preventive care that women need at no cost") (quoted in id.).

³ According to WHA sponsor Barbara Mikulski, "[w]omen of childbearing age incur 68 percent more out of pocket health care costs than men." Senator Barbara Mikulski, Press Release: Mikulski Puts Women First in Health Care Debate (Nov. 30, 2009), available at http://mikulski.senate.gov/media/pressrelease/11-30-2009-2.cfm. The WHA finally addressed a concern that had been echoed for more than a decade. See, e.g., Senator Barbara Boxer (D-CA), Cong. Record, S-17615 (July 29, 1998) ("[w]omen spend 68 percent more in out-of-pocket costs for health care than men. Much of this difference is due to reproductive health costs.").

comments. Based on an analysis of all of these sources, it then formulated a list of recommendations using the following criteria:

- the condition has a broad population impact;
- the recommended service would have a substantial potential impact on health and wellbeing; and
- the quality and strength of evidence is supportive.

The resulting women's preventive-service requirements provide a critical new public-health protection by requiring all new group health plans to cover all FDA-approved contraception for women (including birth-control pills and intrauterine devices/IUDs) without cost-sharing (i.e. no co-payments or deductibles). We applaud HHS for following the recommendations of the prestigious panel of independent experts convened by IOM in adopting this important rule, including the contraceptive-coverage mandate.

We do not, as some have alleged, characterize pregnancy as a "disease." Yet unplanned pregnancy is undeniably a condition with profound health implications for both the woman and, if the pregnancy is carried to term, for the newborn. As stated by the IOM Committee on Unintended Pregnancy in 1995:

The committee urges, first and foremost, that the nation adopt a new social norm: All pregnancies should be intended – that is, they should be consciously and clearly desired at the time of conception.

This goal has three important attributes. First, it is directed to all Americans and does not target only one group. Second, it emphasizes personal choice and intent. And third, it speaks as much to planning for pregnancy as to avoiding unintended pregnancy. Bearing children and forming families are among the most significant and satisfying tasks of adult life, and it is in that context that encouraging intended pregnancy is so central.⁴

It would be absurd to place the prevention of unintended pregnancy outside the consideration of the nation's health and prevention priorities given the health risks attendant to pregnancy and the vital need to ensure that as many pregnancies as possible are planned. Health insurance already covers the medical issues arising from pregnancy (which are also not "diseases"); it is only logical that coverage also help prevent the medical issues arising from unintended pregnancies.

⁴ The best intentions: unintended pregnancy and the well-being of children and families. 1995. Committee on Unintended Pregnancy, Institute of Medicine, National Academy of Sciences; Sarah S. Brown and Leon Eisenberg, editors.

II. The IOM Panel Correctly Identified the Serious Health Consequences of Unintended Pregnancy

Among the many recommendations of the Committee was coverage for a full range of FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity. The underlying rationale is clear. Virtually all sexually active women will use contraception, yet its expense means that women too often use contraceptives irregularly, contributing to the United States' high rate of unintended pregnancies. These pregnancies are particularly prevalent among young and low-income women, are riskier to women's health than planned pregnancies and, if carried to term, result in less favorable outcomes

A. The Government Has a Compelling Interest in Reducing Unintended Pregnancy

The contraceptive coverage mandate is appropriate because the federal government has an abiding interest in making these services widely available and removing barriers to their use. This interest is compelling because:

- The need for access to contraception is widespread, and particularly acute among certain sectors of the population;
- Access to a full range of available contraceptive methods is essential to women's health and well-being, as unintended pregnancy leads to adverse health outcomes for women and, if the pregnancy is carried to term, for the child;
- Long-acting reversible methods of contraception are the most effective, but also carry higher costs, underscoring the need to remove financial barriers;
- If a pregnancy is unintended, women lose the opportunity to obtain early prenatal care and adjust their behaviors (such as smoking, or prescription-drug or alcohol use) to address the health needs of the fetus, thus risking permanent health impacts for a child carried to term;
- An unintended pregnancy can also have a profound impact on a woman's life, including on educational and career opportunities at a minimum, if carried to term, childbearing implies a lifetime of responsibility and care for the child and is one of the most serious, if not the most serious, commitments a person can make; and
- Reducing unintended pregnancy has emerged as a priority among medical societies and various national prevention initiatives.

Unfortunately, the contraceptive needs of women were not being fully addressed under the pre-PPACA health system. The report of the Committee on Preventive Services for Women⁵ states the following:

- 49% of pregnancies in this country are unintended a rate that is far higher than in other developed countries;
- 42% of unintended pregnancies end in abortion;
- Unintended pregnancy is more likely for women who are younger, unmarried, low income, have less education, and are racial or ethnic minorities.

Data from the Guttmacher Institute further underscore the scope of the problem:⁶

- There are 62 million U.S. women in their childbearing years (15–44);
- 7 in 10 women of reproductive age (43 million women) are sexually active and do not want to become pregnant, but could become pregnant if they and their partners fail to use a contraceptive method; and
- The typical U.S. woman wants only two children. To achieve this goal, she must use contraceptives for roughly three decades.

More than fifteen years ago, the IOM demonstrated the negative associations between early childbearing and a host of economic, social, and health outcomes that have been found in a variety of data sets over time, and noted that the association is "strong, consistent, and persistent." The consequences of unintended pregnancy are numerous and include health risks to the woman and the fetus/newborn, a negative socioeconomic impact, and greater incidence of abortion.

1. Unintended Pregnancy Poses Health Risks to Pregnant Women and to the Developing Fetus or Newborn

The recommendations of the IOM's Committee reflect the consensus of various stakeholders that prevention of unintended pregnancy should be one of the nation's highest health priorities. Private medical societies, federal public health agencies and others have highlighted the myriad risks associated with pregnancies for which women are not physically, emotionally or financially prepared. These risks are briefly summarized below.⁸

⁷ The best intentions: unintended pregnancy and the well-being of children and families. 1995. Committee on Unintended Pregnancy, Institute of Medicine, National Academy of Sciences; Sarah S. Brown and Leon Eisenberg, eds.

⁵ IOM (Institute of Medicine). 2011. *Clinical Preventive Services for Women: Closing the Gaps*. Washington, DC: The National Academies Press.

⁶ Guttmacher Institute, Facts on Contraceptive Use in the United States, June 2010.

⁸ The material in this section was compiled from the following sources: IOM (Institute of Medicine), *Clinical Preventive Services for Women: Closing the Gaps* (2011); Guttmacher Institute, *Facts on Contraceptive Use in the United States*, June 2010; *The best intentions: unintended pregnancy and the well-being of children and families*.

If a woman is unaware that she is pregnant, she is highly likely to delay the initiation of prenatal care, thus losing the opportunity to take steps to maximize both her own well-being while pregnant and, if she decides to complete the pregnancy, the well-being of her offspring. Similarly, she may not discontinue risky behaviors, such as consuming alcohol and drugs (whether illicit or prescription). 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. The Centers for Disease Control and Prevention (CDC) reports that three percent of the women who could potentially become pregnant are taking teratogens, drugs that can cause severe fetal impairments. Medical-practice guidelines for the use of many pharmaceuticals require that women not become pregnant during their course of treatment. Women taking these drugs who might be at risk for pregnancy are advised to use a reliable form of contraception to prevent pregnancy.

In addition to these risks to fetal health, pregnancy can also be dangerous for women themselves. Women with certain chronic conditions, such as diabetes, epilepsy, depression, lupus, obesity, and some forms of cardiovascular disease, are often advised to postpone pregnancy because it can exacerbate the condition. Pregnancy is also contraindicated for women with certain conditions such as hypertension and cyanotic heart disease.

Spacing of pregnancies is also an important reason to facilitate access to contraception. There is an increased risk of adverse outcomes if a pregnancy follows too closely (within 18 months) after a prior pregnancy. These outcomes may include prematurity, low birthweight, and being small for gestational age. The World Health Organization recommends that pregnancies should be spaced at least two years apart. Pregnancy spacing allows the woman's body to recover from the pregnancy, and if she 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 (ACOG), 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.

Women with unintended pregnancies are at higher risk for preterm birth and low-birthweight newborns, and also of premature rupture of membranes. Unintended pregnancy is also associated with shorter or no breastfeeding. Women with unintended pregnancy are at increased risk of experiencing physical violence, and infants born of an unintended pregnancy are also more likely to be abused.

1995. Committee on Unintended Pregnancy, Institute of Medicine, National Academy of Sciences; Sarah S. Brown and Leon Eisenberg, editors; National Health Law Program, Health Care Refusals: Undermining Quality Care for Women, 2010; Mohllajee AP et al. Pregnancy intention and its relationship to birth and maternal outcomes. AM. J. OBSTET. GYNECOL. 2007; 109:678-86; Kuroki L et al. Is a previous unplanned pregnancy a risk factor for a subsequent unplanned pregnancy? Am. J. OBSTET. GYNECOL. 2008; 199:517.e1-517.e7; Bennett et al. Unintended rapid repeat pregnancy and low education status: Any role for depression and contraceptive use? Am. J. OBSTET GYNECOL. (2006) 194, 749-54; Centers for Disease Control and 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 2006; 55 (No. RR-6).

The risks associated with unintended pregnancy can be particularly acute for teens. The 1995 IOM Report noted that in addition to the socioeconomic burdens, young adolescents (particularly those under age 15) experience a maternal death rate 2.5 times greater than that of mothers aged 20–24. Common medical problems among adolescent mothers include poor weight gain, pregnancy-induced hypertension, anemia, sexually transmitted diseases (STDs), and cephalopelvic disproportion. The risks to the infant are even greater. Infants born to mothers under 15 years of age are more than twice as likely to weigh less than 2,500 grams (about 5.5 pounds) at birth and three times more likely to die in the first 28 days of life than infants born to older mothers. After controlling for birthweight, for infants born to mothers under 17 years of age the postneonatal mortality rate is double that for infants born to older women. The incidence of sudden infant death syndrome is higher among infants of adolescents, and these infants also experience higher rates of illness and injuries.

2. Unintended Pregnancy Has a Negative Socioeconomic Impact on Women

Unintended pregnancy presents a serious public health concern in this country, accounting for 49% of all pregnancies (excluding miscarriages) and 44% of pregnancies resulting in a live birth. As set forth above these pregnancies raise a host of concerns that range from economics to the social, psychological, and physical consequences for maternal and child health. Based on data from the 2002 National Survey of Family Growth, the direct medical cost of unintended pregnancies for the United States alone was estimated at \$5 billion. According to Healthy People 2020, the public costs of births resulting from unintended pregnancies were \$11 billion in 2006.

Unintended pregnancy is often a consequence of poverty. Low-income women have higher rates of unintended pregnancy as they are 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. The availability of contraception without cost sharing is thus likely to have a particular impact on this segment of the population.

Teenage mothers tend to get less education, make less money, and are usually single or become divorced. Early childbearing is associated with having more children, and women and their children more likely to end up on public assistance. ¹⁰

3. Unintended Pregnancy Leads to a Higher Incidence of Abortion

Approximately half of all unintended pregnancies end in abortion. Because use of contraception is the most effective way to prevent unintended pregnancy, promoting greater access to contraception is also one of the best ways to reduce the incidence of abortion. While abortion is safer for a woman than pregnancy and childbirth, and is among the safest medical

⁹ The best intentions: unintended pregnancy and the well-being of children and families. 1995. Committee on Unintended Pregnancy, Institute of Medicine, National Academy of Sciences; Sarah S. Brown and Leon Eisenberg, editors, p. 59.

