20 YEARS CENTER FOR REPRODUCTIVE RIGHTS

June 19, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9968-ANPRM
P.O. Box 8016
Baltimore, MD 21244-185

The Center for Reproductive Rights respectfully submits the following comments in response to the Advance Notice of Proposed Rulemaking (ANPRM) on "Certain Preventive Services Under the Affordable Care Act," published in the Federal Register on March 21, 2012.

The Center also signed onto comments submitted by the National Women's Law Center on behalf of a coalition of organizations that work to further women's reproductive rights and equality, and incorporates those comments here by reference. Our comments below further explore certain matters and add other topics that were not part of the coalition comments.

Summary: No Accommodation is Needed, Nor Is One Desirable

The Center applauds the inclusion of the full range of FDA-approved contraceptive methods and counseling within the Affordable Care Act's (ACA's) preventive services rule. As explained in our comments on the proposed religious exemption last fall,[1] the rule does not infringe upon anyone's exercise of religion, and even if it did it is permissible as furthering compelling governmental interests. Thus no exemption from its requirements is legally compelled. Similarly, we here urge the Departments to reconsider the proposal to adopt an accommodation for religious employers, as no such accommodation is required under the law.

The Center also urges the Departments to reject calls to expand the existing religious employer exemption, and insists that they decline to apply a new exemption or any future accommodation to for-profit entities. We do, however, support extending any accommodation to employers that have covered some, but not all, forms of contraception, despite the erroneous factual bases for these employers' inconsistent coverage of various contraceptive methods.

In addition, we request that the Departments reconsider whether male contraceptive methods are included within the scope of the contraception benefit, and urge the Departments to ensure that insurers' application of "reasonable medical management techniques" does not undercut the value of the benefit by allowing overly restrictive formularies that limit access to this critical benefit for women.

[1] Comments of the Center for Reproductive Rights, Interim Final Rules on Preventive Services, CMS-9992-IFC2, submitted September 30, 2011.

1634 Eye Street, NW, Suite 550
Washington, DC 20006
Tel. 202 628 0286
www.reproductiverights.org

I. No Religious Exemption or Accommodation Is Necessary

Those who oppose the rule providing coverage of contraception without cost sharing (hereinafter, the "Contraception Benefit") argue that it infringes upon certain employers' religious freedom. Well-settled law, however, says otherwise.

Our prior comments explained at length that the rule does not violate the First Amendment[2] to the Constitution under the seminal case, *Establishment Division v. Smith*, 494 U.S. 782 (1990), and are incorporated here fully by reference. In those comments and in this section, we demonstrate that the contraception rule also does not violate the Religious Freedom Restoration Act (RFRA).[3]

The Contraception Benefit – even without a religious exemption – does not violate RFRA. First, there is no burden on the exercise of religion. Second, any supposed burden upon religious exercise is not "substantial." Third, 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 the Contraception Benefit is the least restrictive means of accomplishing that compelling goal.

A. The Religious Freedom Restoration Act Is Inapplicable Because the Contraception Benefit 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. In *Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, for example, the Supreme Court applied RFRA to exempt "130 or so" members of a religious sect from the strictures of the Controlled Substances Act, allowing them to engage in a religious exercise – the sacramental consumption of an hallucinogenic tea.[4]

Here, however, those seeking a broadened religious exemption cannot point to a particular religious exercise that the Contraceptive Benefit inhibits. Rather, those seeking an exemption claim that third parties' insurance coverage for contraception violates their beliefs. But we are unaware of any case in which the refusal to provide insurance coverage to a third party – even on religious grounds – was considered to be a religious exercise, and indeed several state supreme

[2] The Contraception Benefit also does not violate the association or speech clauses of the First Amendment. The rule neither compels nor prohibits any associational conduct, nor does compliance with a health insurance regulation implicate expressive association. Compliance with the Contraception Benefit does not constitute an endorsement of the actual use of contraception, and thus does not violate the free speech rights of birth control opponents. *See Catholic Charities of Sacramento, Inc. v. Super. Ct.*, 85 P.3d 67, 89 (Cal. 2004).

[3] Because the rule satisfies RFRA, it also withstands scrutiny under the First Amendment's Free Exercise Clause, as the test that a government burden on religion must meet is less stringent – a neutral, generally applicable law that happens to burden religious exercise survives constitutional scrutiny.

[4] 546 U.S. 418, 433 (2006).

courts have upheld similar contraceptive-coverage requirements over objections by religiously affiliated organizations on similar grounds.[5]

In fact, the Supreme Court 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…"[6] The belief/exercise distinction is of paramount importance to the courts; numerous cases upholding RFRA-based challenges have focused on the practice of religious worship, rather than abstract beliefs. In *Gonzales*, for example, the Court noted that the sacramental use of *hoasca*, an hallucinogenic tea, was 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."[7]

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

2. Even if the Contraception Benefit Imposes a Burden on Religious Exercise, that Burden Is Insubstantial

RFRA subjects government action to a "compelling interest" test only if the burden upon religious exercise is "substantial."[8] Even assuming that the Contraception Benefit does burden "religious exercise," the burden is minimal, or at most, insubstantial.

First, we note that religious employers (as well as non-religious ones) already cover health services to which they may, in principle, object for religious reasons. For example, existing Catholic employers' health insurance plans may cover maternity care for unwed mothers or HIV tests without regard to sexual orientation; existing Latter Day Saints employers' insurance may cover emergency services for injuries that happen to have been caused by reckless, alcohol-fueled behavior.

In similar circumstances involving health plans, courts have found no burden on religious exercise. For example, the Ninth Circuit in *Goehring v. Brophy*, 94 F.3d 1294 (9th Cir. 1996), held that a state university's use of mandatory student fees to subsidize health insurance premiums for a plan that included abortion services did not impose a substantial burden on the

---

[5] *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).
[6] *Cutter v. Wilkinson*, 544 U.S. 709 (2005) (quoting *Employment Division*, 494 U.S. at 877) (emphasis added).
[7] *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).
[8] RFRA, 42 U.S.C. § 2000bb-1.

religious exercise of objecting students. In reaching this conclusion, the court relied on the small size of the subsidy for student insurance premiums under the school plan paid for by registration fees — $18.50 per student, per quarter — and the fact that the plaintiffs were "not required to accept, participate in, or advocate in any manner for the provision of abortion services." *Id*. at 1300.

The court in *Erzinger v. Regents of Univ. of Cal.*, 187 Cal. Rptr. 164, 166 (Ct. App. 1983), held that a similar policy that used mandatory student fees to subsidize abortion services under a state university health care plan did <u>not</u> violate the Free Exercise Clause. The court held that the University's collection of a mandatory fee and use of that fee to provide services the plaintiffs deemed objectionable did not "in any way coerce[ ] their religious beliefs." *Id*. at 166.

Despite claims to the contrary by opponents, employers here are not being compelled under threat of a penalty to *use or dispense* contraceptives. Instead, the Contraception Benefit merely requires employers to offer employees a comprehensive insurance policy that covers many different types of health care for employees, including contraception coverage. Contraception, though critical, is only a very small part of the total health package, and the dollars paid for health care coverage of all kinds are commingled with sources of other funds by insurers, and never kept in a separate account for particular policyholders or claims payments.

Moreover, health care coverage is a fringe benefit and thus a form of compensation similar to wages and vacation that may be dedicated or used to subsidize activity to which the employer has a religious objection. Wages often directly pay for contraceptives, yet the employer is never seen as the source of a "subsidy" for contraception.

In short, an employer's exercise of religion is not burdened because it cannot control how employees spend their money. Cash and health insurance are just two different components of an employee's total compensation package. If employees previously could use cash salaries paid to them to buy contraceptives, the Contraception Benefit simply means that employees can now look to a different bucket of their compensation bundle — employer-provided health insurance, rather than employer-provided cash — to finance their birth control needs.

Moreover, as explained more fully in our previous comments, obeying a law regarding health insurance coverage to which all other employers are also subject does not substantially burden anyone's religious exercise. Religious adherents also obviously remain free to eschew the use of contraception, and to urge others to behave similarly.

B. The Contraception Benefit 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.[9] Even if the Contraception Benefit substantially burdened religious exercise – which it does not – it would still be a permissible governmental exercise of power under RFRA.

[9] RFRA, 42 U.S.C. § 2000bb-1(b)(1)-(2).

1. The Contraception Benefit Furthers a Compelling Governmental Interest

The Contraception Benefit is permissible under RFRA because it furthers a compelling governmental interest in: (1) women's health; (2) children's health; (3) women's equality and autonomy; and (4) the health and wellbeing of third parties. These interests are as compelling when applied to employees of religiously affiliated employers as they are for society as a whole.

Women's Health. 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.[10] The fact that 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."[11]

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.

Children's Health. The government's compelling interest in requiring that all health plans include comprehensive contraceptive coverage extends even beyond protecting the health of women. 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]."[12]

Women's Equality. While promoting women's health was a primary motivation behind the Contraception Benefit, 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.[13]

---

[10] 505 U.S. 833, 846 (1992) (plurality opinion).
[11] *Catholic Charities of Sacramento*, 85 P.3d at 93.
[12] *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.").
[13] Pregnancy Discrimination Act, 42 U.S.C. § 2000e(k).

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 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."[14]

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."[15] 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."[16] The Contraception Benefit was thus designed to address the state's compelling interest in eliminating the discriminatory impact of sex-based healthcare-spending inequalities.

Access to affordable contraception is also 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.[17] 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."[18]

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."[19] 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.'"[20] 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

---

[14] 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.
[15] *See Catholic Charities of Sacramento v. Superior Court*, 85 P.3d 67, 92 (Cal. 2004).
[16] *Id.* at 92.
[17] *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).
[18] *Eisenstadt*, 405 U.S. at 453.
[19] *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 856 (1992).
[20] *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."[21]

As part of any consideration of an accommodation to the Contraception Benefit, 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,"[22] these interests are also acute. Only a rule preserving freedom of a choice of contraception and the accompanying insurance coverage fully respects the rights to privacy and decisional autonomy at the heart of this constitutional sphere.

The Director of Concerned Clergy for Choice put it aptly:

> There has been all too much talk about "religious liberty" in this contraception debate, and most of these "religious liberty" arguments are misdirected. The real religious liberty in this case belongs to the woman who is working for her health care; she is the one who owns it and needs the protection. An outsider's objection – even a faith-based objection by her employer – should play no role in her ability to pay for her health care. The patient – her health needs, decisions and her religious liberty – must always come first.[23]

Third Parties. Finally, the Contraception Benefit, 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 Contraception Benefit must take into account not only the interests of women and children, but also of the women's partners and families.

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 rule's opponents 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."[24]

---

[21] *Id.* at 1271.
[22] *Casey*, 505 U.S. at 852 (*quoting Prince v. Massachusetts*, 321 U.S. 158 (1944)).
[23] Rabbi Dennis S. Ross, "The Birth Control Lawsuits: Lessons Learned from the New York Experience," June 18, 2012, available at http://blogs.rj.org/rac/2012/06/18/the-birth-control-lawsuits-lessons-learned-from-the-new-york-experience/.
[24] *Catholic Charities of Sacramento v. Superior Court*, 85 P.3d 67, 93 (2004).