¹⁰ The best intentions: unintended pregnancy and the well-being of children and families. 1995. Committee on Unintended Pregnancy, Institute of Medicine, National Academy of Sciences; Sarah S. Brown and Leon Eisenberg, eds.

procedures, like any medical procedure it does carry medical risk; reducing the need for abortion furthers the health interests of women.

B. The IOM Panel's Recommendation for Addressing Unintended Pregnancy Fits into the Nation's Broader Prevention Agenda

As noted above, prevention of unintended pregnancy is firmly embedded in the goals of numerous healthcare professional organizations and national preventive health frameworks. Among the organizations recommending the use of family planning services as part of preventive care for women are: the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the American Academy of Pediatrics, the Society of Adolescent Medicine, the American Medical Association, the American Public Health Association, the Association of Women's Health, Obstetric and Neonatal Nurses, and the March of Dimes. In addition, the CDC recommends family-planning services as part of preventive visits for preconception health.

For the past 30 years, HHS has issued a set of health objectives for the nation to guide public health efforts at the start of each decade. Healthy People 2020, released in December of 2010, includes the following family planning goal: "Improve pregnancy planning and spacing, and prevent unintended pregnancy." Family planning is noted as one of the ten great public health achievements of the 20th century, allowing individuals to achieve desired birth spacing and family size, and contributing to improved health outcomes for infants, children, women, and families. Specific family planning objectives in Healthy People 2010 include:

- Increasing the proportion of pregnancies that are intended;
- Reducing the proportion of females experiencing pregnancy despite use of a reversible contraceptive method;
- Increasing the proportion of health insurance plans that cover contraceptive supplies and services; and
- Reducing the proportion of pregnancies conceived within 18 months of a previous birth.

The IOM's recommendation is perfectly aligned with these important objectives.

Similarly, the recently released *National Prevention Strategy* issued by the National Prevention, Health Promotion and Public Health Council created by the Affordable Care Act notes the following:

The National Prevention Strategy builds on the fact that lifelong health starts at birth and continues throughout all stages of life. Prevention begins with planning and having a healthy pregnancy, develops into good eating and fitness habits in childhood, is supported by preventive services at all stages of life, and promotes

the ability to remain active, independent, and involved in one's community as we age. 11

The *Strategy* outlines the priority of Reproductive and Sexual Health as follows:

Healthy reproductive and sexual practices can play a critical role in enabling people to remain healthy and actively contribute to their community. Planning and having a healthy pregnancy is vital to the health of women, infants, and families and is especially important in preventing teen pregnancy and childbearing, which will help raise educational attainment, increase employment opportunities, and enhance financial stability. Access to quality health services and support for safe practices can improve physical and emotional well-being and reduce teen and unintended pregnancies, HIV/AIDS, viral hepatitis, and other sexually transmitted infections (STIs). 12

Specific recommendations in the *Strategy* include the following:

- Increase use of preconception and prenatal care; and
- Support reproductive and sexual health services and support services for pregnant and parenting women.

Again, the IOM's contraception recommendations fit squarely within this agenda.

The elimination of cost sharing for contraception is not without precedent. Since 1972, Medicaid has required coverage for family planning in all state programs and has exempted those services and supplies from cost-sharing requirements. The National Business Group on Health has recommended that employer-sponsored health plans include coverage of family planning services, without cost sharing, as part of a minimum set of benefits for preventive care. Thus, the mandate recommended by the IOM is squarely grounded in existing policy and practice.

Despite this widespread consensus, gaps remain. As identified by the proponents of the Women's Health Amendment, the recommendations of the U.S. Preventive Services Task Force that list services currently mandated for coverage by the Affordable Care Act do not address prevention of unintended pregnancy. Further, the IOM Committee on Women's Health Research has identified unintended pregnancy as a health condition of women for which little progress in prevention has been made, despite the availability of safe and effective preventive methods. This report also found that progress in reducing the rate of unintended pregnancy would be possible by making contraceptives more available, accessible, and acceptable through improved services. ¹³

¹¹ National Prevention Council, *National Prevention Strategy*, Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General (2011), at 6.

¹³ Institute of Medicine, Women's Health Research: Progress, Pitfalls, and Promise, (2010), at 6, 278.

The IOM's women's-preventive-services recommendations on contraception fill a critical gap by requiring health insurers to cover all FDA-approved methods without cost sharing by the insured. This mandate represents a tremendous step forward in moving the reduction in unintended pregnancy from an aspirational to an attainable goal.

C. Coverage of the Full Range of FDA-Approved Contraceptive Methods Is Essential

The failure to use contraception, as well as the imperfect and inconsistent use of contraception, is a key contributor to unintended pregnancy. There are numerous methods of contraception available, allowing a woman to choose the method best suited to her health and lifestyle. Available means of contraception include barrier methods, hormonal methods, emergency contraception, and implanted devices; sterilization is also available for women and for men. Contraceptive choices vary markedly with age. For women younger than 30, the pill is the leading method. Among women aged 30 and older, more rely on sterilization.

For women with certain medical conditions or risk factors, some contraceptive methods are contraindicated. ACOG's practice bulletin provides that:

Decisions regarding contraception for women with coexisting medical problems may be complicated. In some cases, medications taken for certain chronic conditions may alter the effectiveness of hormonal contraception, and pregnancy in these cases may pose substantial risks to the mother as well as her fetus. In addition, differences in content and delivery methods of hormonal contraceptives may affect patients with certain conditions differently. Use of the contraceptive vaginal ring is associated with lower serum ethinyl estradiol levels than is the use of the patch or oral contraceptives, but it is unclear how this may affect risk for a particular condition. Practitioners should recognize that other nonhormonal forms of contraception, such as the copper intrauterine device (IUD), remain safe, effective choices for many women with medical conditions. ¹⁴

While some contraceptive methods are relatively inexpensive, others are costly and some must be administered by a healthcare professional. Elimination of cost-sharing requirements can increase use of contraception and help reduce unintended pregnancy by allowing women access to all available methods, as well as to information and counseling to help them use contraception effectively.

1. Access to Long-Acting, Reversible Contraceptive Methods is Essential to Women

The most common contraceptive methods used in the United States are the oral contraceptive pill and female sterilization. Greater use of long-acting, reversible contraceptive methods – including intrauterine devices and contraceptive implants that require less action by the woman and therefore have lower use failure rates – could help reduce unintended pregnancy rates. This further highlights the importance of the elimination of cost sharing, as long-acting, reversible

ACOG Practice Bulletin No. 73 (June 2006), available at http://pediatrics.uchicago.edu/chiefs/adolescent/documents/ContracepCoexistCondit.pdf.

contraceptive methods and sterilization have high up-front costs, and the research on the impact of cost sharing on the use of healthcare services shows that cost-sharing requirements, such as deductibles and copayments, can pose barriers to care and result in reduced use of preventive and primary care services, particularly for low-income populations. According to ACOG:

High unintended pregnancy rates in the United States may in part be the result of relatively low use of long-acting reversible contraceptive (LARC) methods, specifically the contraceptive implant and intrauterine devices. Top-tier reversible methods share the characteristic of requiring a single act of motivation for long-term use, eliminating adherence and user-dependence from the effectiveness equation. According to the World Health Organization's evidence-based Medical Eligibility Criteria for contraceptive use, LARC methods have few contraindications, and almost all women are eligible for implants and intrauterine devices. Because of these advantages and the potential to reduce unintended pregnancy rates, LARC methods should be offered as first-line contraceptive methods and encouraged as options for most women. To increase use of LARC methods, barriers such as lack of health care provider knowledge or skills, low patient awareness, *and high upfront costs* must be addressed. ¹⁵

2. Access to Emergency Contraception is Essential to Women

The inclusion of emergency contraception within the mandate will be critically important to the goal of reducing unintended pregnancy. Opponents of access to contraception often obscure the discussion with false statements about emergency contraception, asserting that its use is equivalent to an abortion. This is at odds with the scientific reality, as stated by ACOG:

Emergency contraception is sometimes confused with medical abortion. However, whereas medical abortion is used to terminate an existing pregnancy, emergency contraception is effective only before a pregnancy is established. Emergency contraception can prevent pregnancy during the 5 or more days between intercourse and implantation of a fertilized egg, but it is ineffective after implantation. Studies of high-dose oral contraceptives indicate that emergency contraception confers no increased risk to an established pregnancy or harm to a developing embryo. ¹⁶

In the United States, the FDA-approved dedicated emergency contraceptive pills are Plan B® (a two-pill regimen of levonorgestrel, a progestin-only formula), Plan B® One-Step (one pill of levonorgestrel), Preven™ and Next Choice® (a generic two-pill form of levonorgestrel). Other emergency contraceptive therapies include insertion of a copper intrauterine device (IUD) and regimens of multiple oral contraceptives (combination progestin and estrogen). Emergency contraception is more effective the sooner it is taken, and it can prevent pregnancy after unprotected or inadequately protected intercourse if used within 72 to 120 hours. Again, emergency contraception does not interfere with an established pregnancy, and, therefore, is not an abortifacient.

¹⁵ ACOG Committee Opinion No. 450 (December 2009) (emphasis added).

¹⁶ ACOG Practice Bulletin No. 112 (May 2010).

The use of emergency contraception can reduce the risk of an unwanted pregnancy by 75 percent or more if used correctly. The American Academy of Pediatrics Policy Statement on Emergency Contraception finds that use of emergency contraception could prevent half of all unintended pregnancies and abortions in the United States. Given the grave consequences of unintended pregnancy outlined above, it is essential that ideology and misinformation not be allowed to sway public health decision making.

D. Contraception is Widely Used and Widely Supported

Available data show conclusively that contraceptive use is not only widely accepted but widely practiced. A CDC analysis of data from the 1982, 1995, 2002, and 2006-2008 National Surveys of Family Growth revealed the following: 17

- More than 99% of women 15-44 years of age who have ever had sexual intercourse with a male (referred to as "sexually experienced women") have used at least one contraceptive method. The percentage of women who have ever used emergency contraception, the contraceptive patch, and the contraceptive ring increased between 2002 and 2006–2008;
- Virtually all sexually experienced women have used some method of contraception: 98% in 1995 and 2002, and 99% in 2006-2008. In 2006-2008, about 93% had ever had a partner use the male condom; 82% of women had used the oral contraceptive pill; and 59% had had a partner who used withdrawal. About 1 in 5 women had used the 3-month injectable or shot, Depo-ProveraTM (22%); and
- The leading current method of contraception in the United States in 2006-2008 was the oral contraceptive pill. At the time of the survey, the pill was *currently* being used by 10.7 million women aged 15-44 years. The second leading current method of contraception was female sterilization, used by 10.3 million women. The pill and female sterilization have been the two leading methods in the United States since 1982.

Religious leaders from numerous faiths and with disparate views on abortion recognize the critical importance of ensuring access to contraception. Following the IOM Committee's deliberations in 2010, Faith in Public Life issued a press release stating that:

Prominent national faith leaders on both sides of the abortion debate are joining their voices to call for affordable contraception to help women and families stay healthy and address a root cause of economic distress and abortion. ... [R]ecent polls found extremely high support for contraception among evangelical Protestants, who are overwhelmingly opposed to abortion. An April 2010 survey found nearly 90 percent of evangelicals leaders said they approved of artificial methods of contraception, and a 2009 poll conducted by the National Association of Evangelicals (NAE) in partnership with Gallup showed that 90 percent of

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¹⁷ CDC, NATIONAL SURVEY OF FAMILY GROWTH, VITAL AND HEALTH STATISTICS, USE OF CONTRACEPTION IN THE UNITED STATES 1982-2008 (Aug. 2010) *available at* http://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.

evangelicals find hormonal/barrier methods of contraception to be morally acceptable for adults. 18

Religious adherents not only support access to contraception, they use it. A 2011 CDC analysis of data from the 2006-2008 National Survey of Family Growth demonstrates that:

- Sexually active Catholic women older than 18 are just as likely (98%) to have used some form of contraception banned by the Vatican as women in the general population (99%). Among sexually active Hispanic Catholic women, 96% have used a contraceptive method banned by the Vatican;
- Even among those who attend church once a week or more, 83% of sexually active Catholic women use a form of contraception that is banned by the Vatican;
- 69% of Catholic women have used birth control pills and 88% have used condoms;
- The percentage of married Hispanic Catholic women who use a modern contraceptive method (90%) is the same as that of married non-Hispanic Catholic women (88%); and
- The percentage of sexually active Catholic women aged 15-44 who have ever used
 modern contraceptive methods is similar to that of women with other religious views or
 no religious views as well as the population as a whole. Fewer than 2% of sexually active
 Catholic women use Vatican-approved methods as their primary form of family
 planning.¹⁹

These data belie the notion that religious adherents will somehow have their religious beliefs compromised if their health plans offer contraception without cost sharing. To the contrary, it is clear that all women, regardless of their faith, have a need for these critical preventive services.

III. The No-Copay-Contraception Mandate Does Not Violate the Constitution, Nor Is a Religious Exemption Required

The interim final regulation requiring group health plans and health insurance issuers to cover all FDA-approved contraceptive methods and sterilization procedures without cost sharing (the "no-copay-contraception mandate") is not unconstitutional, nor does the Constitution require that HHS extend an exemption to religious employers. ²⁰ Comments suggesting otherwise –

¹⁸ Faith in Public Life, *Pro-Choice and Pro-Life Faith Leaders Call for Contraception Access, Stake Claim to Prevention as Common Ground*, Nov. 23, 2010, *available at* http://faithinpubliclife.org/content/press/2010/11/pro-choice and pro-life faith.html.

¹⁹ CDC, NATIONAL SURVEY OF FAMILY GROWTH, NATIONAL HEALTH STATISTICS REPORT, SEXUAL BEHAVIOR, SEXUAL ATTRACTION, AND SEXUAL IDENTITY IN THE UNITED STATES: DATA FROM THE 2006–2008 NATIONAL SURVEY OF FAMILY GROWTH (Mar. 3, 2011) available at http://www.cdc.gov/nchs/data/nhsr/nhsr036.pdf.
²⁰ We note that the HHS's justification for the proposed religious exemption is *not* grounded in either the Constitution or RFRA. Instead, HHS proposed the religious exemption as an attempted "accommodation" of the "religious beliefs of certain religious employers." 76 Fed. Reg. at 46623. We agree with HHS's determination that nothing in the Constitution or federal law compels an exemption from the no-copay-contraception requirement.

notably, those submitted by the United States Conference of Catholic Bishops²¹ (the "Bishops") – are based upon a flawed understanding of both First Amendment and RFRA jurisprudence.

A. The Constitution Permits Neutral, Generally Applicable Laws that May Burden Religious Exercise

The Supreme Court has made it clear that neutral, generally applicable laws do not violate the Free Exercise Clause of the First Amendment, even if they burden the exercise of religion. In *Employment Division, Department of Human Resources of Oregon v. Smith*, the Supreme Court rejected a challenge to a statute that denied unemployment benefits to drug users, including Native Americans who consumed sacramental peyote. Writing for the Court, Justice Scalia explained that under the Constitution, a neutral law of general applicability that happens to burden one's religious practice does not violate the Free Exercise Clause of the First Amendment: "[t]he government's ability...to carry out...aspects of public policy, 'cannot depend on measuring the effects of a governmental action on a religious objector's spiritual development." The alternative, according to the Court, was to permit every religious objector to "become a law unto himself" a result which "contradicts both constitutional tradition and common sense."

The *Employment Division* decision demonstrates that the Constitution permits the enactment of neutral laws that burden religion; it also makes it clear that no exemption or opt-out provision is required. As Justice Scalia wrote, the fact that a religious exemption "is permitted, or even that it is desirable, is not to say that it is constitutionally required..." In other words, with respect to the Constitution, the question is not whether a religious exemption is required; it is whether a religious exemption is sensible. For the reasons set forth in this comment, a religious exemption to the no-copay-contraception mandate is not "desirable."

B. The No-Copay-Contraception Mandate is Neutral and Therefore Constitutional

After *Employment Division*, the only laws that remain constitutionally suspect are those based on anti-religious animus. According to the Court, laws targeting "acts or abstentions *only* when they are engaged in for religious reasons, or *only* because of the religious belief that they display" would be presumptively unconstitutional.²⁹ Short of such animus, however, "neutral law[s] of general applicability"³⁰ are consonant with the First Amendment, regardless of the fact that they might burden individuals' religious exercise.

²¹ Comments of the U.S. Conference of Catholic Bishops, Interim Final Rules on Preventive Services (CMS-9992-IFC2) (submitted Aug. 31, 2011) ("Bishops' Comments").

²² 494 U.S. 872 (1990) (abrogated by statute).

²³ As examined below, Congress subsequently created a *statutory* – not constitutional – obligation for government to justify any substantial burden on religious exercise by demonstrating a compelling state interest. *See* Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq*.

²⁴ 494 U.S. at 885 (citation omitted).

²⁵ *Id.* at 885 (citation omitted).

²⁶ *Id.* at 885.

²⁷ *Id.* at 890.

²⁸ *Id.* at 890.

²⁹ Employment Division, 494 U.S. 872, at 877 (emphasis added).

³⁰ *Id.* at 879.

The no-copay-contraception mandate is a neutral rule that is part of a comprehensive effort to ensure that important preventive services for women are available and affordable. The critical role that contraception plays in preventing unintended pregnancy and promoting healthy birth spacing was articulated in the Institute of Medicine's comprehensive report, Clinical Preventive Services for Women: Closing the Gaps. And as the IOM report noted, "[n]umerous health care professional associations...recommend the use of family planning services as part of preventive care for women," as described above.

Nonetheless, comments submitted by the United States Conference of Catholic Bishops allege that the IOM's recommendation is nothing more than a "'religious gerrymander' that targets Catholicism for special disfavor *sub silentio*." This wholly unsupported allegation is absurd on its face, and the HHS should dismiss it out-of-hand. There is not a shred of evidence to suggest that the Institute of Medicine's recommendations were based on anti-Catholic or antireligious animus. This unsupported and unsupportable claim is an insult to the countless doctors, researchers, and public-health experts who contributed to the IOM's conclusions and the rigorous scholarship upon which they rest.

To bolster its outlandish claim, the Bishops' comment compares the no-copay-contraception mandate to a statute outlawing animal sacrifice, the subject of the Supreme Court's decision in Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah. ³¹ In that case, the City of Hialeah promulgated a thinly veiled ordinance designed to prohibit members of the Santeria religion from practicing the ritual slaughter of animals. The ordinance was preceded by various animusdriven resolutions, such as one condemning "any and all religious groups which are inconsistent with public morals, peace or safety;" another resolution noted "great concern regarding the possibility of public ritualistic animal sacrifices."³² In light of these resolutions targeting Santeria religious rituals, and a number of other facts, the Court had no trouble determining that "suppression of the central element of the Santeria worship service was the object of the ordinances," and on that basis held that the ordinance was unconstitutional under the Free Exercise Clause.

In contrast, the Bishops provide no proof whatsoever that the IOM panel was motivated by an anti-Catholic or anti-religious bias. Instead, the Bishops claim that the no-copay-contraception mandate "implicitly" targets Catholicism "by imposing burdens on conscience that are well known to fall almost entirely on observant Catholics." But *Employment Division* and *Church of* the Lukumi stand for the proposition that a party seeking to challenge a government action that burdens religious exercise must demonstrate that the law is not neutral. Merely saying that it is not neutral is not sufficient. And unlike in the case of the ordinance in Church of the Lukumi that plainly targeted Santeria practitioners, there is no evidence that the IOM intended to discriminate against Catholics, nor is there a history of actions by the IOM or HHS that demonstrate antireligious or anti-Catholic animus.

 ³¹ 508 U.S. 520 (1993).
 ³² Id. at 526, 527.
 ³³ Comments of the United States Conference of Catholic Bishops, Interim Final Rules on Preventive Services, CMS-9992-IFC2, Aug. 31, 2011, at 8.

Indeed, IOM took testimony from all members of the public wishing to present it, including representatives of religious organizations, who testified both in support of, and in opposition to, a mandate for contraception. HHS, in adopting the IOM's recommendations, has provided an unprompted (and, we believe, unnecessary) exemption from the mandate's requirements for religious employers, and solicited further comment on the rulemaking, thus inviting submissions regarding the views of religious institutions. Moreover, the legislative history on the WHA is replete with information regarding the financial challenges women face in accessing preventive health services. Nothing in the record suggests even the slightest animus towards religious institutions. In sum, every decision maker, at every stage of the process, has acted with nothing less than civility and solicitude to produce an open and accountable process for decisions. Instead of targeting religious institutions, the IOM and HHS have consistently engaged religious institutions and sought out their views.

In addition, we note that this rule also would fail to affect Catholics in a manner that is any different than the manner in which it affects the general population, underscoring the lack of animus towards religious practice or believers. Like everyone else, those religious adherents who decline to benefit from no-copay contraceptive coverage need not use it. Yet for the 98 percent of Catholic women who use contraception at essentially the same rate as the general population, the benefit will serve their interests as it does those of everyone. Because it will actually provide a benefit to, rather than harm, an overwhelming majority of Catholics, the Bishops' argument that the law demonstrates an anti-Catholic animus must fail.

IV. The No-Copay-Contraception Mandate Does Not Violate the Religious Freedom Restoration Act, Nor is a Religious Exemption Required

The Supreme Court has not vacillated on its understanding of the Free Exercise Clause, and it is clear that under the Constitution, the no-copay-contraception mandate is a permissible exercise of governmental authority. For its part, Congress responded to the *Employment Division* decision by enacting the Religious Freedom Restoration Act (42 U.S.C. § 2000bb-1 *et seq.*) ("RFRA"). RFRA explicitly reinstated the compelling-interest test for laws that burden religious exercise – the same test rejected in *Employment Division*. Junder RFRA, where the federal government seeks to "substantially burden" a person's exercise of religion, it must demonstrate that the application of the burden to the person—

- (1) is in furtherance of a compelling governmental interest; and
- (2) is the least restrictive means of furthering that compelling governmental interest.³⁷ RFRA applies to all federal law and the implementation of that law, unless the law "explicitly excludes such application."³⁸

³⁴ CENTERS FOR DISEASE CONTROL, NATIONAL SURVEY OF FAMILY GROWTH, NATIONAL HEALTH STATISTICS REPORT, SEXUAL BEHAVIOR, SEXUAL ATTRACTION, AND SEXUAL IDENTITY IN THE UNITED STATES: DATA FROM THE 2006–2008 (Mar. 3, 2011) *available at* http://www.cdc.gov/nchs/data/nhsr/nhsr036.pdf. ³⁵ 42 U.S.C. § 2000bb(b)(1).

³⁶ RFRA was originally applicable to the States as well as the federal government. However, in *City of Boerne v. Flores*, 521 U.S. 507 (1997), the Supreme Court held that Congress lacked the statutory authority to apply RFRA to the States. It remains applicable to the federal government.