The Government Has the Same Compelling Interest in Extending the Contraception Benefit to Employees of Religiously Affiliated Institutions. In previous cases where the Supreme Court has applied strict scrutiny to government actions purporting to burden religious exercise, the religious dissenters were in a qualitatively different position than members of society as a whole. For example, in *Wisconsin v. Yoder*, the Supreme Court examined compulsory school attendance laws in the context of Amish children between the ages of 14 and 16.[25] In determining whether broadly applicable school attendance laws ought to apply, the Court paid particular attention to the unique history of the Amish, and noted the unique threat of the compulsory attendance law on the traditional Amish way of life: "As the record shows, compulsory school attendance to age 16 for Amish children carries with it a very real threat of undermining the Amish community and religious practice as they exist today; they must either abandon belief and be assimilated into society at large, or be forced to migrate to some other and more tolerant region."[26] Based on this, the Court concluded that "Wisconsin's interest in compelling the school attendance of Amish children to age 16 emerges as somewhat less substantial than requiring such attendance for children generally."[27] Similarly, in *Gonzalez*, the Court's analysis focused not on the merits of the Controlled Substances Act, but on the unique characteristics of the 130 members of the *O Centro Espírita Beneficente Uniao do Vegetal*.

In contrast, there is nothing that distinguishes employees at religiously affiliated institutions from other employees. Indeed, many of the employees at religious affiliated institutions – including math teachers at religiously affiliated high schools, cafeteria workers at religiously affiliated hospitals, and clerical employees at religiously affiliated charities – are in no sense different from employees at wholly secular institutions. Many of the employees at religiously affiliated institutions do not share their institution's official faith, and only a tiny percentage are members of the clergy. For example, more than 96 percent of Catholic-school employees are laity, and many of them are not Catholic. And to the extent that employees <u>do</u> share their employer's official faith, we know that their use of contraception is virtually the same as members of the public at large: 98 percent of sexually active Catholic women have used contraception, compared to 99 percent for the general public.[28]

It therefore follows that the compelling interest that the government has in ensuring employees' access to affordable contraception – a compelling interest in women's and children's health, in combating sex-based inequality, in promoting women's autonomy, and in protecting the interests of third parties (such as employees' spouses and dependents) – is no different for the employees of religiously affiliated institutions as it is for employees at secular employers.

Appendix A hereto is a compilation of selected comments submitted to the docket by a range of organizations last year in response to the proposed religious exemption to the Contraception Benefit. These selections further underscore the compelling nature of the government's interest

---

[25] *Wisconsin v. Yoder*, 406 U.S. 205 (1972). An analysis of *Yoder* is particularly important because the stated purpose of RFRA was to restore the compelling interest test "as set forth in *Sherbert v. Verner* and *Wisconsin v. Yoder*…" Religious Freedom Restoration Act, 42 U.S. C. § 2000bb(b)(1).

[26] *Yoder*, 406 U.S. at 218.

[27] *Id.* at 228-29.

[28] 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.

in requiring health plans to cover the full range of women's preventive health care services without cost sharing, including contraceptive services and counseling.

2. The Contraception Benefit Is the Least Restrictive Means of Furthering the Government's Compelling Interest

Not only does the Contraception Benefit 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 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."[29] 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."[30]

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."[31] 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."[32] 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]."[33] 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.[34]

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 <u>uniform application</u> of a particular program by offering evidence that granting the requested religious accommodations would seriously compromise its ability to administer the program."[35]

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*,[36] the Second Circuit

---

[29] 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.

[30] 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.

[31] 455 U.S. 252, 259-60 (1982).

[32] *Id*. at 260.

[33] *Id.* at 260.

[34] *Tony and Susan Alamo Foundation v. Secretary of Labor*, 471 U.S. 290 (1985).

[35] 546 U.S. 418, 435 (2006) (emphasis added).

[36] 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.[37] Other courts have denied RFRA-based claims seeking exemptions to the Bald and Golden Eagle Protection Act,[38] the Endangered Species Act,[39] and the Controlled Substances Act.[40] 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.[41]

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, 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 Supreme Court has explicitly used such a potential economic advantage for exemption-seekers as a basis for rejecting such exemptions. The Court's 2006 *Gonzalez* decision cites with approval an earlier Supreme Court case – *Braunfeld v. Brown*, in which the Court refused to permit an Orthodox Jew to opt out of a criminal statute prohibiting the Sunday sale of certain goods. The Court explained that permitting a religious exemption to the law "might well provide [those seeking an exemption] with an economic advantage over their competitors who must remain closed on that day."[42] The *Braunfeld* court went on to speculate that some businesses might even falsely claim a religious exemption to achieve a greater profit.

Opponents of the rule cavalierly suggest that if contraception is so important to the government, it should simply create a special government program to provide coverage for contraception. For example, the Catholic Health Association (CHA) in its comments on the proposed accommodation states: "if the Departments unfortunately continue to pursue the course that all employees must have access to contraceptive services without cost, then the government will need to develop a way to pay for and provide such services directly to those employees who desire such coverage without <u>any</u> direct or indirect involvement of religious employers" (emphasis in original).

Yet courts have made it clear that alternatives proposed for such consideration must be both feasible and achievable by the decision maker, which in this case is the Departments. *See, e.g.*, *United States v. Wilgus*, 638 F.3d 1274, 1289 (10th Cir. 2011) ("Not requiring the government to

---

[37] *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).
[38] *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).
[39] *United States v. Adeyemo*, 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).
[40] *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).
[41] *See Vasquez-Ramos*, *supra*.
[42] *Braunfeld v. Brown*, 366 U.S. 599, 608-09 (1961), *quoted in Gonzales*, 546 U.S. 418, 435 (2006).

do the impossible – refute each and every conceivable alternative regulation scheme – ensures that scrutiny of federal laws under RFRA is not 'strict in theory, but fatal in fact.'" (quoting *Fullilove v. Klutznick*, 448 U.S. 448, 507 (1980) (Powell, J., concurring))); *United States v. Lafley*, 656 F.3d 936, 942 (9th Cir. 2011) (rejecting proffered alternative because it "would place an unreasonable burden" on the Government); *New Life Baptist Church Acad. v. Town of E. Longmeadow*, 885 F.2d 940, 946 (1st Cir. 1989) (Breyer, J.) ("The term 'least restrictive means,' however, is not self-defining. In applying that term, one must pay heed to Justice Blackmun's caution, offered in another context, that '"least drastic" means is a slippery slope . . . [, for a] judge would be unimaginative indeed if he could not come up with something a little less "drastic" or a little less "restrictive" in almost any situation, and thereby enable himself to vote to strike legislation down.'" (quoting *Illinois State Bd. of Elections v. Socialist Workers Party*, 440 U.S. 173, 188–89 (1979) (Blackmun, J., concurring))). Any program requiring congressional authorization is not, by definition, an adequate alternative, as its creation would be beyond the authority of the Departments. In addition, many of the opponents of the Contraception Benefit are also on record as opposing funding for family planning programs as well, making it clear that their "alternatives" are hollow, cynical offerings meant to kill the Benefit altogether.

There are other profound difficulties with such a proposal. If what these organizations are proposing is a special government-funded carve-out for women employed by religious organizations, this would raise significant Establishment Clause problems, as these objecting employers would receive a windfall and an exemption from a neutral rule solely due to stated religious concerns, evidencing government favoring of religion over non-religion.

Even if they *are* advocating a separate government-funded contraception-only benefit for *all* women, or only for those who otherwise lack contraception coverage for any reason, such a proposal is an unacceptable option. Contraception is an integral part of women's preventive health care, and should not be carved out and separated due to the religious objections of some.

Employment-based healthcare is the norm, and it would be deeply inappropriate for some kinds of care women need to be divorced from their overall healthcare program, and for a separate government system, requiring a distinct network and enrollment procedure, to be established. Indeed, the primary benefit of the program is its seamless integration with the overall source for insurance coverage for employees.

The President said the following when announcing the final rule on women's preventive services that included an exemption for houses of worship and signaling the forthcoming accommodation:

> When it comes to women, preventive care <u>should include</u> coverage of contraceptive services such as birth control.
>
> We decided to follow the judgment of the nation's leading medical experts and make sure that free preventive care <u>includes</u> access to free contraceptive care.
>
> Under the rule, women will still have access to free preventive care <u>that includes</u> contraceptive services -– no matter where they work. So that core principle remains.

Remarks by the President on Preventive Care, February 10, 2012 (emphasis added). These remarks make clear the importance of including contraception within the broader spectrum of preventive services women receive.

Indeed, fuller integration – not separation – is essential to make gains in women's health. A comment published in a recent issue of the Journal of the American Medical Association makes the following observations:

> Despite the availability of contraceptive technology with failure rates of less than 1%, a consistently high proportion of pregnancies are still unintended (estimated at 49%). … The promise of continuous health insurance coverage provides an opportunity to transform women's health with comprehensive care for women over their life course. To achieve that goal, health systems will need to examine the unique health promotion and prevention opportunities for women, especially for pregnancy planning. … The US Centers for Disease Control and Prevention (CDC) recognizes the need for … highly effective forms of contraception, especially among women with chronic medical conditions for whom pregnancy could pose serious health risks. However, this need has not been met by the existing fragmented US system of health care payers, organizations, and clinicians.
>
> In integrated health care systems, screening for pregnancy intentions and pregnancy prevention (when requested) must receive as much attention as screening and prevention of cervical, breast, and colon cancer. To date, care integration remains an elusive goal of preconception health programs and should become a priority under the ACA.
>
> This time of innovation in health care presents the opportunity to shift the model for women's health care. The ACA provides the framework of continuous insurance coverage and integration of care over women's life course. Pregnancy planning and prevention should be part of the standard preventive services offered within the patient-centered medical home. Physicians and other clinicians should have incentives via reimbursement structures to ensure that this focus on prevention becomes mainstream practice.[43]

Carving out contraceptive coverage would be directly contrary to efforts that have been underway for years, and that the Affordable Care Act has sought to accelerate, to make healthcare more comprehensive and integrated, both in terms of payment for and delivery of care. Thus the government's compelling interest in the Contraception Benefit is not only making the services available, but integrating them into women's overall healthcare coverage. Inclusion of the Contraception Benefit within the broader preventive services rule is essential, and would advance the government's clearly compelling interests, while a separately funded and administered benefit would not.

---

[43] Erin Saleeby, MD, MPH; Claire D. Brindis, DrPH, MPH. "Women, Reproductive Health, and Health Reform." *JAMA*. 2011;306(11):1256-1257, available at http://jama.jamanetwork.com/article.aspx?volume=306&issue=11&page=1256.

C. Although No Accommodation Is Necessary or Desirable, if the Departments Decide One Will Be Granted, There Are Numerous Models Available

Opponents of the Contraception Benefit blithely dismiss the notion of compromise, calling suggestions by the Departments unworkable without offering a meaningful alternative. In its comment on the accommodation, the United State Conference of Catholic Bishops rejects every possible permutation in which a religious organization's health plan facilitates access to contraception, arguing that it is simply unacceptable for a Catholic organization to in any way provide a "conduit" to contraception coverage for employees. In reality, however, examples of accommodations abound in related contexts that could serve as models for this benefit.