³⁷ 42 U.S.C. § 2000bb-1(b).

The no-copay-contraception mandate – even without a religious exemption – does not violate RFRA. First, the burden upon religious exercise is not "substantial," as required by the statute. And second, even if the burden were substantial, the government has sufficiently demonstrated a compelling interest in ensuring access to no-copay contraception, and has shown that a nocopay-contraception mandate is the least restrictive means of accomplishing that compelling goal.

- A. The Religious Freedom Restoration Act's Compelling-Interest Test is Inapplicable Because the No-Copay-Contraception Mandate Does Not "Substantially Burden" the "Exercise" of Religion
 - 1. Providing Preventive Health Services Without Cost Sharing Has Nothing to Do With the "Exercise" of Religion

RFRA's compelling-state-interest test only applies where the underlying government action places a substantial burden upon a person's "exercise" of religion. RFRA's "definition" of the term, "exercise of religion," is entirely unhelpful; it defines the "exercise of religion" as "any exercise of religion, whether or not compelled by, or central to, a system of religious belief."³⁹ The Supreme Court, however, has held that the "exercise of religion" "often involves not only belief and profession but the performance of...physical acts [such as] assembling with others for a worship service [or] participating in sacramental use of bread and wine..."⁴⁰

The Bishops make no claim that unprotected sexual activity is central to, or even a part of, their worship or religious practice. In fact, health needs addressed by the mandate have no relation to any recognized religious practice, and therefore the Bishops' statements of their disapproval of contraception constitutes part of their religious beliefs, rather than an exercise of religion.

The Bishops are also unable to point to any case in which the refusal to provide insurance coverage – even on religious grounds – was considered to be a religious exercise, and, as described below, several State supreme courts have upheld similar contraceptive-coverage requirements over objections by religious organizations on similar grounds.⁴¹

The belief/exercise distinction is of paramount importance to the courts. And, indeed, virtually all cases upholding RFRA-based challenges have focused on the practice of religious worship, rather than abstract beliefs. The Supreme Court, for example, in Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal, 42 upheld a RFRA-based challenge to the Controlled Substances Act, which prohibited members of a religious sect from imbibing *hoasca*, an

³⁹ 42 U.S.C. § 2000cc-5(7). RFRA's definition of "exercise of religion" is the same as "religious exercise" in the Protection of Religious Exercise in Land Use and by Institutionalized Persons Act (RLUIPA), 42 U.S.C. § 2000cc et seq. ⁴⁰ Cutter v. Wilkinson, 544 U.S. 709 (2005) (quoting Employment Division, 494 U.S. at 877) (emphasis added).

³⁸ 42 U.S.C. § 2000bb-3(b).

⁴¹ Catholic Charities of the Diocese of Albany v. Serio, 859 N.E.2d 459 (N.Y. 2006); Catholic Charities of *Sacramento, Inc. v. Superior Court*, 85 P.3d 67 (Cal. 2004). 42 546 U.S. 418 (2006).

hallucinogenic tea – a "central" part of the sect's communion ritual. The lower courts have similarly focused on religious rituals when determining whether a practice constitutes a "religious exercise." 43

What the Bishops seek is to deny access to needed health services in an effort to coerce employees into kowtowing to church dogma. While religious employers may urge and cajole others to obey religious proscriptions on sexual activity, they may not withhold needed health services from their employees to enforce their will. The very notion that the Bishops would hold their employees' health hostage flies in the face of the very definition of sexual health used by the Centers for Disease Control and the World Health Organization:

Sexual health is a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, *free of coercion*, discrimination and violence.⁴⁴

Moreover, it is clear that the mere availability of a benefit does no violence to their beliefs. Should the Bishops' arguments related to the undesirability of using contraception be accepted, those who accept them will not use the benefit. But those 98 percent of Catholics who use contraception should be entitled to make that choice for themselves, as a matter of their own beliefs and health.

For this reason, it is critical that HHS not permit an exemption that would allow the Bishops or others to deny coverage for needed health services in an attempt to coerce behavior utterly unrelated to religious practice.

2. Even if the No-Copay-Contraception Mandate Imposes a Burden on Religious Exercise, that Burden is Not "Substantial"

RFRA imposes no restrictions whatsoever on government actions that burden religious exercise. Rather, it subjects government action to a "compelling interest" test *only* if the burden upon religious exercise is "substantial." Even assuming, *arguendo*, that the no-copay-contraception mandate did burden "religious exercise," the burden would be *de minimus*, or at most insubstantial.

Religious employers (as well as non-religious ones) already cover health services to which they may, in principle, object. For example, existing Catholic employers' health insurance plans may cover maternity care for unwed mothers or HIV tests without regard to sexual orientation;

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⁴³ See, e.g., Van Wyhe v. Reisch, 581 F.3d 639 (8th Cir. 2009) (inmate deprived of the use of sukkah, a mandatory part of the Jewish "Sukkot" festival made a threshold showing of a burden upon "religious exercise"); Rouser v. White, 630 F. Supp. 2d 1165 (E.D. Cal. 2009) (prison's failure to hire a chaplain to attend to Wiccans' religious needs constituted a burden upon the exercise of religion); Henderson v. Ayers, 476 F. Supp. 2d 1168 (C.D. Cal. 2007) (inmate prohibited from attending Friday Islamic prayer services stated a claim that his exercise of religion had been burdened).

⁴⁴ Centers for Disease Control, *Sexual Health*, *available at* http://www.cdc.gov/sexualhealth (emphasis added). ⁴⁵ RFRA, 42 U.S.C. § 2000bb-1.

existing Latter Day Saints employers' insurance may cover emergency services for injuries that happen to have been caused by reckless, alcohol-fueled behavior.

In their comments, the Bishops attempt to bolster their claim that the religious-exercise burden is "substantial" by claiming that the no-copay-contraception mandate interferes with church governance; that it compels speech; and that it compels unwanted association. Each of these three claims rings hollow.

a. The No-Copay-Contraception Mandate Does Not Interfere With Church Governance

The no-copay-contraception mandate does not interfere with church governance. The Bishops, in their comments, quote the Supreme Court's decision in *Kedroff v. St. Nicholas* Cathedral for the proposition that churches can "decide for themselves, free from state interference, matters of church government as well as those of faith and doctrine."46 As a preliminary matter, Kedroff concerned an intra-church dispute within the Russian Orthodox Church between those deferring to the head of the American branch and the Moscow-based church hierarchy. The dictum cited by the Bishops stands for the proposition that government should not weigh in on intra-church disputes, and is wholly irrelevant to the instant matter: promulgation of a neutral, generally applicable policy that affects all employers – whether secular or religious – equally.

Moreover, the Bishops only selectively quote the *Kedroff* decision. The very next sentence following the quotation above makes it even more obvious that the Court's admonition that government not interfere with church governance was strictly limited to *internal* church policies: "Freedom to select the clergy, where no improper methods of choice are proven, we think, must now be said to have federal constitutional protection as a part of the free exercise of religion against state interference." Indeed, the notion that government should not interfere in the inner workings of religious institutions is obvious and non-controversial. Thus, for example, courts presumptively avoid wading into religiously motivated hiring decisions: "it would surely be unconstitutional under the First Amendment to order the Catholic Church to reinstate, for example, a priest whose employment the Church had terminated on account of his excommunication based on a violation of core Catholic doctrine."⁴⁷

Here, however, HHS has articulated a neutral and generally applicable policy that requires all employers, including all religiously affiliated employers, to offer insurance coverage for certain preventive services, including contraception. There is no governmental intrusion upon the internal doctrinal workings of the church. The government is not mandating that women be ordained as priests. It is not determining the proper relationship between cardinals and bishops. In short, the no-copay-contraception mandate has nothing to do with church governance.

 ⁴⁶ 344 U.S. 94, 116 (1952).
 ⁴⁷ Rweyemamu v. Cote, 520 F.3d 198, 205 (2d Cir. 2008).

b. The No-Copay-Contraception Mandate Does Not Compel Speech

The Bishops also contend that the no-copay-contraception mandate compels speech. The gist of this claim is that by requiring religious employers to cover contraception without cost sharing, the religious employers are being forced to communicate a pro-contraception message in violation of their beliefs. This argument is not credible, because nothing in the no-copay-contraception mandate requires the Catholic Church – or any religious institution – to articulate its support for the government policy. It must simply obey the law and provide the coverage. At the same time, religious institutions are free to speak out against contraception; priests may inveigh against birth control in sermons; churches may publish anti-contraception broadsides. They may even indicate to one and all that the extension of coverage for contraception is not the organization's choice, but the result of a government requirement.

The limited instances where the courts have found unconstitutional compelled speech are cases in which the speaker was forced to make a particular statement of belief. For example, the Supreme Court struck down as unconstitutional a law requiring motorists to display the motto, "Live Free or Die," on license plates. Esimilarly, the state may not compel students to salute the flag or recite the Pledge of Allegiance. But as the California Supreme Court held, "Catholic [organizations'] compliance with a law regulating health care benefits is not speech." Indeed, the very idea that mere compliance with a law is compelled speech is absurd on its face. Thus, for example, a court dismissed as "ludicrous" a motorcyclist's claim that a compulsory-helmet law compelled speech in support of the law.

c. The No-Copay-Contraception Mandate Does Not Force Believers to Associate

The no-copay-contraception mandate does not violate religious organizations' freedom of association. The Bishops claim that including no-cost-sharing contraceptive coverage violates their "freedom of expressive association." For support, they cite two cases in which groups were permitted to exclude *individuals* from their midst: a gay scoutmaster in the case of the Boy Scouts, ⁵² and a gay and lesbian group in the case of the St. Patrick's Day parade. ⁵³ The Bishops try to analogize paying for an insurance benefit they disapprove of to being forced to include an unwanted individual in a group.

Here, there is no unwanted association whatsoever. The law is not forcing the Bishops to allow atheists to become members, or to allow women to become ordained priests. Instead, the no-copay-contraception mandate merely requires religious employers to offer coverage to all employees already part of the organization or hired in the normal course of business. Because there is no forced association, the Bishops' claim must be rejected. ⁵⁴

⁴⁹ Board of Educ. v. Barnette, 319 U.S. 624 (1943).

⁵³ Hurley v. Irish-American Gay, Lesbian & Bisexual Group, 515 U.S. 557 (1995).

⁴⁸ Wooley v. Maynard, 430 U.S. 705 (1977).

⁵⁰ Catholic Charities of Sacramento, Inc. v. Superior Court, 85 P.3d 67 (Cal. 2004).

⁵¹ Buhl v. Hannigan, 16 Cal. App. 4th 1612, 1226 n. 11 (1993).

⁵² Boy Scouts of Am. v. Dale, 530 U.S. 640 (2000).

⁵⁴ In addition, the Bishops' comments conveniently ignore the Supreme Court's most recent case about religion and expressive association – *Christian Legal Society Chapter of the University of California, Hastings College of the*

B. The No-Copay-Contraception Mandate Furthers a Compelling Governmental Interest and Is the Least Restrictive Means of Furthering that Compelling Interest

Under RFRA, the government is permitted to substantially burden a person's exercise of religion if: (1) it is in furtherance of a compelling governmental interest; and (2) if the burden being challenged is the least restrictive means of furthering that compelling governmental interest. 55 Even if the no-copay-contraception mandate substantially burdened religious exercise - which it does not - it would still be a permissible governmental exercise of power under RFRA.