For example, Catholic health insurance companies have been providing or arranging for contraceptive coverage for years. A 2000 survey found that half of Catholic managed care plans were providing contraceptive coverage for enrollees; almost half covered tubal ligations. Due to their desire to enter this market, plans have devised various ways of providing these needed services despite the religious teachings of the church, including contracting with non-Catholic providers to provide the services; arranging for the funds received from the employer or government program that pay for contraception to go to a third-party administrator; or arranging with another insurer to handle payment and provision of contraception.[44]

In addition, many Catholic health plans participate in the Medicaid program, in which coverage for contraception/family planning is not only a mandatory service, but one that must be provided to enrollees without cost sharing (and therefore is under similar parameters as the Contraception Benefit). Catholic Medicaid plans, like their commercial counterparts, have figured out ways to participate in this insurance program. For example, they form a partnership with a non-Catholic insurer that provides coverage for contraception, or set up a billing arrangement in which funds for family planning go to a third party that, in turn, pays claims for contraceptive services and supplies.

These arrangements demonstrate that Catholic insurers have little difficulty administering health care coverage that includes contraception. Moreover, they belie the loud complaints by opponents of the rule and new accommodation that even being associated with a plan that includes contraceptive coverage is an assault on religious freedom. Catholic health plans have voluntarily entered the Medicaid managed care market with full knowledge that family planning is a covered service. These plans have not deemed the program so problematic that they refuse to participate in the overall Medicaid program. Instead, they simply devised administrative workarounds to avoid directly paying for contraception while still affording their enrollees access to that coverage, as required by law.[45]

Some objectors to the Contraception Benefit 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. In light of the Catholic Bishops' implied

[44] Catholics for Choice, "Catholic HMOs and Reproductive Health Care," 2000.

[45] For further explication of this point and additional examples of compromises that have been implemented around the nation we refer the Departments to the comments submitted on this ANPRM by MergerWatch.

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.[46] The reality is that while religiously affiliated institutions frequently *threaten* to close their doors in the face of having to comply with secular rules, these threats are rarely carried out. Rather, organizations figure out a way to work within the system by devising solutions that all parties can live with. This program would be no different.

Should the Departments conclude that an accommodation for non-exempted non-profit religious employers will be adopted, many examples of workable compromises exist that could serve as models for objecting religious employers who evidence a willingness to compromise. Their role as public facing institutions in a pluralistic society requires no less.

II. The Exemption Should Not Be Expanded

The Catholic Health Association (CHA) suggests in its letter that, rather than crafting an accommodation for non-exempted religious employers, the Departments should instead expand the existing exemption, which currently includes only houses of worship, to include a vast array of other institutions with varying degrees of religious affiliation. Specifically, CHA suggests allowing an undefined new universe of entities to qualify for the accommodation, using concepts from the definition of "church plan" in ERISA and the Internal Revenue Code as a starting point. This suggestion should be rejected.

The existing church plan definition itself would be unacceptably broad, and the proposed CHA definition renders it even broader and more open-ended. In fact, expanding the existing exemption would run afoul of the First Amendment's Establishment Clause, which prohibits the government from subjecting a public benefit to religious restrictions and forbids religious exemptions that impose costs on third parties. Additionally, neither the existing exemption nor any future accommodation should be extended to for-profit employers.

A. Expanding the Exemption Would Violate the Establishment Clause

One of the primary evils the Establishment Clause is designed to combat is the "active involvement of the sovereign in religious activity."[47] That is precisely what is at issue here, where the government is seeking to delegate its authority to religious institutions. The government, through a transparent, scientifically rigorous process, has determined that it has a compelling interest in ensuring that women have access to FDA-approved contraceptives without affordability barriers. An expanded exemption would allow religiously affiliated employers to interpose themselves between this benefit and the intended recipients – their employees. But the Supreme Court has made clear that the government may not delegate to a religious organization the decision of whether or not to extend a benefit.

---

[46] Lois Uttley & Ronnie Pawelko, *No Strings Attached: Public Funding of Religiously-Sponsored Hospitals in the United States*, (2002), at 5.
[47] *Comm. For Public Educ. and Religious Liberty v. Nyquist*, 413 U.S. 756, 772 (1973).

For example, in *Larkin v. Grendel's Den, Inc.*,[48] the Supreme Court overturned a statute that allowed religious institutions to veto liquor licenses within a 500-foot radius from the house of worship. In so holding, the Court held that the liquor law unconstitutionally delegated state power to a religious institution.[49] In particular, the *Larkin* court noted that the statute in question "delegate[ed] important…governmental powers to religious bodies," thus "impermissibly entangling government and religion."[50]

More recently, in *Board of Education of Kiryas Joel Village School District v. Grumet*,[51] the Supreme Court invalidated a statute creating a special school district for a religious community. At issue, the Court's plurality opinion explained, was the fact that the statute "deleg[ated] the State's discretionary authority…to a group defined by its character as a religious community."[52]

The greater the extent of the exemption, the greater the scope of impermissible delegation of authority. Indeed, vesting a religious entity with secular authority – ceding implementation of the preventive-services mandate to religious institutions – strikes at the very core of the anti-establishment principle dating back to Jefferson's original *Memorial and Remonstrance Against Religious Assessments*: "The core of that principle…is that 'no man shall be compelled to frequent or support any religious worship, place, or ministry whatsoever…"[53] The exemption, by forcing employees to live out the religious beliefs of their employers – notwithstanding a national government requirement to provide no-copay contraception – violates the Establishment Clause.

The economic impact of an expanded religious exemption would be to impose a *de facto* tax in the amount of the cost of contraception on those working for religiously affiliated employers. This is because *only* employees at religiously affiliated entities would pay for their contraception out-of-pocket – a cost that the Institute of Medicine recommendation demonstrated is sometimes prohibitive. And, conversely, all religious employers would receive a *de facto* tax benefit – the savings from not having to pay for contraceptive coverage.

Courts have struck down religious exemptions that exact a toll on third parties as this one does. This was precisely the Supreme Court's holding in *Texas Monthly v. Bullock*.[54] In *Texas Monthly*, the Court struck down a Texas sales tax exemption for religious periodicals. In so doing, the Court rejected the state's argument that a tax exemption was constitutionally required to avoid a Free Exercise violation. In a critical footnote, the Court explained that the Constitution does not, *per se*, prohibit religious exemptions to generally applicable laws, and listed several examples of permissible exemptions, such as an exemption to the military-dress requirement allowing religious adherents to wear certain headgear or other attire. However, the Court emphasized that the common thread in these permissible exemptions was that they "did not, or would not, impose substantial burdens on non-beneficiaries while allowing others to act

[48] 459 U.S. 116 (1982).
[49] *Id.* at 122.
[50] *Id.* at 126.
[51] 512 U.S. 687 (1994).
[52] *Id.* at 696.
[53] Thomas Jefferson, *Memorial and Remonstrance Against Religious Assessments*, *quoted in Comm. For Public Educ. and Religious Liberty v. Nyquist*, 413 U.S. 756, 770 n.28 (1973).
[54] 489 U.S. 1 (1989).

according to their religious beliefs…nor [would they] impose monetary costs on [those] who opposed…the religious instruction…"[55]

Whereas there is no cost – economic or otherwise – of allowing, for example, Jewish soldiers to wear a yarmulke, there is a significant cost associated with allowing a broad exemption for religiously affiliated institutions – one that these institutions will pass on to their employees. Indeed, the broad religious exemption sought by religious charities and hospitals would impose both "substantial burdens" *and* "monetary costs" on nonbelievers by stripping them of a critically important health benefit, and forcing them to pay for contraception out of pocket.

Not only does allowing an institutional employer's "conscience" to trump employees' conscience right violate the Establishment Clause, it is also fundamentally unfair. The proposed rule would not require any employer to purchase contraception – it only requires that employers offer coverage for those services – allowing each employee's conscience to determine whether she wishes to avail herself of the benefit or not. It is particularly unfair, given that affordability remains a significant barrier to contraceptive access, to have a corporate employer's "conscience" trump the consciences of individual workers, and at the same time, jeopardize their health.

As stated by the Departments when the final rule was issued on the exemption:

> A broader exemption, as urged by some commenters, would lead to more employees having to pay out of pocket for contraceptive services, thus making it less likely that they would use contraceptives, which would undermine the benefits described above. Employers that do not primarily employ employees who share the religious tenets of the organization are more likely to employ individuals who have no religious objection to the use of contraceptive services and therefore are more likely to use contraceptives. Including these employers within the scope of the exemption would subject their employees to the religious views of the employer, limiting access to contraceptives, and thereby inhibiting the use of contraceptive services and the benefits of preventive care.

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed Reg 8728 (February 15, 2012) (emphasis added). The Departments are thus already on record as opposing any expansion of the exemption, and that position should not change.

B. A Religious Exemption that Undermines Public Health Is Invalid

The Contraceptive Benefit is intended to promote women's and children's health – both of which have been recognized by the Supreme Court as compelling interests.[56] Excluding employees at

[55] *Id.* at 18 n.8. The lower courts have similarly looked at whether a religious exemption imposes a cost on third parties in determining whether it violates the Establishment Clause. *See, e.g.*, *Children's Healthcare is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084 (8th Cir. 2000); *Charles v. Verhagen*, 220 F. Supp. 2d 955 (W.D. Wis. 2002).
[56] For women's health, *see, e.g.*, *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *Stenberg v. Carhart*, 530 U.S. 914 (2000); for children's health *see, e.g.*, *Globe Newspaper Co. v. Superior Ct. for Norfolk Cty.*, 457 U.S. 596, 607 (1982), *quoted in PJ ex rel. Jensen v. Wagner*, 603 F.3d 1182, 1182 (10th Cir. 2010) (states have a "compelling

religiously affiliated institutions from receiving the Contraceptive Benefit would consequently jeopardize their health and well-being relative to employees at secular institutions, who will receive the Contraceptive Benefit. However, the Supreme Court has repeatedly emphasized that religious exemptions are impermissible where they threaten public health.

Thus in *Yoder*, the Supreme Court repeatedly emphasized that a religious exemption to the compulsory-attendance law would have no ill effects on Amish children: "There is no intimation that the Amish employment of their children on family farms is in any way deleterious to their health…"[57] Elsewhere in the decision, the Court exclaimed that "This case, of course, is not one in which any harm to the physical or mental health of the child or to the public safety, peace, order, or welfare has been demonstrated or may be properly inferred. The record is to the contrary, and any reliance on that theory would find no support in the evidence."[58]

Similarly, in *Gonzalez*, the Supreme Court emphasized that an exemption to the Controlled Substances Act for the sacramental use of an hallucinogenic tea would not jeopardize public health. Indeed, the Supreme Court emphasized the district court's finding that the evidence on health risks was "in equipoise."[59] The Court later downplayed the health risks of a religious exemption, holding that while Congress might have determined that while DMT might be dangerous in the abstract, that Congress never considered the "***particular*** use at issue here – the circumscribed, sacramental use of [DMT] by the [religious exemption-seekers]."[60]

In contrast, because the contraceptive use of employees of religiously affiliated institutions is not distinguishable from the contraceptive use of employees generally, the health impact of failing to extend the Contraception Benefit is identical for both groups. The government's compelling interest in extending the benefit to employees of secular organizations similarly applies to employees of religiously affiliated institutions.