1. The No-Copay-Contraception Mandate Furthers a Compelling Governmental Interest

The no-copay-contraception mandate is permissible under RFRA because it furthers a compelling governmental interest in women's health; in children's health; in women's equality; in women's autonomy; and in the health and wellbeing of third parties. In other words, religious employers seek a religious exemption that would adversely affect a host of other actors – women, children, and the families of those employed by religious organizations. The Bishops thus seek a religious exemption from a neutral law at the expense of third parties. But as the court observed in the California decision upholding a similar contraceptive-coverage mandate, "[w]e are unaware of any decision in which...the United States Supreme Court...has exempted a religious objector from the operation of a neutral, generally applicable law despite the recognition that the requested exemption would detrimentally affect the rights of third parties."56

a. The No-Copay-Contraception Mandate Furthers the Government's **Compelling Interest in Women's Health**

It ought to be axiomatic to state that the government has a compelling interest in the health of its people, including women. For example, in *Planned Parenthood v. Casey*, the Supreme Court held that while the state has an interest in protecting post-viability fetal life, even that interest must give way to the more compelling interest in protecting a woman's health.⁵⁷ Similarly, the Court struck down a law prohibiting so-called "partial birth abortions" as unconstitutional precisely because of the lack of "any exception for the preservation of the...health of the mother.5,,58

Law v. Martinez, 130 S.Ct. 2971 (2010). In that case, the Court held that a religious law-school club can be required to admit all-comers pursuant to a neutral, non-discrimination policy. There is no expressive association at stake with regard to the no-copay-contraception mandate; if there were, it would be pursuant to a neutral, generally applicable policy (all employers must offer no-copay contraception), and thus be governed by Martinez rather than Dale or *Hurley*, neither of which involved the application of a neutral, non-discriminatory policy. ⁵⁵ RFRA, 42 U.S.C. § 2000bb-1(b)(1)-(2).

⁵⁶ Catholic Charities of Sacramento v. Superior Court, 85 P.3d 67, 93 (2004).

⁵⁷ 505 U.S. 833, 846 (1992) (plurality opinion).

⁵⁸ Stenberg v. Carhart, 530 U.S. 914, 930 (citation omitted). While the Supreme Court subsequently upheld a federal prohibition on so-called "partial birth abortions," it do so on the basis of congressional findings – to which the Court deferred – that the procedure was "never medically necessary" to protect a woman's health. Gonzales v. Carhart, 550 U.S. 124, 141 (2007).

These cases, and others, "unequivocally express the Supreme Court's view as to the state's compelling interest in preserving women's health." And the fact that the Bishops and other religious objectors seek special treatment at the expense of women only strengthens the government's interest. The California Supreme Court, for example, in reviewing claims regarding a similar law held, "[s]trongly enhancing the state's interest is the circumstance that any exemption from the [contraceptive-coverage mandate] sacrifices the affected women's interest in receiving equitable treatment with respect to health benefits." 60

As discussed at length above, the IOM panel fully explained why access to a full range of FDA-approved contraceptives is essential for women's health. In particular, women without access to safe and affordable contraceptives are more likely to experience unintended pregnancies, leading to a host of health-related complications. Reducing the numbers of pregnant women who suffer from health complications is a critically important state interest: the "United States Supreme Court has recognized that the state has a compelling interest in preserving the health of expectant mothers." 61

b. The No-Copay-Contraception Mandate Furthers the Government's Compelling Interest in Improving Children's Health

In addition, the IOM panel catalogued the numerous health problems that affect the development of children that result from unintended or improperly spaced pregnancies when those pregnancies are taken to term. Such children can experience low birth weight and developmental difficulties. It is obvious that the state has a compelling interest in ensuring the health of the nation's children, as the Supreme Court has stated directly: "[s]afeguarding the physical and psychological well-being of a minor...is a compelling [interest]." 62

c. The No-Copay-Contraception Mandate Furthers the Government's Compelling Interest in Combating Sex-Based Inequality

While promoting women's health was a primary motivation behind the no-copay-contraception mandate, it was also designed to help eliminate sex-based inequalities in the healthcare system – namely, the fact that women significantly outspend men on healthcare-related services, in significant part due to costs associated with contraception and unintended pregnancies. And Congress has recognized that discrimination against women based on "pregnancy, child-birth, or related medical conditions" constitutes discrimination on the basis of sex. 63

Not surprisingly, the Women's Health Amendment, which added no-copay coverage of preventive services for women, was motivated by a desire to eliminate sex-based inequalities in

⁵⁹ Simat Corp. v. Arizona Health Care Cost Containment Sys., 56 P.3d 28, 35 (Ariz. 2002).

⁶⁰ Catholic Charities of Sacramento, 85 P.3d at 93.

⁶¹ Simat, 56 P.3d at 33-34.

⁶² Globe Newspaper Co. v. Superior Court for Norfolk Cty., 457 U.S. 596, 607 (1982), quoted in PJ ex rel. Jensen v. Wagner, 603 F.3d 1182, 1198 (10th Cir. 2010) (holding that "states have a compelling interest in and a solemn duty to protect the lives and health of the children within their borders.").

⁶³ Pregnancy Discrimination Act, 42 U.S.C. § 2000e(k).

healthcare spending. Senator Barbara Mikulski, the driving force behind the Women's Health Amendment, emphasized that "[w]omen of childbearing age incur 68 percent more out of pocket health care costs than men," and stated that "We [women] face gender discrimination." 64

Consequently, the elimination of sex-based discrepancies is a compelling state interest. For example, in Catholic Charities of Sacramento v. Superior Court, the California Supreme Court held that a contraceptive-coverage statute "serves the compelling state interest of eliminating gender discrimination."65 The discrimination the court referred to was the same fact pointed to by Senator Mikulski: "women during their reproductive years spent as much as 68 percent more than men in out-of-pocket health care costs, due in part to the cost of prescription contraceptives and the various costs of unintended pregnancies, including health risks, premature deliveries and increased neonatal care."66 The no-copay-contraception mandate was thus designed to address the state's compelling interest in eliminating the discriminatory impact of sex-based healthcarespending inequalities.

d. The Government Has a Compelling Interest in Promoting Women's **Autonomy**

Access to affordable contraception is essential – unlike almost any other health service – in ensuring individuals' independence and autonomy. The Supreme Court has long held, for example, that laws prohibiting the use of contraceptives are an unconstitutional violation of the right to privacy. ⁶⁷ In so doing, the Court held that, "[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child "68

Because, by virtue of biology, only women can become pregnant, the importance of contraceptive access to women is particularly compelling. As Justice O'Connor explained, "[t]he 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." Other courts have similarly noted the important role contraception plays in assuring women's equal participation as citizens: "the adverse economic and social consequences of unintended pregnancies fall most harshly on women and interfere with their choice to participate fully and equally in the 'marketplace and the world of ideas."⁷⁰ Consequently, the law recognizes women's special need for access to contraception: "the law is no longer blind to the fact that only women can get pregnant, bear children, or use prescription contraception. The special or increased healthcare needs associated

⁶⁴ Senator Barbara Mikulski, Press Release: Mikulski Puts Women First in Health Care Debate (Nov. 30, 2009), available at http://mikulski.senate.gov/media/pressrelease/11-30-2009-2.cfm.

⁶⁵ See Catholic Charities of Sacramento v. Superior Court, 85 P.3d 67, 92 (Cal. 2004). 66 Id. at 92.

⁶⁷ See, e.g., Griswold v. Connecticut, 381 U.S. 479 (1965) (law prohibiting the use of contraceptives violates married couple's right to privacy); Eisenstadt v. Baird, 405 U.S. 438 (1972) (law prohibiting the distribution of contraceptives to unmarried people violates the right to privacy).

⁶⁸ Eisenstadt, 405 U.S. at 453.

⁶⁹ Planned Parenthood of Southeastern Pennsylvania v. Casev, 505 U.S. 833, 856 (1992).

⁷⁰ Erickson v. Bartell Drug Co., 141 F.Supp.2d 1266, 1273 (W.D. Wash. 2001).

with a woman's unique sex-based characteristics must be met to the same extent, and on the same terms, as other healthcare needs."⁷¹

Under RFRA, the government must demonstrate a compelling interest to justify a substantial burden of religious exercise. But with respect to contraception, that burden is effectively neutralized, because the government would be required to simultaneously demonstrate a compelling interest in limiting access to contraception. The Supreme Court has held that "[r]egulations imposing a burden on a decision as fundamental as whether to bear or beget a child may be justified only by compelling state interests, and must be narrowly drawn to express only those interests."72

As part of any consideration of broadening the exemption, the government must also weigh the resulting incursion on women's fundamental reproductive rights. Because "the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood," and preserves the autonomy of decision making concerning the "private realm of family life which the state cannot enter, "73 these interests are also acute. Only a rule preserving freedom of a choice of contraceptive and the accompanying insurance coverage fully respects the rights to privacy and decisional autonomy at the heart of this constitutional sphere.

Indeed, we have amply demonstrated that the choice of health-plan coverage is ancillary to any reasonable definition of religious exercise, whereas access to contraception is a constitutionally protected right. The government cannot and should not allow third parties to interpose themselves and thereby interfere with employees' access to affordable contraception.

e. The No-Copay-Contraception Mandate Furthers the Government's **Compelling Interest in Protecting the Interests of Third Parties**

The no-copay-contraception mandate, in addition to promoting women's and children's health and women's equality, also protects others. Pregnancy is a unique condition because it impacts other people – spouses and domestic partners, other children, and extended families. An unintended pregnancy affects the woman, her partner, and often her family in a qualitatively different way than other kinds of medical conditions. Consequently, any determination of the relevant state interest in the no-copay-contraception mandate must take into account not only the interests of women and children, but also of the women's partners and families.

2. The No-Copay-Contraception Mandate is the Least Restrictive Means of **Furthering the Government's Compelling Interest**

Not only does the no-copay-contraception mandate serve a compelling government interest; it is also the least restrictive means of furthering that interest. The system of ensuring coverage for preventive services for women is an essential part of the Affordable Care Act. As Senator

⁷² Carey v. Population Services Int'l, 431 U.S. 678, 686 (1977). See also Casey, 505 U.S. at 851 ("Our law affords") constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education"), *quoting Carey*, 431 U.S. at 685.

73 Casey, 505 U.S. at 852 (*quoting Prince v. Massachusetts*, 321 U.S. 158 (1944)).

Mikulski noted, "[a]ccess to preventive health care is essential for improving the health of our nation and bringing our health care costs back under control."⁷⁴ This "essential" element of the Affordable Care Act cannot function if every religious objector is permitted to opt out of parts of the system: "[i]nsurance would basically become unworkable if everyone got a veto over what services any other member of the insurance pool could use."⁷⁵

In *United States v. Lee*, the Supreme Court denied a religious exemption to the social-security system, reasoning that "it would be difficult to accommodate the comprehensive social security system with myriad exceptions flying from a wide variety of religious beliefs." Its holding recognized that any complex and all-encompassing system cannot function if every individual is permitted to opt out based on a religious qualm: "The tax system could not function if denominations were allowed to challenge the tax system because tax payments were spent in a matter that violates their religious belief." The "broad public interest" in maintaining a cohesive system "is of such a high order," the Court stated, that "religious belief in conflict…affords no basis for resist[ance]." The Supreme Court has similarly held that religious foundations are not entitled to an exemption from the system of labor standards and must comply with minimum wage, overtime, and employment-related recordkeeping requirements.