C. For-Profit Employers Should Not Be Granted an Exemption

The Departments also seek comment as to whether for-profit religious employers with objections to the contraceptive coverage rule should be considered for the exemption. The Departments do not define what would constitute a for-profit religious employer, but a for-profit employer cannot be considered a religious organization.

Any for-profit business is, by definition, not organized for a religious purpose, and its employees (many of whom will likely not share the employer's religious beliefs) do not obtain employment on the grounds that they will adhere to or participate in a religious mission or a particular set of religious values. To expand the exemption to include such an employer would be to create an exception that swallows the rule.

---

interest in and a solemn duty to protect the lives and health of children within their borders). By promoting healthy birth spacing, the Contraceptive Benefit is intended to reduce the number of below-weight births.

[57] *Yoder*, 406 U.S. at 229.

[58] *Yoder*, 406 U.S. at 230.

[59] *Gonzalez*, 546 U.S. at 426.

[60] *Gonzalez*, 546 U.S. at 432 (emphasis added).

For-profit, secular companies and their religious owners would become laws unto themselves, able to claim a virtually unlimited number of exemptions from generally applicable commercial laws designed to improve the health and well-being of employees. Such a system would be unworkable; by extension, it would also completely deprive the government of any ability to solve national problems using generally applicable laws.

As discussed above, the government may substantially burden religious exercise under RFRA if it "(1) is in further of a compelling governmental interest; and (2) is the least restrictive means of further that compelling governmental interest."[61] In the case of the for-profit employer, however, the contraceptive coverage rule does not substantially burden religious exercise.[62]

Having chosen to enter the commercial marketplace and operate as a for-profit, secular employer, an organization may not style itself a religious organization by opting to impose the religious beliefs of its owner on its employees. As the Supreme Court has recognized, "[w]hen followers of a particular sect enter into commercial activity as a matter of choice, the limits they accept on their own conduct as a matter of conscience and faith are not to be superimposed on the statutory schemes which are binding on others in that activity."[63] Any burden placed on a for-profit business by the Contraception Benefit is the result of a "choice to enter into a commercial activity" that is regulated by generally applicable laws pertaining to employee welfare.[64]

Nor can a for-profit owner make the claim that his own, personal religious beliefs justify an exemption from the rule for his business. As the Supreme has recognized, "To strike down, without the most critical scrutiny, legislation which imposes only an indirect burden on the exercise of religion, *i.e*., legislation which does not make unlawful the religious practice itself, would radically restrict the operating latitude of the legislature."[65] Any burden placed on a for-profit business owner's personal religious exercise stems from obligations imposed on legally separate, secular entities: the applicable group health plan or insurance issuer and, to an even more attenuated degree, the business itself. This type of attenuated, indirect burden is not cognizable under RFRA.[66]

[61] 42 U.S.C. § 2000bb-1(b).
[62] *See Levitan v. Ashcroft*, 281 F.3d 1313, 1320 (D.C. Cir. 2002) ("[T]he practice[] at issue must be of a religious nature."); *see also Holy Land Found. For Relief & Dev. V. Ashcroft*, 219 F. Supp. 2d 57, 83 (D.D.C. 2002), *aff'd on other grounds*, 333 F.3d 156 (rejecting a FRFA claim because "nowhere in Plaintiff's Complaint does it content that it is a religious organization. Instead, [Plaintiff] defines itself as a 'non-profit charitable corporation,' without any references to its religious character or purpose.").
[63] *United States v. Lee*, 455 U.S. 252, 261 (1982).
[64] *See Swanner v. Achorage Equal Rights Comm'n*, 874 P.2d 274, 283 (Alaska 1994) (interpreting the Free Exercise Clause of the Alaska Constitution). *Cf. Roberts v. U.S. Jaycees*, 468 U.,S. 609, 635 (1984) (O'Connor, J., concurring) (observing in the First Amendment expressive association context that "[o]nce [an organization] enters the marketplace of commerce in any substantial degree it loses the complete control over its membership that it would otherwise enjoy if it confined its affairs to the marketplace of ideas").
[65] *Braunfeld v. Brown*, 366 U.S. 599, 606 (1961).
[66] Cases in which a substantial burden has been found uniformly involve a direct prohibition on the plaintiff rather than an indirect burden falling on some other person or entity. *See Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418 (2006); *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 (1983); *Potter v. District of Columbia*, 558 F.3d 542 (D.C. Cir. 2009).

For-profit employers voluntarily enter into the for-profit, commercial world and do so by forming legally separate business entities; to allow these employers to avoid facilitating conduct that they personally object to by picking and choosing the laws they comply with would be to abandon the rule of law as we know it.[67] Accordingly, the exemption should not be extended to include for-profit employers.

D. Expanding the Exemption Would Harm Women

It should be emphasized that the question of how many women will be denied the Contraception Benefit is no mere academic exercise. Denial of coverage for contraception works genuine harm to women. First, the number of women affected is significant. For example, Catholic hospitals employ nearly 800,000 people nationwide – 532,011 full-time employees and 237,657 part-time employees.[68] Many of these employees are not themselves Catholic – regardless, 98 percent of Catholic women use contraception.[69] 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.[70] Of these more than 300,000 employees, more than 150,000 work at Catholic schools.[71] 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.[72] 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,[73]

---

[67] Extending this rationale, any employer could object to paying a salary to employees that use their money in ways the employer does not approve of, or the employer could opt out of contributing to other forms of insurance or taxes that involve a conflict with his or her personal religious beliefs. Indeed, in concluding that the minimum coverage provision of the ACA did not substantially burden the plaintiffs in *Seven-Sky v. Holder*, the D.C. Circuit recently reasoned, among other things, that "Plaintiffs routinely contribute to other forms of insurance, such as Medicare, Social Security, and unemployment taxes, which present the same conflict with their belief that God will provide for their medical and financial needs." *Mead v. Holder*, 766 F. Supp. 2d 16, 42 (D.D.C. 2011). The court of appeals adopted the district court's substantial burden analysis. *See Seven-Sky v. Holder*, 661 F.3d 1, 5 n.4 (D.C. Cir. 2011).

[68] *Id.*

[69] 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.

[70] U.S. Dep't of Education, National Center for Education Statistics, *Characteristics of Private Schools in the United States: Results from the 2009-2010 Private 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.

[71] 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.

[72] 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...").

[73] 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/.

including 244 Catholic degree-granting institutions.[74] 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 no-copay access to contraception if the exemption were broadened.

Second, 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. Hackley Hospital in Muskegon, Michigan, was acquired by a Catholic health system, Trinity Health, in 2008. Employees there 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.[75]) 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?"

---

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

[75] YourContraception.com, *Tubal Ligation*, *available at* http://www.yourcontraception.com/birth-control-methods/tubal-ligation/tubal-ligation.html.

III. If an Accommodation Is Adopted, It Should Be Available to Employers That Cover Some, But Not All, Forms of Contraception

The Departments seek comment on whether religious organizations should be allowed to qualify for the accommodation with respect to some forms of contraception, while providing other forms of contraceptives without cost-sharing. While we believe that no accommodation is legally required, nor is allowing one good public health policy, should the Departments decide to adopt an accommodation, those objecting employers that are currently covering some forms of contraception but not others should be allowed to avail themselves of the accommodation if they otherwise qualify. Such employers could take the accommodation only for those forms of contraception to which they have a religious objection, or, for ease of plan administration, they could opt for the accommodation for all forms of contraception even if they were previously covering it.

We note that we are advocating for this position out of a desire for both ease of administration and to avoid penalizing those employers that have covered all but a few forms of contraception. We do so despite the fact that the reason some employers will cover most forms of contraception but not emergency contraception is the false assertion that emergency contraception is an "abortifacient drug."

The science shows that emergency contraception (EC) works primarily by preventing ovulation, not implantation of a fertilized embryo. But even if it were to prevent implantation, this still would not make EC an "abortion-inducing" drug because there can be no abortion without a pregnancy, which is defined as when implantation occurs. While those opposed to the Contraception Benefit are entitled to their own opinions and religious beliefs, they cannot manufacture their own medical facts. EC does not interfere with an established pregnancy, and is therefore not an abortifacient. As stated by the American College of Obstetricians and Gynecologists (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.[76]

The March 2012 mechanism of action fact sheet from the International Federation of Gynecology and Obstetrics concludes that levonorgestrel-only emergency contraceptive pills interfere with the process of ovulation and may possibly prevent the sperm and the egg from meeting but do not inhibit implantation and thus are in no way "abortion-inducing."

---

[76] 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[77] 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.

Some critics of the Contraception Benefit oppose it because it differs from most state contraceptive equity laws in that it includes sterilization. Inclusion of sterilization in the coverage requirement is appropriate and necessary, however, because it is a critically important method of contraception for many women.

Most state contraceptive coverage requirements use a parity approach -- requiring coverage of prescription contraception if a health insurance plan covers other forms of prescription drugs. As such, sterilization does not fall within the ambit of these coverage requirements. The Contraception Benefit, however, is not similarly limited, nor should it be.

The facts on sterilization clearly demonstrate the need for such coverage on a no-copay basis. American women rely increasingly on sterilization as a form of contraception as they age. In 2002, 50% of women 40 and older relied on this method.[78] Sterilization is more commonly used by women with higher numbers of children, and those with lower education and income.[79] One-half of women who choose sterilization have the procedure performed on an inpatient basis following childbirth. The other half have what are referred to as outpatient "interval" sterilizations, which take place six weeks or more postpartum, typically in an outpatient surgery center or physician office.[80]

Tubal sterilization following a cesarean section ("c-section") has the significant benefits of combining two surgical procedures into one, thereby lowering the woman's risk of complications, as well as shortening her recovery time, when compared with a c-section followed by an interval tubal sterilization. Post-partum sterilization is often recommended for women who have had three or more c-sections because these women face increased risk of significant pregnancy complications with a subsequent c-section delivery.

Despite the clinical importance of sterilization for many women – for some it can literally be life-saving – religious doctrine often impedes women's ability to obtain the procedure. Research by Dr. Lori Freedman reveals that the primary disadvantage of working in a Catholic hospital that was cited by physicians was an inability to perform sterilizations, particularly following a c-section delivery.[81]

This physician sentiment was borne out by fact-finding research conducted by the Center for Reproductive Rights in three communities in which previously secular hospitals came under

---

[77] Available at http://ec.princeton.edu/news/aap-ecstatement.pdf.
[78] Chan and Westoff, "Tubal sterilization trends in the United States," FERTILITY AND STERILITY (June 2010).
[79] Id.
[80] Id.
[81] Presentation at American Public Health Association annual meeting, November 1, 2011.

Catholic control. The explicit prohibition on tubal sterilization was overwhelmingly identified by physicians as the most significant change in women's access to reproductive healthcare services after the hospitals adopted the Religious and Ethical Directives for Catholic Healthcare. Because many women living in these predominantly low-income communities face significant barriers to leaving the community for care due to transportation and cost concerns, they cannot easily access services at other hospitals, even when it is available.

Our research revealed that many physicians were outraged by the blanket denial of sterilization following Catholic control of the hospital; a family physician who served on the Board of Directors of one hospital resigned in protest. Another physician described in vivid detail the impact of the denial of sterilization services required by strict adherence to Catholic doctrine:

> There are only so many c-sections a woman should have. With every one the next pregnancy is markedly compromised. [T]here's a higher risk the placenta can implant on the uterine scar … you can't get the placenta out, there's morbid hemorrhage [she demonstrates by turning on the faucet until the water runs vigorously]. …It's absolutely unconscionable … The Pope, the Cardinal, the Board is not going to be there, not going to be here when she is hemorrhaging, bloody, you can't see, it's horrible, the uterus is cut, she needs a massive transfusion. Six months later she still looks awful, like death warmed over; she can't take care of the little ones she has.[82]

Some providers retired from the practice of obstetrics or moved their practices to other communities because they felt that practicing under the Catholic healthcare directives required them to practice sub-standard medicine. Others risked disciplinary action (and the potential for loss of staff privileges and associated malpractice coverage) by doing tubal sterilizations after the prohibition went into effect, when their medical and ethical duties – and their consciences – would not allow them to follow hospital policy prohibiting performance of tubal sterilization.

The documented impact on patients was even harsher, and sometimes tragic. Some had to go to hospitals in other communities to deliver their babies so that they could have post-partum sterilizations, while others who lacked the ability to do this had to simply forego the procedure, even when future pregnancies were medically contraindicated. Physicians interviewed by the Center told stories of women who were unable to obtain sterilizations who subsequently became pregnant when they did not want to; one with six children died in childbirth. On top of the clinical problems presented by denying women access to sterilization, the impacted women also reported feelings of anger and disrespect at having their wishes overridden by a rigid and out-of-touch hospital policy. For women with difficulty accessing reversible contraceptive methods, or who lack control over their reproductive lives, sterilization is often the only viable option; making it unavailable can literally be fatal for some women.

These stories vividly illustrate how severely one-sided the discussion over so-called "conscience" protections has been in the context of women's reproductive healthcare. The primary concern has been over the consciences of a handful of religious institutions. Absent from

---

[82] Interview with Dr. Gwen Patterson, Sierra Vista Regional Health Center in Sierra Vista, Arizona, November 17, 2010.

the discourse is concern for the consciences of healthcare providers who seek to provide medically necessary care to their patients and who are prevented from doing so by religious – not medical – guidelines, and of the consciences of the individual women who need access to contraception to control their reproductive lives and manage their health. The consciences of those would refuse to provide legal, necessary healthcare should not be elevated over the consciences of doctors, nurses and others who seek to provide access to necessary services, or the consciences of the patients who rely on these providers for care and have a right to health and self-determination.

IV. The Departments Should Ensure That The Contraception Benefit Is Comprehensive

A. The Scope of Covered Contraceptive Services Should Include Methods Used by Men

The Departments have not yet issued guidance providing any details about what specific contraceptive methods, services or information are included in the contraceptive coverage requirement under Sec. 2713 of the Public Health Service Act. We are therefore concerned that the ANPRM states as settled fact—in a footnote, no less—that the requirement "excludes items and services such as vasectomies and condoms," presumably on the grounds that those items and services are used by men, rather than by women.

The question of whether these items and services are excluded from the contraceptive coverage requirement merits serious consideration and public comment. Other federal programs, most notably Medicaid, have long allowed for the coverage and provision of male condoms for female beneficiaries, by prescription. Moreover, vasectomies and male condoms—despite being used by men—offer their health benefits to men's female partners, and should be appropriately seen, therefore, as preventive services for women. Indeed, vasectomy's *only* health benefits accrue to women.

Even if the Departments determine conclusively that vasectomies and/or male condoms cannot be included under the Sec. 2713 requirement as women's preventive care, the Departments should be encouraging, not discouraging, insurance plans from covering those services without cost-sharing. Indeed, it would be a mistake for an insurance plan to provide a financial incentive via cost-sharing to couples to choose tubal ligation over vasectomy, given that vasectomy is less expensive, less invasive and has less risk of complications. Moreover, other sections of federal law, such as Title VII of the Civil Rights Act and Sec. 1557 of the ACA, could be interpreted as prohibiting health plans' disparate treatment of "male" contraceptive methods as sex discrimination.

B. The Use of Formularies Should Not Be Allowed to Undercut the Contraception Benefit

The ANPRM notes that "a number of questions have been raised about the scope and application of the contraceptive coverage requirement more generally." The notice goes on to mention the interim final regulations implementing section 2713 of the ACA, which address the use of "reasonable medical management techniques" in the context of covering preventive services. We would like to reiterate our concern, expressed previously in a separate letter to the Department, that drug formularies not undercut the clear value of the Contraception Benefit.

The Center is concerned that the value of the Contraception Benefit could be undermined by an overly restrictive interpretation of the allowed medical management techniques. So that this core benefit for women is not rendered hollow by insurer limitations, we encourage the Department to ensure that certain safeguards are put in place.

Due to the unique nature of contraception, it is important to cover a wide range of brands and formulations, as not all methods work equally well for all women. In addition, some women must use particular methods or medications due to other health conditions. And for some, the side effects mean they cannot tolerate certain methods or medications. Research also indicates that women and couples are more likely to use contraception successfully if given their contraceptive method of choice, thus coverage of a full range of contraceptive options is needed.[83]

In sum, hormonal contraceptives vary in their effectiveness in highly personal and medically important ways. It is essential that all methods be made available without cost sharing as the rule requires, as inconsistent use of contraception leads to numerous unintended pregnancies, the core problem that the requirement is designed to combat.

But within methods, the question as to the extent of coverage without cost sharing also arises. The Center encourages the Department to treat contraceptives in the same manner that HIV and certain other drugs are treated by the Medicare Part D program. Under Medicare Part D, prescription drug plans must cover all drugs in the antiretroviral drug class, along with five other drug classes, and they may not apply utilization management techniques (such as prior authorization) to such drugs. These "classes of clinical concern" are afforded such treatment because of the importance of matching patients to therapies that work best.

Given the fundamental importance of preventing unintended pregnancy, it is similarly critical that women have the ability to obtain the optimal method of birth control for their particular needs without cost sharing. Allowing insurers to cover only one or two formulations of oral contraceptives could render the benefit virtually meaningless for women who, for various reasons, cannot use those particular types of pills. It is essential that individual women and their physicians be able to determine the contraceptive method that is most suited for them to ensure maximum efficacy, and that they not have that choice artificially constrained by a restrictive formulary.

If, however, the Department concludes that it must permit health insurers to apply *some* limitations to the contraception requirement,[84] it must include strong protections for consumers in the rule. The Center urges the Department to ensure that, if health insurers are permitted to establish formularies for the FDA-approved contraceptive methods that must be covered without cost sharing, such formularies include a sufficient number of brand-name or generic products in each category of hormonal contraceptives and contraceptive devices (for example, monophasic,

---

[83] Noone J. *Finding the Best Fit: A Grounded Theory of Contraceptive Decision Making in Women*, Nursing Forum Oct-Dec 2004; 39(4); Henshaw SK. *Unintended pregnancy in the United States*. Family Planning Perspectives, 1998; 30:24-29.

[84] The regulations governing implementation of the preventive services rule, including the contraception requirement, are currently an interim final rule, and thus subject to modification. The Department is therefore able to adjust the "reasonable medical management" provision in the rule with respect to its applicability to contraception.

biphasic, triphasic and other forms of oral contraception). As is true in the Medicare Part D program, any contraception formularies should include within each therapeutic category and class at least two drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs.

In addition, insurers should be required to cover a medically necessary non-formulary product without cost sharing if prior authorization is obtained. These protections are similar to the requirements under federal law for Medicaid coverage of outpatient drugs. *See* 42 USC § 1396r-8(d)(4) (states offering coverage for outpatient drugs in their Medicaid programs may establish formularies if they permit coverage of an excluded drug pursuant to a prior authorization program that provides a response within 24 hours of an authorization request). The Medicare Part D program also requires access to non-formulary drugs when medically necessary through an exception process, and private insurance plans also typically include a similar process. Such an approach is consistent with the guidelines of medical professionals: "The American College of Obstetricians and Gynecologists supports patient or clinician requests for branded OCs or continuation of the same generic or branded OC if the request is based on clinical experience or concerns regarding packaging or compliance, or if the branded product is considered a better choice for that individual patient."[85]

If restrictive formularies are permitted, it is also important that the insurer pharmacy and therapeutics committee that make decisions about which contraceptive products to include on a formulary must include members who possess clinical expertise in contraception. With dozens of brands and generics on the market, the process must ensure that a sufficient number of different oral contraceptives be on a formulary to allow for the widest possible choice within those constraints. The process for selecting products for inclusion must be guided by medical experts with current knowledge of the state of the art in contraceptive options.

Finally, insurers should not be allowed to adopt “step therapy” as a medical management technique. This mechanism, also known as “fail first,” requires patients to try less expensive therapies before more expensive ones will be covered, and provides that only if the less expensive therapy proves ineffective will coverage for more costly alternatives be approved. In the case of contraception, even one act of sexual intercourse with no contraception or an ineffective method can result in a pregnancy. Restricting women to methods that they are unable to tolerate or use effectively, and requiring “failure” before granting access to more suitable methods, would be potentially disastrous, and would dramatically undercut the underlying goal of the rule – preventing unintended pregnancy.

V. Conclusion

The Department of Health and Human Services has taken a bold step forward for women’s health, equality, and autonomy by ensuring that employers (other than houses of worship) provide insurance coverage for all FDA-approved contraceptive methods and counseling without a copay. The Contraceptive Benefit will go a long way towards reducing America’s sky-high

[85] "Brand versus generic oral contraceptives." ACOG Committee Opinion No. 375. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2007; 110:447-8.

unintended pregnancy rate, improve women's and children's health, and promote healthy birth spacing.

The Contraceptive Benefit is constitutional and a permissible policy under the Religious Freedom Restoration Act (RFRA). The Administration's proposed accommodation for religiously affiliated institutions, while well-intended, is neither required by law nor sound policy -- nor does it appear to be acceptable to most religiously affiliated institutions.

The Center for Reproductive Rights therefore urges the Department to reconsider its proposed accommodation. Such an accommodation is not required by RFRA, because there is no substantial infringement on religious exercise, and because the government has a compelling interest in ensuring that all employees – including employees working for religiously affiliated institutions – have access to affordable contraception.

In addition, the Department must not consider expanding its already-generous religious exemption. Doing so would result in millions of women of all faiths (and none) losing access to affordable contraception based solely on their employers' religious dogma. Such a result would be contrary to public health and would subordinate government policy to individual employers' religious dictates – a result that offends both the Constitution and sound public policy.