More recently, and in the context of RFRA, the Supreme Court in *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal* held that "the Government can demonstrate a compelling interest in *uniform application* of a particular program by offering evidence that granting the requested religious accommodations would seriously compromise its ability to administer the program." While in *O Centro Espirita* the Court permitted a religious exception to the Controlled Substances Act to allow a religious sect to use a hallucinogenic tea, the facts there were utterly different from those present here. For example, in *O Centro Espirita*, the government conceded that it did not have a compelling interest in enforcing the law, and the health impact at stake from permitting the very limited use of the tea was "in equipoise." In contrast, with respect to the no-copay-contraception mandate, the government has a compelling interest and the health impact of permitting employers to opt out of providing contraceptive coverage without a copay for women is great.

Other courts have similarly recognized in the context of RFRA that comprehensive systems admitting no exemptions are the least restrictive means of furthering compelling governmental objectives. For example, in *Jenkins v. Commissioner of Internal Revenue*, 82 the Second Circuit

⁷⁴ Sen. Barbara Mikulski, Press Release: *Mikulski, Senate Colleagues Urge Secretary Sebelius to Swiftly Adopt IOM's New Recommendations on Women's Preventive Health* (July 22, 2011), *available at* http://mikulski.senate.gov/media/pressrelease/7-22-2011-6.cfm.

⁷⁵ Adam Sonfield, Senior Public Policy Associate, Guttmacher Institute, *quoted in* Lucia Rafanelli, *Inaccurate Conceptions*, AMERICAN SPECTATOR: THE SPECTACLE BLOG (Sept. 26, 2011), *available at* http://spectator.org/blog/2011/09/26/inaccurate-conceptions.

⁷⁶ 455 U.S. 252, 259-60 (1982).

⁷⁷ *Id.* at 260.

⁷⁸ Id. at 260

⁷⁹ Tony and Susan Alamo Foundation v. Secretary of Labor, 471 U.S. 290 (1985).

⁸⁰ 546 U.S. 418, 435 (2006)

⁸¹ *Id.* at 426.

^{82 483} F.3d 90 (2d Cir. 2007).

Court of Appeals noted that "It is...well settled that RFRA does not afford a right to avoid payment of taxes for religious reasons" and consequently rejected the claim of a taxpayer challenging on religious grounds the collection of a portion of his taxes to be used for military spending. 83 Other courts have denied RFRA-based claims seeking exemptions to the Bald and Golden Eagle Protection Act, 84 the Endangered Species Act, 85 and the Controlled Substances Act. 86 Certainly the government's ability to enforce a comprehensive system to protect women's health is at least as important as one to prevent the trade in eagle feathers.⁸⁷

International Human Rights Law Requires Governments to Ensure Access to V. Affordable Contraception and to Prevent Third Parties – Such as Employers – from **Interfering With that Access**

A. International Human Rights Law Requires States to Ensure Access to Affordable Contraception

Binding international human rights law recognizes women's fundamental right to access to contraception. For example, Article 3 of the International Covenant on Civil and Political Rights – to which the United States is a state party – requires states to "ensure the equal right of men and women to the enjoyment of all civil and political rights set forth in the...Covenant." The Human Rights Committee, the treaty-monitoring body charged with authoritatively interpreting the Convention, has specifically cited the "high cost of contraception" as a potential treaty violation. 88 And only last year, the Human Rights Committee instructed a state party to "strengthen measures aimed at the prevention of unwanted pregnancies, by inter alia making a comprehensive range of contraceptives widely available at an affordable price and including them on the list of subsidized medicines."89

Other human rights instruments, all of which the United States has signed, similarly require affordable access to contraception. For example, the Convention on the Elimination of All Forms of Discrimination Against Women includes article 12, which requires states to "eliminate discrimination against women in the field of health care in order to ensure...access to health care services, *including those related to family planning*."90 The Committee on the Elimination of All Forms of Discrimination Against Women, the treaty-monitoring body tasked with interpreting the Convention, has held that article 12 obligates states to "take measures to increase

88 Concluding Observations of the Human Rights Committee: Poland, U.N. Doc. CCPR/CO/82/POL (2004), at

⁸⁹ Concluding Observations of the Human Rights Committee: Poland, U.N. Doc. CCPR/C/POL/CO/6 (2010), at

⁸³ Id. at 92. See also Browne v. United States, 176 F.3d 25 (2d Cir. 1999) (RFRA does not prohibit the collection of revenue that will be used for purposes religious adherents find objectionable).

84 United States v. Vasquez-Ramos, 531 F.3d 987 (9th Cir. 2008) (denying RFRA claim where defendant sought a

religious exemption to law prohibiting the possession of eagle feathers and talons).

⁸⁵ United States v. Adevemo, 624 F. Supp. 2d 1081 (N.D. Cal. 2008) (denying RFRA claim where defendant sought a religious exemption to a prohibition on the importation and transportation of leopard skins into the United States). ⁸⁶ United States v. Lepp, No. CR 04-0317 MHP, 2007 WL 2669997 (N.D. Cal. 2007) (denying RFRA claim where defendant sought a religious exemption to the Controlled Substances Act).

See Vasquez-Ramos, supra.

para. 12. 90 G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, entered into force Sept. 3, 1981, at art. 12(1).

the access of women and adolescent girls to affordable health-care services, including reproductive health care, and *to increase access to information and affordable means of family planning*..."⁹¹

The Committee on Economic, Social and Cultural Rights, charged with monitoring the International Covenant on Economic, Social and Cultural Rights (another treaty the United States has signed) emphasized the importance of access to affordable contraception in its General Comment on the Right to the Highest Attainable Standard of Health. In order to fulfill their treaty obligations, states must endeavor to "provide access to a full range of high quality and *affordable health care, including sexual and reproductive services*..." ⁹²

B. International Human Rights Law Requires Governments to Protect Access to Contraceptive Service from Interference by Third Parties, Such as Employers

Under international human rights law, the right to health – including the aforementioned right to access affordable contraception – must be respected, protected, and fulfilled by governments. A government meets its obligation to *respect* the right to health by not interfering with individuals' enjoyment of the right. And it *fulfills* the right by affirmatively facilitating access to health-related services, including "sexual and reproductive health services." The nocopay-contraception mandate is a positive step towards respecting and protecting women's right to health, including reproductive health.

However, under international human rights law, a government must also *protect* the right to health from interference: "States should also ensure that third parties do not limit people's access to health-related information and services." This means that in order to abide by the United States' international commitments, it is not enough for HHS to facilitate no-cost-sharing access to contraceptives. Instead, HHS must also ensure that third parties – such as religious employers – are not permitted to do what government may not, and interfere with individuals' right to access affordable contraception. Consequently, the proposed religious exemption, which allows private employers to impede individuals' right to access affordable contraception, violates international norms and our commitments under the international human rights treaties that the United States has signed.

⁹¹ See, e.g., Concluding Observations of the CEDAW Committee: Slovakia, U.N. Doc. CEDAW/C/SVK/CO/4 (2008), at para. 22.

⁶² Committee on Economic, Social and Cultural Rights, General Comment 14, The right to the highest attainable standard of health (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000), reprinted in Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies, U.N. Doc. HRI/GEN/1/Rev.6 at 85 (2003), at para. 21.

⁹³ *Id.* at para. 33.

⁹⁴ *Id.* at para. 36.

⁹⁵ *Id.* at para. 35.

VI. Embracing a Religious Exemption Will Only Lead to Calls for Further Exemptions, Weakening the Health Protections for Women and their Families

A. Permitting a Limited Religious-Employer Exemption Will Only Lead to Broader Exemptions, Undermining the Preventive-Services Mandate

The proposed HHS religious-exemption rule threatens to create a system in which the exception swallows the rule because the number of religious entities that would seek exemptions is potentially limitless. Although the rule's exemption only covers, in effect, houses of worship, religious groups have made it clear that they seek exemptions for *all* religiously affiliated organizations. In New York and California, where an identical exemption was offered, Catholic Charities sought a broader exemption. And in late August a group of Catholic leaders and professors wrote to Secretary Sebelius, asking HHS to "expand[] the definition of religious organization in the final rule to extend conscience protection to religious charities, religious hospitals, and religious schools in regard to mandated health insurance coverage." Each of these suggestions – exemptions for religious charities, hospitals, and schools, threaten to undermine the entire system of preventive care for women.

The notion that Catholic charities should be exempted from contraceptive-coverage requirements has been consistently rejected by the highest courts in California and New York. In *Catholic Charities of Sacramento, Inc. v. Superior Court*, ⁹⁸ the California Supreme Court held that Catholic Charities was not an arm of the church, but a "nonprofit public benefit corporation," and emphasized that most of the organization's employees "do not belong to the Catholic Church." Consequently, it would be grossly unfair to allow the church hierarchy to veto the health rights of employees – a majority of whom are non-believers. The court also highlighted the distinction between believers and employees: "*Only* those who join a church impliedly consent to its religious governance on matters of faith and discipline." ¹⁰⁰

Similarly, in *Catholic Charities of the Diocese of Albany v. Serio*, ¹⁰¹ the New York Court of Appeals – the state's highest court – flatly rejected Catholic Charities demand that it be exempted from a contraception-coverage requirement. In so holding, the Court noted that Catholic Charities did not serve to inculcate religious values; that it did not serve only Catholic adherents; and that it employed primarily non-adherents. ¹⁰²

Giving religious hospitals an exemption would similarly create a system in which exemptions swallow the rule and thus become unworkable. According to the Catholic Health Association of the United States, Catholic Hospitals account for 15.8 percent of all hospital admissions – about one out of every six patients – nationwide, and more than one-fifth of all admissions in 22

⁹⁶ Catholic Charities of the Diocese of Albany v. Serio, 859 N.E.2d 459 (N.Y. 2006); Catholic Charities of Sacramento v. Superior Court. 85 P.3d 67 (Cal. 2004)

Sacramento v. Superior Court, 85 P.3d 67 (Cal. 2004).

97 Michael Sean Winters, Prominent RCs Write to Sebelius on Conscience Protections, NAT'L CATHOLIC REPORTER, Aug. 26, 2011.

⁹⁸ 85 P.3d 67 (Cal. 2004).

⁹⁹ *Id.* at 77.

¹⁰⁰ *Id.* at 77 (emphasis added).

¹⁰¹ 859 N.E.2d 459 (N.Y. 2006).

¹⁰² *Id.* at 463.

states.¹⁰³ And Catholic hospitals employ nearly 800,000 people nationwide – 532,011 full-time employees and 237,657 part-time employees.¹⁰⁴ Many of these employees are not themselves Catholic – regardless, 98 percent of Catholic women use contraception.¹⁰⁵ Extending the exemption to Catholic hospitals would make Swiss cheese out of the coverage requirement.

Extending a religious exemption to religious schools would strip more than 300,000 workers and their families of critical preventive services, including no-copay contraception. ¹⁰⁶ Of these more than 300,000 employees, more than 150,000 work at Catholic schools. ¹⁰⁷ But the National Catholic Education Association admits that only a tiny fraction of these Catholic school employees – 3.7 percent – are actually members of the clergy. The remaining 96.3 percent of Catholic school employees are laity – and a substantial number of them are not even Catholic. ¹⁰⁸

Allowing religious universities to receive an exemption would further frustrate the purpose of the preventive-services requirement. There are about 900 religiously affiliated colleges and universities, with 1.7 million students in the United States, ¹⁰⁹ including 244 Catholic degreegranting institutions. ¹¹⁰ These institutions employ tens, if not hundreds, of thousands of people – the vast majority of whom are not members of the clergy, and a substantial percentage of whom are not even Catholic. These thousands of people – plus their families – would be stripped of nocopay access to contraception if the exemption were broadened.