Sincerely,

Laura MacCleery
Director of Government Relations

Julianna S. Gonen
Policy Counsel for Federal Legislation

Aram A. Schvey
Policy Counsel for Foreign Policy and Human Rights

Appendix

The Government's Compelling Interest in Universal Contraception Coverage

The following excerpts detail the government's compelling interest in ensuring that all women who wish to use contraception have access to it through no-cost insurance coverage. Footnotes have been omitted.

I. Institute of Medicine (IOM), *Clinical Preventive Services for Women: Closing the Gaps,*[86] pages 102-110

PREVENTING UNINTENDED PREGNANCY AND PROMOTING HEALTHY BIRTH SPACING

Unintended pregnancy is highly prevalent in the United States. In 2001, an estimated 49 percent of all pregnancies in the United States were unintended— defined as unwanted or mistimed at the time of conception— according to the National Survey of Family Growth (Finer and Henshaw, 2006). The unintended pregnancy rate is much lower in other developed countries (Trussell and Wynn, 2008). In 2001, 42 percent of U.S. unintended pregnancies ended in abortion (Finer and Henshaw, 2006). Although 1 in 20 American women has an unintended pregnancy each year, unintended pregnancy is more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group (Finer and Henshaw, 2006).

The consequences of an unintended pregnancy for the mother and the baby have been documented, although for some outcomes, research is limited. Because women experiencing an unintended pregnancy may not immediately be aware that they are pregnant; their entry into prenatal care may be delayed, they may not be motivated to discontinue behaviors that present risks for the developing fetus; and they may experience depression, anxiety, or other conditions. According to the IOM Committee on Unintended Pregnancy, women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy (IOM, 1995).

A more recent literature review found that U.S. children born as the result of unintended pregnancies are less likely to be breastfed or are breastfed for a shorter duration than children born as the result of intended pregnancies and that mothers who have experienced any unwanted birth report higher levels of depression and lower levels of happiness (Gipson et al., 2008). Finally, a recent systematic literature review found significantly increased odds of preterm birth and low birth weight among unintended pregnancies ending in live births compared with pregnancies that were intended (Shah et al., 2008).

The risk factors for unintended pregnancy are female gender and reproductive capacity. Although certain subgroups of women are at greater risk for unintended pregnancy than others (e.g., women aged 18 to 24 years, unmarried women, women with low incomes, women who are

---

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

not high school graduates, and women who are members of a racial or ethnic minority group), all sexually active women with reproductive capacity are at risk for unintended pregnancy. In 2008, approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years) were estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant (Frost et al., 2010). More than 99 percent of U.S. women aged 15 to 44 years who have ever had sexual intercourse with a male have used at least one contraceptive method (Mosher and Jones, 2010).

Pregnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy). Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small for gestational age births (Conde-Agudelo et al., 2006; Fuentes-Afflick and Hessol, 2000; Zhu, 2005). In addition, women with certain chronic medical conditions (e.g., diabetes and obesity) may need to postpone pregnancy until appropriate weight loss or glycemic control has been achieved (ADA, 2004; Johnson et al., 2006). Finally, pregnancy may be contraindicated for women with serious medical conditions such as pulmonary hypertension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and for women with the Marfan Syndrome (Meijboom et al., 2005; Regitz-Zagrosek et al., 2008; Warnes, 2004).

Existing Guidelines and Recommendations

Numerous health care professional associations and other organizations recommend the use of family planning services as part of preventive care for women, including ACOG, AAFP, the American Academy of Pediatrics (AAP), the Society of Adolescent Medicine, the AMA, 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 (Johnson et al., 2006).

The USPSTF does not address prevention of unintended pregnancy. Bright Futures recommends that information about contraception be offered to all sexually active adolescents and those who plan to become sexually active (AAP, 2008).

The IOM Committee on Women's Health Research recently identified unintended pregnancy to be a health condition of women for which little progress in prevention has been made, despite the availability of safe and effective preventive methods (IOM, 2010b). 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 (IOM, 2010b). Another IOM report on unintended pregnancy recommended that "all pregnancies should be intended" at the time of conception and set a goal to increase access to contraception in the United States (IOM, 1995). *Healthy People 2020* (HHS, 2011a), which sets health goals for the United States, includes a national objective of increasing the proportion of pregnancies that are intended from 51 to 56 percent. In addition, *Healthy People 2020* sets goals to increase the number of insurance plans that offer contraceptive supplies and services, to reduce the proportion of pregnancies conceived within 18 months of a previous birth, and to increase the

proportion of females or their partners at risk of unintended pregnancy who used contraception during the most recent sexual intercourse (HHS, 2011a).

Effective Interventions

Family planning services are preventive services that enable women and couples to avoid an unwanted pregnancy and to space their pregnancies to promote optimal birth outcomes. A wide array of safe and highly effective FDA-approved methods of contraception is available, including barrier methods, hormonal methods, emergency contraception, and implanted devices; sterilization is also available for women and for men (FDA, 2010). This range of methods provides options for women depending upon their life stage, sexual practices, and health status. Some methods, such as condoms, spermicides, and emergency contraceptives, are available without a prescription, whereas the more effective hormonal and long-acting reversible methods, such as oral contraceptives and intrauterine devices, are available by prescription or require insertion by a medical professional. Sterilization is a surgical procedure. For women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated. These can be assessed clinically so that an appropriate method can be elected for the individual (CDC, 2010; Dragoman et al., 2010).

The effectiveness of contraceptives is determined by studying the rate of failure (i.e., having an unintended pregnancy) in the first year of use (Table 5-3). The failure rates of all FDA-approved methods in both U.S. and international populations have been well documented and are negligible with proper use (Amy and Tripathi, 2009; Hatcher et al., 2007; Kost et al., 2008; Mansour et al., 2010). Female sterilization, the intrauterine device, and the contraceptive implant have failure rates of 1 percent or less in the first 12 months of use (Fu et al., 1999; Hatcher et al., 2007). Injectable and oral contraceptives have use failure rates of seven and 9 percent, respectively, because some women miss or delay an injection or pill (Kost et al., 2008). Failure rates for both male and female condoms and other barrier methods are higher (e.g., 15 percent for the male condom) (Amy and Tripathi, 2009). These rates compare with an 85 percent chance of an unintended pregnancy within 12 months among couples using no method of contraception (Hatcher et al., 2007; Trussell and Kost, 1987).

In addition to this evidence of method effectiveness, evidence exists that greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally. Studies show that as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined (Boonstra et al., 2006). Other studies show that increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use (Santelli and Melnikas, 2010).

As with all pharmaceuticals and medical procedures, contraceptive methods have both risks and benefits. Side effects are generally considered minimal (ACOG, 2011a,b,c; Burkman et al., 2004). Death rates associated with contraceptive use are low and, except for oral contraceptive users who smoke, lower than the U.S. maternal mortality rate (Hatcher et al., 1998). For example, the oral contraceptive death rate per 100,000 users under the age of 35 years who are

nonsmokers was 1.5 per 100,000 live births (Hatcher et al., 1998), compared with 11.2 maternal deaths per 100,000 live births in 2006 (age adjusted) (CDC, 2010c).

Contraceptive methods often have benefits separate from the ability to plan one's family and attain optimal birth spacing. For example, the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain (ACOG, 2010a). Long-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).

Education and counseling are important components of family planning services because they provide information about the availability of contraceptive options, elucidate method-specific risks and benefits for the individual woman, and provide instruction in effective use of the chosen method (NBGH, 2005; Shulman, 2006). Research on the effectiveness of structured contraceptive counseling is limited (Halpern et al., 2006; Lopez et al., 2010b; Moos et al., 2003). However, studies show that postpartum contraceptive counseling increases contraceptive use and decreases unplanned pregnancy (Lopez et al., 2010a), that counseling increases method use among adolescents in family planning clinics (Kirby, 2007), that counseling decreases nonuse of contraception in older women of reproductive age (35 to 44 years) who do not want a future baby (Upson et al., 2010), and that counseling of adult women in primary care settings is associated with greater contraceptive use and the use of more effective methods (Lee et al., 2011; Weisman et al., 2002).

Although it is beyond the scope of the committee's consideration, it should be noted that contraception is highly cost-effective. The direct medical cost of unintended pregnancy in the United States was estimated to be nearly $5 billion in 2002, with the cost savings due to contraceptive use estimated to be $19.3 billion (Trussell, 2007). The cost-effectiveness of family planning is also documented in an evaluation of FamilyPact, California's 1115 Medicaid Family Planning Waiver Program. The unintended pregnancies averted in this program in 2002 would have cost the state $1.1 billion within two years, and $2.2 billion within five years, for public-sector health and social services that otherwise would have been needed (Amaral et al., 2007).

In a study of the cost-effectiveness of specific contraceptive methods, all contraceptive methods were found to be more cost-effective than no method, and the most cost-effective methods were long-acting contraceptives that do not rely on user compliance (Trussell et al., 2009). The most common contraceptive methods used in the United States are the oral contraceptive pill and female sterilization. It is thought that 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—might help further reduce unintended pregnancy rates (Blumenthal et al., 2011). Cost barriers to use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods and sterilization have high up-front costs (Trussell et al., 2009).

Contraceptive coverage has become standard practice for most private insurance and federally funded insurance programs. For example, contraceptive services are covered for all federal employees and individuals who obtain their care through federally financed programs, such as VA, TRICARE for active-duty military and their dependents, and IHS. Federal programs provide funding for family planning services in community health centers through the Public Health Service Act, in family planning centers through Title X [Population Research and Voluntary Family Planning Programs (P.L. 91-572)], through the Maternal and Child Health Block Grant, and through the Medicaid program.

Since 1972, Medicaid, the state-federal program for certain low-income individuals, has required coverage for family planning in all state programs and has exempted family planning services and supplies from cost-sharing requirements. In addition, 26 states currently operate special Medicaid funded family planning programs for low-income women who either no longer qualify for Medicaid or do not meet the program's categorical requirements.

In Massachusetts, family planning services with no copayments will be included as part of the preventive benefits offered to members of Commonwealth Care, a program of subsidized health insurance for low and moderate-income people (Personal communication, Stephanie Chrobak and Nancy Turnbull, Massachusetts Health Connector, May 10, 2011). Private employers have also expanded their coverage of contraceptives as part of the basic benefits packages of most policies. This expansion has occurred in response to state and federal policies. Twenty-eight states now have regulations requiring private insurers to cover contraceptives, and 17 of these states also require that insurance cover the associated outpatient visit costs (Guttmacher Institute, 2011) (see Chapter 3). A federal court ruling issued in 2000 by the Equal Employment Opportunity Commission found an employer's failure to cover prescription contraceptive drugs and devices in a health plan that covers other drugs, devices, and preventive care to be discrimination against women in violation of Title VII of the Civil Rights Act (EEOC, 2000).

In 2007, NBGH 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. The Guttmacher Institute also calls comprehensive coverage of contraceptive services and supplies "the current insurance industry standard," with more than 89 percent of insurance plans covering contraceptive methods in 2002 (Camp, 2011). A more recent 2010 survey of employers found that 85 percent of large employers and 62 of small employers offered coverage of FDA-approved contraceptives (Claxton et al., 2010).