And, of course, there are numerous other kinds of businesses beyond charities, hospitals, schools, and universities that are affiliated with religious organizations – everything from radio 111 and television stations 112 to condominiums 113 to paintball courses. 114 These businesses,

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¹⁰³ Catholic Health Association of the United States, *Catholic Health Care in the United States*, Jan. 2011, *available at* http://www.chausa.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=2147489259.

 $^{^{105}}$ Centers for Disease Control, National Survey of Family Growth, National Health Statistics Report, Sexual Behavior, Sexual Attraction, and Sexual Identity in the United States: Data From the 2006–2008 (Mar. 3, 2011) available at http://www.cdc.gov/nchs/data/nhsr/036.pdf.

¹⁰⁶ U.S. Dep't of Education, National Center for Education Statistics, *Characteristics of Private Schools in the United States: Results from the 2009-2010 Prviate School Universe Survey*, at 7, Table 2, May 26, 2011, *available at* http://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2011339. Indeed, because the statistics indicate 314,489 full-time equivalent employees, the real number of religious-school employees, in light of the fact that some employees are part-time, is actually larger.

¹⁰⁷ According to the National Catholic Education Association, Catholic schools in the United States employee 151,473 "full-time equivalent professional staff." Given the number of part-time workers, and non-professional staff (such as groundskeepers and maintenance workers), the number is even greater.

While schools may give a preference to Catholics, it is not a requirement for employment in most positions. *See, e.g.*, Archdiocese Chicago Catholic Schools, *Careers, available at*

http://schools.archchicago.org/careers/elementaryschool/ ("[p]reference in hiring *may* be given to teachers who are Catholic...").

¹⁰⁹ United States Conference of Catholic Bishops, *The Catholic Church in the United States at a Glance*, (figures through 2009) http://www.usccb.org/comm/catholic-church-statistics.shtml; Council for Christian Colleges and Universities, *About CCCU*, http://www.cccu.org/about; Lutheran Colleges, *Our Colleges* http://www.lutherancolleges.org/.

Association of Catholic Colleges and Universities, *Colleges and Universities*, *available at* http://www.accunet.org/i4a/pages/index.cfm?pageid=3489.

For example, Bonneville International, which owns more than a dozen radio stations, is owned by the Church of Latter Day Saints. http://bonneville.com.

¹¹² See, e.g., KSL-TV Utah (NBC affiliate owned by the Church of Latter Day Saints), http://www.ksl.com/.

many of which operate as secular businesses, employ untold thousands of people across the nation – all of whom could be stripped of their access to no-copay contraception if HHS widens the exemption. Given the life-altering impact of an unintended pregnancy, even one woman's health interest should be sufficiently compelling to provide a basis for the rule.

The fact that there exists within the Employee Retirement Income Security Act (ERISA) an exemption from certain requirements for "church plans" is of no moment. Congress expressly chose to place the preventive services mandate not only within ERISA, but also into the Public Health Service Act and the Internal Revenue Code, to ensure that the broadest number of plans would be covered by the mandate's requirements. The strong impetus for the mandate – the need to reduce the number of unintended pregnancies – favors the broadest possible application. Critics of the proposed religious exemption for the contraceptive services mandate argue that it arbitrarily draws a line between certain types of religious employers and others, and suggest that the ERISA church plan definition would be preferable because it includes organizations that share religious bonds and convictions with a church. At the same time, they argue that the ERISA church plan exemption would actually not go far enough, because other individuals and entities affected by the mandate would fall outside its definition. By their own argument it is clear that adopting the church plan definition would be no less arbitrary than the proposed HHS exemption, and that those who seek to broaden the exemption would not stop until the exemption swallowed the rule. If an exemption is to be adopted, it should be as narrow as permissible under prevailing legal standards to ensure that as many women as possible gain access to criticallyneeded family planning services.

B. Expansion of the Religious Exemption to Include Hospitals and other Religiously Affiliated Institutions is Unwarranted Under the Law and Would Be Terrible Policy

The weight of precedent is squarely with HHS in defending the scope of the proposed exemption. In the two court challenges related to the similar exemptions in California and New York, courts have roundly rejected claims of religiously-affiliated institutions that the scope of the exemption burdened the exercise of religion.

In 2000, the Supreme Court of California, in Catholic Charities of Sacramento v. Superior Court of Sacramento County, 115 upheld that state's Women's Contraception Equity Act against the challenge from Catholic Charities, which did not fall within the exemption. The court found that the contraception mandate did not impermissibly impair the religious rights of Catholic Charities by requiring that they include prescription contraceptives in their health benefit program, and also found that the mandate served the compelling state interest of eliminating gender discrimination.

While the case involved several discrete constitutional challenges, two are of importance here. First, Catholic Charities argued that defining a religious employer violated the

¹¹³ See Lesley Mitchell, Mormon Church Has Built Downtown Housing; Will People Come?, SALT LAKE TRIBUNE, Sept. 27, 2011, available at http://www.sltrib.com/sltrib/news/52583204-78/creek-units-church-lake.html.csp. ¹¹⁴ See, e.g., Joshua's Paintball Jungle, a ministry of First Bible Baptist Church in Rochester, NY. http://jpj.fbbc.info/about.shtml. 115 85 P.3d 67 (Cal. 2004).

Establishment Clause by creating an impermissible distinction between the religious and secular activities of a religious institution. The court dismissed this argument, noting that exemptions are permissible and would be impossible to implement without distinguishing between "religious" and "secular" activities. Second, Catholic Charities argued that requiring it to provide contraceptive coverage violated the Free Exercise clause by coercing it to violate its religious beliefs. The court rejected this argument as well, holding that the coverage mandate was a neutral and generally applicable law regulating matters that the state may permissibly regulate, and that it only incidentally conflicted with Catholic Charities' religious beliefs.

The case in New York was also brought by Catholic Charities and others, and garnered a similar result. In *Catholic Charities of Albany, et al v. Gregory v. Serio*, ¹¹⁶ the New York Court of Appeals, referencing the California case, also held that limiting the religious exemption from the state's contraceptive equity law to institutions meeting a specific definition of "religious employer" did not violate the Constitution's free exercise clause, as any burden on the plaintiffs' religious exercise was the incidental result of a neutral law of general applicability. The court also noted the state's strong interests in both women's health and equal treatment for men and women and how the law furthers those interests (citing some of the same statistics advanced by the legislative proponents of the federal Women's Health Amendment).

In addition, an expansion would be terrible public policy and would impose burdens on the autonomy and privacy rights of millions of women. Expanding the exemption to include religiously-affiliated hospitals and social services centers would make line-drawing exceedingly difficult beyond the narrow exemption already proposed. It would also impose unconscionable practical hardships upon millions of women and families who do not agree with the religious beliefs of the Bishops regarding contraception, who believe that use of contraception is either consistent with, or supported by, their own religious beliefs, and who have the same compelling interests in insurance coverage for contraception as the general public.

There is simply no reason to expand the already overbroad proposed exemption. First, many hospitals, even those with "religious affiliations," do not receive funding from any religious sources, or receive only very *de minimus* funding from religious sources. When St. Joseph's, the Phoenix hospital in which an abortion was performed last year, lost its Catholic designation, hospital officials indicated to news reporters that the only change in hospital practice would be related to the performance of religious services at the hospital. As ABC News reported, "[h]ospital officials insist the severing of ties with the Catholic Church will have no practical implications for health care delivery although the bishop will no longer allow mass to be said at the hospital."

Such hospitals are also subject to hundreds, if not thousands, of state and federal laws regulating hospital practices, as well as to generally applicable accreditation standards. To name a few, the Medicare Conditions of Participation regulate hospital practice at the federal level, while states license facilities and grant their Certificates of Need. In addition, the Emergency Medical Treatment and Active Labor Act ("EMTALA") imposes conditions requiring

¹¹⁶ 859 N.E.2d 459 (N.Y. 2006).

¹¹⁷ Dan Harris, *Bishop Strips Hospital of Catholic Status After Abortion*, ABC NEWS, Dec. 22, 2010. See http://abcnews.go.com/Health/abortion-debate-hospital-stripped-catholic-status/story?id=12455295.

emergency treatment when a patient is presented, without consideration of economic or other factors related to the characteristics of the patient. Even more importantly, a majority of employees at most institutions are likely to have no connection to the religious affiliation of the institution. The actions of hospitals and affiliated providers are also subject to generally applicable standards of medical negligence as determined by state law. In sum, hospitals, including those with religious affiliations, serve the health needs of the general public. In both function and form, these institutions perform a secular purpose for the broad and general public.

Separately incorporated social services centers, even if faith-based, are also subject to generally applicable tort standards and a host of federal and state laws and regulations, including those related to hiring practices, discrimination, hygiene and other standards. Those that serve a majority of religious adherents and employ a majority of religious adherents may qualify for the exemption; others, who do not qualify on these two grounds, are clearly serving the general public and employ members of general public who deserve to be able to avail themselves, as they choose, of the benefits of contraceptive coverage. The lines drawn by HHS, while unnecessarily overbroad, do some service by clearly excluding institutions that are performing a secular function. Should HHS wish to expand the exemption, the agency will have to articulate why the exemption it proposed does not do an adequate enough job of separating primarily religious from primarily secular organizations.

In both situations, an expansion of the exemption would also raise the specter that some institutions that lack an obvious religious function will claim the exemption for reasons unrelated to religious sentiment. To the extent that no-copay contraception is an expense for insurers, it is indisputable that employers who seek to price and obtain coverage could prefer insurance coverage within the exemption for cost reasons alone. Without a narrowly tailored exemption, it will be exceedingly difficult for HHS to patrol the boundaries of the exemption, and to ascertain whether its invocation is purely a pretext for an economic rationale.

The Bishops also claim that a failure to expand the refusal provision will result in hospital and social-services closures. Yet in California and New York, where a similar exemption is in operation, there is no evidence to suggest that religiously-affiliated institutions have closed or are offering diminished care. Indeed, some Catholic Universities, such as Loyola Marymount, apparently offer contraception despite being permitted not to by virtue of a self-insurance loophole. In light of the Bishops' implied threat that a key source of charity care for low-income individuals might be at risk, it is important to note that, in fact, Catholic hospitals appear to provide less care to Medicaid patients and less charity care than hospitals under other forms of sponsorship.

The implied threat of religious hospital and social-services closures also rings hollow given the broad nature of responsibilities for compliance with the mandate under the proposed rule. The HHS regulation does not place the burden of compliance on any particular individual within

119 Lois Uttley & Ronnie Pawelko, No Strings Attached: Public Funding of Religiously-Sponsored Hospitals in the United States, (2002), at 5.

¹¹⁸ See Catholics for Choice, "Student Bodies: Reproductive Health Care at Catholic Universities" (2002), at 18; http://www.catholicsforchoice.org/topics/healthcare/documents/2002studentbodies.pdf; Brochure, Aetna's health care coverage for Loyola Students, at 22; http://www.aetnastudenthealth.com/schools/lmu/brochure1112.pdf.

the institutions regulated. Instead, the mandate rests with the institution as a whole. It begs credulity that the hostility to insurance coverage for contraception is so uniform across healthcare institutions the size and scope of hospital systems; and this notion appears particularly dubious in light of the data regarding religious adherents' widespread use of, and support for, contraception.

C. Evidence Demonstrates Harm to Employees of Catholic Institutions from Denial of Coverage

Research interviews conducted over the past year by the Center for Reproductive Rights underscore the hardships faced by employees at Catholic hospitals from denial of insurance coverage for contraception. At one hospital in Muskegon, Michigan, Hackley Hospital, that was acquired by a Catholic health system, Trinity Health, in 2008, employees told us of their dismay and distress when, without notice, contraceptive coverage was dropped for staff members and employees of affiliated medical practices.

All of the former Hackley employees we interviewed reported that the ban had a harmful impact on themselves and their colleagues. One nurse indicated that the out-of-pocket costs of permanent contraception were prohibitive. (While costs vary by location, costs for tubal ligation generally range from \$1500 to \$6000. Another spoke of her difficult situation and the stress on her relationship:

We are just praying I don't get pregnant until we can figure out how to get something. My doctor is Mercy-employed and he doesn't have samples. ... I got pregnant twice on birth control. One was the Nuva Ring, the second was the minipill when my baby was 4 and a half months old. I'm an OB nurse, so I know how to use birth control. Some patients like me need some form of permanent birth control. ... My third pregnancy I lost twins. ... I can't go through more. It's taken a toll on my marriage.

IUDs were also unaffordable for the employees we interviewed. In response, some nurses paid up to \$40 per month for birth control pills or made a special trip to obtain them more cheaply elsewhere. Some hospital employees initially sought sliding scale services at the local Title X clinic, which closed in 2009.

Even employees who had a history of pregnancy complications, high-risk pregnancies or a history of contraceptive failure could not obtain insurance coverage for contraception following the merger at Hackley Hospital. Moreover, medical conditions for which the use of oral contraceptives are recommended went untreated: One nurse had endometriosis, a medical indication for birth control pills, but still had to pay out-of-pocket for her pills.

Every hospital employee we interviewed in this setting condemned the lack of coverage as an unwelcome intrusion by their new employer into a private healthcare decision. One employee noted, "All these other insurances [sic] paid for it. ... If I have health insurance, I should get birth control. ... Why should I have to follow what they believe?"

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 $^{{\}it Your Contraception.com}, {\it Tubal\ Ligation,\ available\ at\ http://www.yourcontraception.com/birth-control-methods/tubal-ligation/tubal-ligation.html.}$

VII. Any Religious Exemption to the No-Copay Contraception Requirement Must be Limited to Individuals Employed Specifically for Ministerial Duties

For the reasons set forth above, the no-copay-contraception mandate – without any exemption – is both constitutional and permissible under RFRA. However, if HHS is determined to offer a religious exemption, the current proposal is overbroad. Any exemption should be strictly limited to employees in ministerial positions. ¹²¹ Thus, the proposed language in section 147.130 should be changed as follows:

(a)(1)(iv)(A)) In developing the binding health plan coverage guidelines specified in this paragraph (a)(1)(iv), the Health Resources and Services Administration shall be informed by evidence and may establish exemptions from such guidelines with respect to group health plans established or maintained by religious employers and health insurance coverage provided in connection with group health plans established or maintained by religious employers with respect to any requirement to cover contraceptive services under such guidelines <u>for those</u> <u>individuals employed specifically for ministerial duties.</u>

This is a more narrow and targeted means of achieving HHS's stated goal of providing a "religious accommodation that respects the unique relationship between a house of worship and its *employees in ministerial positions*." ¹²²

A. Religious-Conscience Rights Belong to Individuals, Not Institutions

As currently phrased, however, the proposed religious exemption protects the rights of religious employers at the expense of individual employees, giving houses of worship a *de facto* veto over the health coverage of their employees. But the Supreme Court has repeatedly emphasized that conscience rights inure to individuals, not institutions. For example, in *McCreary County, Kentucky v. ACLU of Kentucky*, the Court noted that "[t]he Framers and the citizens of their time intended...to protect the integrity of *individual* conscience in religious matters..." *Wallace v. Jaffree* similarly held that "the Court has unambiguously concluded that the *individual* freedom of conscience protected by the First Amendment embraces the right to select any religious faith or none at all." And in *Glickman v. Wileman Brothers & Elliott, Inc.*, the Court proclaimed that "at the 'heart of the First Amendment [is] the notion that an *individual* should be free to believe as he will, and that in a free society one's beliefs should be shaped by his mind and his conscience." ¹²⁵

¹²¹ We use the term "ministerial position" here to refer to those hired to perform exclusively or almost exclusively religious functions as part of the house-of-worship's religious hierarchy, such as priests, rabbis, nuns, or imams. We do not endorse the broader meaning of the term that has been used by some of the lower courts, which have incorrectly broadened the term to include music directors, teachers at religiously affiliated colleges, and the like.

¹²² Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621 (Aug. 1, 2011), at 46,623.

¹²³ 545 U.S. 844, 876 (2005) (emphasis added).

¹²⁴ 472 U.S. 38, 53 (1985) (emphasis added).

¹²⁵ 521 U.S. 457, 472 (1997) (emphasis added).

As written, the proposed HHS exemption cedes to employers the religious conscience rights that rightfully belong to the employees. But individual employees – and not their employer – should have the religious conscience right to decide whether they wish to receive co-copay coverage for contraception. The draft exemption, however, permits a religious institution to trample upon the religious beliefs of their employees – whether or not they agree with those views, and whether or not they are even members of the same religious group. For example, a Methodist groundskeeper employed by a Catholic parish will be unable to access no-copay contraception – regardless of her own conscience or religious beliefs – by virtue of happening to work for a church. The fact that the groundskeeper does not share the religious beliefs of the church¹²⁶ and engages in no religious duties whatsoever – and indeed, that she performs an essentially secular function – is of no moment. Under the interim rule, the church, as her employer, can dictate to her which health benefits she can access. Indeed, the logic underlying the interim rule would also allow a church to deny neonatal benefits to a mother whose child was born out of wedlock; ¹²⁷ or to all male employees; ¹²⁸ or to gay or lesbian employees. ¹²⁹ And Christian Scientist churches would be entitled to deny all medical coverage except spiritual care. 130

B. Religious Exemptions Should Be Limited to Employees Employed Specifically for **Ministerial Duties**

Any religious exemption to the no-copay-contraception mandate should be limited to religious-institution employees hired to perform ministerial duties, such as rabbis, priests, or imams. These employees are hired specifically because of their religious beliefs and leadership of the religious institution and have specifically volunteered for such designation. The Fifth Circuit Court of Appeals noted, for example, that "[t]he relationship between an organized church and its ministers is its lifeblood. The minister is the chief instrument by which the church seeks to fulfill its purpose." Similarly, the Fourth Circuit Court of Appeals recognized that "[t]he right to choose ministers...underlies the wellbeing of a religious community...for perpetuation of a church's existence may depend upon those whom it selects to preach its values, teach its message, and interpret its doctrine both to its own membership and to the world at large."132

Because ministers are selected precisely because of their religious beliefs and leadership, offering them an exemption is a permissible – though unrequired – accommodation of religion.

¹²⁶ Although the interim rule limits its applicability to organizations that "*primarily* employ[] persons who share [their] religious tenets," (emphasis added) it is clear that religious institutions would be exempt from providing nocopay contraception to any non-believers who work there.

127 Numerous religions, including Roman Catholicism, disapprove of sexual relations outside of marriage.

¹²⁸ See, e.g., Re-Formed Congregation of the Goddess, International, RCG-I Membership, available at http://www.rcgi.org/members/members.asp (congregation only permits women to become full members). Numerous religions disapprove of homosexuality.

Lest this sound like hyperbole, see Fox13now.com, Should State Health Exchanges Pay for Spiritual Care, Sept. 25, 2011, available at http://www.fox13now.com/news/kstu-spiritual-care-should-state-health-exchanges-pay-forspiritual-care-20110925,0,5284457,story (Utah's Legislative Health Care Reform Task Force discussed proposals to permit insurance coverage for 'spiritual care'..."[t]he legislature heard personal stories [from the] Christian Science...a church[, which] believes spiritual care should replace medical care.").

¹³¹ McClure v. Salvation Army, 460 F.2d 553, 558-59 (5th Cir. 1972).

¹³² Rayburn v. General Conference of Seventh-Day Adventists, 772 F.2d 1164, 1167-68 (4th Cir. 1985).

But other employees of religious institutions – be they secretaries, groundskeepers, or receptionists – are not the "lifeblood" of a house of worship; nor does a house of worship depend upon such non-ministerial employees to "preach its values, teach its message, and interpret its doctrine." Because non-ministerial employees are not hired because of their religious beliefs and leadership, they ought not to be held hostage to the religious employers' religious dogma and denied a health benefit generally available to everyone else.

VIII. Other Key Protections Would Be Required If the Exemption is Maintained or Expanded, Including a Mechanism to Allow Affected Employees to Obtain No-Copay Contraceptive Coverage

As the above history indicates, if HHS decides to maintain or expand the exemption, the agency must establish a robust and clear set of protections for women's health. For example: 1) HHS should exclude from any exemption contraception prescribed for a medical purpose unrelated to birth control; 2) employees subjected to an employer exemption should be allowed to otherwise obtain contraceptive coverage free of cost through a state or federal program for an extension of coverage; 3) employees should be given appropriate advance notice of the employer's exemption and the resulting absence of coverage and provided at the same time with information required to obtain coverage elsewhere; and 4) employers should be required to certify that they comply with each of the exemption's requirements and this documentation should be submitted to HHS.

The distinct autonomy and privacy interests that individuals have in accessing family planning services and in reproductive health require that HHS design a system in which individuals denied contraceptive coverage due to the HHS exemption are provided with an alternative means to obtain contraceptive coverage. Such coverage could be offered through a federally mandated insurance supplement or through a special program in the Exchanges. Without such a mechanism, the religious beliefs or consciences of the many individuals who are employed at houses of worship will be trampled upon by their employers' decision to seek an exemption.

Consistent with privacy safeguards, HHS should publish annually data on the extent to which exemptions have been allowed from the rule, the number of policyholders impacted by the exemption by state, the mechanisms by which these policyholders have been offered contraceptive coverage from another source, and any monitoring and enforcement activity related to the exemption or certification of exemption.

IX. Conclusion

The IOM panel's recommendations provide a clear blueprint for change, and a compelling case for transformative improvements in the availability of contraception that can lead, at last, to measurable improvements in the sky-high rates of unplanned pregnancy in the United States, as well as to an increase in the number and rate of planned pregnancies among American women.

The vast majority of Americans already use contraception, albeit inconsistently. Too many today find the most highly effective, long-acting forms of contraception out-of-reach for cost

reasons. The significance of the HHS mandate for contraceptive coverage cannot be overstated: It will allow millions of women who today cannot afford regular access to contraception the ability to take control over their health and the direction of their lives.

The sweeping character of the mandate – its critical wide reach and scope – will particularly assist women with fewer resources. Such a transformative change cannot happen, and will not happen, if the rule is permitted to be punched full of holes in an attempt to prioritize religious institutions' dogmatic views over the needs and wishes of those who are employed by them.

The nature of insurance coverage for a service is that it asks nothing of those individuals who do not need, want, or use the full scope of coverage. Millions of women attend religiously affiliated universities and schools, or are employed by religiously affiliated hospitals and social-service centers. Studies show that the health needs of these women are identical to those of the general population, and that they want and need coverage for contraception.

There is no reason to allow an exemption at all, given the mandate's lack of incursion on any identified religious practice. And there is even less support in this record to expand the mandate to permit denial of a benefit needed by millions of women – a benefit that operates as a hedge against happenstance in the crucible of health and identity, and that has been recognized as a compelling interest essential to wellbeing, autonomy, and privacy.

For the foregoing reasons, we urge HHS to reject the proposed religious exemption to the no-copay-contraception mandate.