Despite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years. In fact, a review of the research on the impact of cost sharing on the use of health care services found 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 (Hudman and O'Malley, 2003).

Even small increments in cost sharing have been shown to reduce the use of preventive services, such as mammograms (Trivedi et al., 2008). The elimination of cost sharing for contraception therefore could greatly increase its use, including use of the more effective and longer-acting

methods, especially among poor and low-income women most at risk for unintended pregnancy. A recent study conducted by Kaiser Permanente found that when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods (Postlethwaite et al., 2007).

Identified Gaps

Contraception and contraceptive counseling are not currently in the array of preventive services available to women under the ACA. Systematic evidence reviews and other peer-reviewed studies provide evidence that contraception and contraceptive counseling are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020* (HHS, 2000, 2011a).

Recommendation 5.5: The committee recommends for consideration as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

II. Comments on Interim Final Rules on Preventive Services (CMS-9992-IFC2) Submitted to the Departments in September 2011

1. American Congress of Obstetricians and Gynecologists (ACOG), 9/29/11, page 2

We fully support the Institute of Medicine's finding that family planning is an essential part of basic preventive health care for women, especially for the two-thirds of American women of reproductive age who wish to avoid or postpone pregnancy. Access to family planning counseling and a full array of family planning services—including permanent contraception—is vital for women's health and well-being. By helping women control the timing, number, and spacing of births, family planning has many benefits for a woman and children she may have in the future. Planned pregnancies—which for most women require contraception— allow women to optimize their own health before pregnancy and childbirth. An unintended pregnancy may have significant implications for a woman's health, sometimes worsening a preexisting health condition such as diabetes, hypertension, or coronary artery disease. Planned pregnancies improve the health of children as well, as adequate birth spacing lowers the risk of low birth weight, preterm birth, and small-for-gestational age. The United States has the highest rate of unintended pregnancy in the developed world; approximately half of all pregnancies are unintended. Unintended pregnancies can also result in tremendous individual and societal consequences including family upheaval, nonattainment of educational goals, and financial burdens.

2. Guttmacher Institute. 9/30/11, pages 6-11

The Preventive Benefits of Contraceptive Services and Supplies

This is not the first time that the Institute of Medicine has considered contraception and unintended pregnancy in the United States. In a 1995 report, *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families*, the Institute's Committee on Unintended Pregnancy described in detail the potential consequences of unintended pregnancy and the importance of contraceptive use for preventing them. That report linked unintended pregnancy to a wide array of health, social and economic consequences, from delayed prenatal care and poor birth outcomes to maternal depression and family violence to a failure to achieve educational and career goals. And, indeed, one of its key recommendations for addressing unintended pregnancy was the same as our recommendation today: to reduce "financial barriers" to contraceptive use by "increasing the proportion of all health insurance policies that cover contraceptive services and supplies, including both male and female sterilization, with no copayments or other cost-sharing requirements, as for other selected preventive health services."

A 2009 report from another Institute of Medicine panel, this one assigned to review the Title X national family planning program, echoed the 1995 report's findings about the risks of unintended pregnancy and also emphasized the importance of birthspacing in preventing such complications as low birth weight and premature birth. A considerable amount of new research on these subjects has been published since the 1995 report, and the overall conclusions are well established: Contraceptive services and supplies are effective in helping women and couples time and space their pregnancies, and that in turn has important health, social and economic benefits.

Preventing Unintended Pregnancy and Helping Women Plan and Space Pregnancies

• *Contraceptive methods are highly effective for the prevention of pregnancy.*

The Food and Drug Administration has approved a wide range of contraceptive methods for preventing unintended pregnancy. All of these methods, if used perfectly, would have negligible failure rates. In practice, methods vary in how effective they are, with methods that require more user involvement having higher "typical use" failure rates than those that require less. Still the use of any method is still far more effective than using no method at all, since couples using no method of contraception have approximately an 85% chance of an unintended pregnancy within 12 months.

Female and male sterilization, the IUD and the implant all have typical use failure rates of 1% or less, meaning that couples have a 1% or less change of an unintended pregnancy within the first 12 months of using them. The typical use failure rates for injectable and oral contraceptives are 7% and 9%, respectively, due to some women missing or delaying an injection or pill. The probability of failure for couples using condoms (17%) is somewhat higher, again primarily due to imperfect use of the method. And, the failure rate for couples using fertility-awareness-based methods results is even higher (25%), although use of such methods is still far more effective than using no method at all.

- *Contraceptive use reduces the occurrence of unintended pregnancy and abortion.*

The effectiveness of contraceptive use for individual women and couples translates into lower rates of unintended pregnancy and subsequent abortion among the broader population. Cross-country comparisons provide some evidence for this relationship: Unintended pregnancy in the United States is higher than in other developed countries, and contraceptive use is lower. Whereas 49% of pregnancies in the United States are unintended, the corresponding percentage in France is only 33%, and in Edinburgh, Scotland, it is only 28%. Compared with the United States, these countries have much lower proportions of women at risk for unintended pregnancy who use no contraception at all; while this figure is 11% in the United States, it is only 3% in France and 3% in the United Kingdom.

International comparisons also provide evidence that contraceptive use reduces women's recourse to abortion. A 2005 analysis of trends in central Asia and eastern Europe, for example, found that as use of modern contraceptive methods increased rapidly in those regions during the 1990s, abortion rates declined significantly, even as fertility rates and the number of children desired also declined. A 2010 study focusing on the nation of Georgia found that the increased use of modern contraception was a significant contributor to that country's drop in abortion rates between 1999 and 2005, explaining 54% of the decline.

Trends in unintended pregnancy rates in the United States provide further evidence of the effectiveness of contraceptive use. The proportion using contraceptives among unmarried women at risk of unintended pregnancy increased from 80% in 1982 to 86% in 2002; this increase was accompanied by a decline in unmarried women's unintended pregnancy and abortion rates over the same period, with the abortion rate for unmarried women falling from 50 per 1,000 women in 1981 to 34 per 1,000 in 2000.

Similarly, increased contraceptive use led to a decline in the risk of pregnancy among adolescents. One study found that from 1991 to 2003, contraceptive use improved among sexually active U.S. high school students, with an increase in the proportion reporting condom use at last sex (from 38% to 58%), and declines in the proportions using withdrawal (from 19% to 11%) and no method (18% to 12%); these adolescents' risk of pregnancy declined 21% over the 12 years. Another study found that increased contraceptive use was responsible for 77% of the sharp decline in pregnancy among 15–17-year-olds between 1995 and 2002 (decreased sexual activity was responsible for the other 23%); and increased contraceptive use was responsible for all of the decline in pregnancy among 18–19-year-olds.

Contraception's impact on unintended pregnancy can be seen in the accomplishments of federal and state programs providing public funding for family planning services. More than nine million clients received publicly funded contraceptive services in 2006, and that national effort helped women avoid 1.94 million unintended pregnancies, including 810,000 abortions. By facilitating access to a more effective mix of contraceptive methods, publicly funded family planning centers enable their clients to have 78% fewer unintended pregnancies than are expected among similar women who do not use or do not have access to these services. Indeed, in the absence of this public effort, levels of unintended pregnancy and abortion would be nearly two-thirds higher among U.S. women overall and close to twice as high among poor women. Similar results have been found through evaluations of specific state programs. For example,

California's Family PACT program, which provides expanded access to family planning services under Medicaid,

Guttmacher Institute 4 January 12, 2011 provided contraceptives to nearly one million women in 2007, and helped them avoid 287,000 unintended pregnancies, including 79,000 to teenagers, and as a result, 118,200 abortions

• *Contraceptive use helps women and couples time and space their births.*

Medicaid family planning eligibility expansions that have been implemented in about half the states also provide evidence of the effectiveness of contraceptive use in helping women avoid short intervals between births, thereby reducing the risk of poor birth outcomes (see Improving Maternal and Child Health, below). In Arkansas, repeat births within 12 months dropped 84% between 2001 and 2005 for women enrolled in the family planning expansion, and the proportion having a repeat delivery within 48 months fell by 31%. In New Mexico, women accessing family planning services under the expansion were less likely to have a repeat delivery within 24 months than were women who did not access expansion services, 35% compared with 50%. In Rhode Island, the proportion of mothers on Medicaid with birth intervals of less than 18 months fell from 41% in 1993 to 28% in 2003, and the gap between privately insured and publicly insured women narrowed from 11 percentage points to less than one point. And in Texas, 18% of expansion participants had a repeat birth within 24 months, compared with 29% of Medicaid-eligible women who did not participate in the program.

Improving Maternal and Child Health

• *Helping women and couples time and space their pregnancies improves birth outcomes.*

The most direct, positive effects of helping women and couples plan the number and timing of their pregnancies and births are those related to improving birth outcomes. Short birth intervals have been linked with numerous negative perinatal outcomes. U.S. and international studies have found a causal link between the interpregnancy interval (the time between a birth and a subsequent pregnancy) and three major measures of birth outcomes: low birth weight, preterm birth and small size for gestational age. For this reason, contraceptive use to help women achieve optimal spacing is important to help them improve their infants' health.

- *Planned and wanted pregnancies improve pregnancy-related behavior and outcomes.*

Unintended pregnancy has also been linked with a range of negative outcomes, particularly in regard to maternal behavior. A comprehensive review of the literature from 2008 reports that numerous U.S. and European studies have found a significant association between pregnancy intention and delayed initiation of prenatal care. This stems in part from the fact that women are less likely to recognize a pregnancy early (within the first six weeks) if it is unplanned. Early recognition of pregnancy also affects the frequency of prenatal care visits, although after controlling for early recognition, pregnancy intention itself does not.

According to the same literature review, nearly all the relevant U.S. and European studies have found that children who are born from unintended pregnancies are less likely to be breastfed and are more likely to be breastfed for a shorter duration, compared with children whose births were

intended. Breastfeeding, in turn, has been linked with numerous positive outcomes throughout a child's life.

Moreover, although evidence is limited, several studies from the United States, Europe and Japan suggest an association between unintended pregnancy and subsequent child abuse. There is also some evidence of an association between unintended pregnancy and maternal depression and anxiety, although the strength of this finding is limited by poor study design.

By contrast, maternal risk behaviors, receipt of preventive and curative care during infancy and childhood, and birth outcomes (e.g., low birth weight and premature delivery) are not strongly related to pregnancy intention, as measured by the mother's preferences, once family-background variables are included.

There is some evidence, however, that the father's intention status has significant effects on prenatal behaviors and some measures of child health. Several studies have found that unintendedness of the pregnancy by the father has negative effects on the father's involvement during pregnancy and post-birth. The level of father involvement during pregnancy, in turn, is associated both with the mother's receipt of prenatal care and the likelihood of the mother reducing smoking during pregnancy. And parental discordance in pregnancy intentions can have adverse effects. In particular, infants born to mothers and fathers who differed in their pregnancy intention face significantly higher risks of several adverse maternal behaviors and birth outcomes than those born to parents both intending the birth.

Securing Additional Health, Social and Economic Benefits

• *Preventing unintended pregnancy can reduce risks to relationship stability.*

There is also some evidence that unintended pregnancy has significant negative effects on relationship stability. Both marriages and cohabitations are more likely to dissolve after an unintended first birth than after an intended first birth, even after controlling for a range of socio-demographic variables.

Moreover, mothers and fathers who have an unplanned birth report less happiness and more conflict in their relationship and more depressive symptoms for the mother, compared with similar women and men who have a planned birth. Unintendedness of the pregnancy by the father, in particular, is associated with greater relationship conflict and has very slight (though statistically significant) negative effects on children's attachment security and mental proficiency.

• *Prevention of unintended pregnancy with increased access to effective contraception improves social and economic conditions for women and society.*

Several studies have examined the role that contraceptive use has played in improvements in social and economic conditions for women. These studies have focused on oral contraceptives, the introduction of which in the 1960s marked the beginning of the era of modern contraceptive use. The pill remains the most popular form of reversible contraception in the United States today.

The advent of the pill allowed women greater freedom in career decisions in two main ways. The first is that having a reliable form of contraception allowed women to invest in higher education and a career with far less risk of an unplanned pregnancy. Secondly, the pill led to an increase in the age at first marriage across the total population; as a result, a woman could pursue a career or education before marrying while facing less of a risk that she would be unable to find a desirable husband later.

Researchers have been able to study these phenomena by looking at data over time and across states, taking advantage of changes in state policies during the late 1960s and early 1970s that lifted restrictions on access to the pill for young, unmarried women. One study found that legal access to the pill led to increased pill use and age at first marriage in these states, and in turn, increased these women's participation in the workforce. A second study concluded that legal access to the pill before age 21 significantly reduced the likelihood of a first birth before age 22, increased the number of women in the paid labor force and raised the number of annual hours worked. And a third study found that early legal access to the pill led to more children born to mothers who were married, college-educated and had pursued a professional career.

• *Contraceptive methods have additional health benefits unrelated to preventing and timing pregnancy.*

A 2010 practice bulletin from the American College of Obstetricians and Gynecologists summarizes a large body of literature discussing the noncontraceptive benefits of hormonal contraceptive methods. It finds that hormonal methods can help address several menstrual disorders, including dysmenorrhea (severe menstrual pain) and menorrhagia (excessive menstrual bleeding, which can lead to anemia if untreated). Methods that contain both estrogen and progesterone can address excess hair growth and acne. Hormonal contraceptives can also prevent menstrual migraines, treat pelvic pain due to endometriosis and treat bleeding due to uterine fibroids. Perhaps most notably, oral contraceptives have been shown to have clear, long-term benefits in reducing a woman's risk of developing endometrial and ovarian cancer, and to provide short-term protection against colorectal cancer.

And, of course, the male and female condom can help prevent sexually transmitted infections, including HIV, among sexually active women and men. According to the most recent summary of the evidence by the Centers for Disease Control and Prevention (CDC):

> Latex condoms, when used consistently and correctly, are highly effective in preventing the sexual transmission of HIV, the virus that causes AIDS. In addition, consistent and correct use of latex condoms reduces the risk of other sexually transmitted diseases (STDs), including diseases transmitted by genital secretions, and to a lesser degree, genital ulcer diseases. Condom use may reduce the risk for genital human papillomavirus (HPV) infection and HPV-associated diseases, e.g., genital warts and cervical cancer.

3. American Academy of Pediatrics (AAP), 9/27/2011, pages 3-4

Although adolescent pregnancy rates in the United States have decreased significantly over the past decade, births to adolescents remain both an individual and public health issue. An unintended pregnancy may have significant implications for an adolescent's physical and emotional health. As advocates for the health and well-being of all young people, the AAP

strongly supports the recommendation that adolescents postpone consensual sexual activity until they are fully ready for the emotional, physical, and financial consequences of sex. We recognize, however, that some young people will choose not to postpone sexual activity, and as health care providers, the responsibility of pediatricians includes helping teens reduce risks and negative health consequences associated with adolescent sexual behaviors, including unintended pregnancies and sexually transmitted infections. The AAP strongly encourages the use of contraception—including emergency contraception—by adolescents when prescribed and counseled by a pediatrician or other primary care physician in an appropriate and recommended manner. It is also important to note that, despite claims to the contrary, emergency contraception does not cause abortion and it is not teratogenic if taken in early pregnancy. Therefore, the Academy applauds the agency's adoption of the Institute of Medicine's recommendation that "all Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity" be covered as part of *HRSA's Women's Preventive Services*.

4. National Health Law Program (NHeLP), 9/30/11, pages 3-5

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

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

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

Low-income women are the least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy. On average, women generally have less income than men. Women earn only 78 cents for every dollar that men earn, and the median earnings of women working full time, year round, were $35,549 in 2009, compared to $45,485 for men. Women are more likely than men to forgo or postpone obtaining health care and treatment for themselves because of cost. Women of reproductive age spend 68 percent more in out-of-pocket costs than men, in part because of reproductive health-related needs.

Family planning services enable women to avoid unwanted pregnancies. In 2008, there were 66 million United States women of reproductive age (ages 13-44).Over half of them—36 million women—were in need of contraceptive services and supplies because they were sexually active with a male, capable of becoming pregnant, and neither pregnant nor seeking to become pregnant. Each year, nearly half of pregnancies in the United States are unintended—meaning they were either unwanted or mistimed. By age 45, more than half of all American women will have experienced an unintended pregnancy, and three in ten will have had an abortion. Current methods for preventing pregnancy include hormonal contraceptives (such as pills, patches, rings, injectables, implants, and emergency contraception), barrier methods (such as male and female condoms, cervical caps, contraceptive sponges, and diaphragms), intrauterine contraception, and male and female sterilization. The wide range of pregnancy prevention options allows a woman to choose the most effective method for her lifestyle and health status.

5. Healthcare for All New York 9/29/11, page 2

The Committee of IOM experts who produced the report conducted a comprehensive review of the evidence and recommended that contraceptive coverage should include the full range of contraception approved by the Food and Drug Administration. The evidence further shows that cost-sharing requirements, like co-payments, make people, especially low-income people, less likely to get health services, including preventive care and prescription drugs. In 2009, 30

percent of sexually active low- and middle-income women reported having put off a gynecology or birth control visit to save money; one-quarter of those who used the contraceptive pill reported saving money by using the method inconsistently. Additionally, research shows that in states that made it easier for low-income women to afford contraception by extending Medicaid family planning coverage to more people, there was a dramatic drop in the incidence of short birth intervals (a year or less between babies) for women in the program. Shorter times between a birth and a subsequent pregnancy make preterm birth and low birth weight more likely, which has serious negative consequences for the infants' health.

6. Physicians for Reproductive Choice and Health 9/30/11, page 2

Regular use of contraception prevents unintended pregnancy and reduces the need for abortion. Contraception also allows women to determine the timing and spacing of pregnancies, protecting their health and improving the well-being of their children. Contraceptive use saves money by avoiding the costs of unintended pregnancy and by making pregnancies healthier, saving millions in health care expenses. Several contraceptives also have non-contraceptive health benefits, such as decreasing the risk of certain cancers and treating debilitating menstrual problems. Making contraception more affordable is a significant step forward for the health of women and their families.

PRCH recognizes the importance of the Department's decision to include in the draft regulations the coverage of all forms of birth control, allowing patients access to the method that best meets their needs. Contraceptive methods vary and women with their health care providers need to be free to select from the full range of FDA-approved contraceptives. Not all contraceptives are clinically appropriate for every woman. We also know that women and couples are more likely to use contraception successfully when they are given their contraceptive method of choice, be it a birth control pill, a vaginal ring, or an intrauterine device (IUD).10 The draft regulations hold the promise of making contraception more affordable and easier to access for millions of women.

7. Raising Women's Voices et al., 9/30/11, pages 1-2; Women's Way, 9/30/11, pages 1-2

The Committee of IOM experts who produced the report conducted a comprehensive review of the evidence and recommended that contraceptive coverage should include the full range of contraception approved by the Food and Drug Administration. The evidence further shows that cost-sharing requirements, like co-payments, make people, especially low-income people, less likely to get health services, including preventive care and prescription drugs. In 2009, 30 percent of sexually active low- and middle-income women reported having put off a gynecology or birth control visit to save money; one-quarter of those who used the contraceptive pill reported saving money by using the method inconsistently. Additionally, research shows that in states that made it easier for low-income women to afford contraception by extending Medicaid family planning coverage to more people, there was a dramatic drop in the incidence of short birth intervals (a year or less between babies) for women in the program. Shorter times between a birth and a subsequent pregnancy make preterm birth and low birth weight more likely, which has serious negative consequences for the babies' health.

Even before the IOM reached this conclusion, there was already a strong public health consensus that contraception is an essential tool in preventing bad health outcomes for women and children. The Centers for Disease Control cites family planning as one of the top 10 public health achievements of the 20th century, noting that access to contraceptive services and supplies is responsible for expanding intervals between births, "contribut[ing] to the better health of infants, children and women."

8. Family Planning Advocates of NSY, 9/30/11, page 2

Contraception enables women to better prevent unintended pregnancy and plan and space pregnancy when they do want to have a child. When women plan their pregnancies, they are more likely to seek prenatal care, improving their own health and the health of their children. In addition, the ability to time and space pregnancy allows a woman to seek treatment for preexisting conditions, such as diabetes or hypertension, that may complicate pregnancy and compromise her health. The ability to plan pregnancy also reduces the risk of premature birth and low-birth weight. Given the significant impact of contraception in reducing unintended pregnancy, it is no surprise that access to family planning is directly linked to declines in maternal and infant mortality rates.

Contraception also provides other important health benefits for women, including reducing the risk of endometrial and ovarian cancers, ectopic pregnancy, iron deficiency anemia related to heavy menstruation, osteoporosis, ovarian cysts, and pelvic inflammatory disease. These are important preventive and life-saving benefits that should be made available to every woman.

9. American Civil Liberties Union (ACLU), 9/30/11, pages 4-5

Contraceptive Coverage Is Essential for Women's Health and Equality
Access to safe and effective contraception is a critical component of basic health care for women. Virtually all sexually active women use contraception over the course of their lives. Since 1965, when the U.S. Supreme Court first protected a woman‟s access to contraception, maternal and infant mortality rates have declined. Without contraception, women have more unplanned pregnancies and are less likely to obtain adequate prenatal care in a timely manner. Controlling pregnancy spacing affects birth outcomes such as low birth-weight and premature birth. Pregnancy planning can also help women control a number of conditions that negatively impact their health, such as gestational diabetes and high blood pressure.

Access to contraception gives women control of their fertility, enabling them to decide whether and when to become a parent. Contraception not only furthers the health of women and their children but equality as well, allowing women to make educational and employment choices that benefit themselves and their families. It is imperative that the benefits of access to birth control reach all women.

The HRSA Guidelines contraceptive coverage requirement is based on decades of experience with the benefits of family planning, recognized by the Centers for Disease Control and Prevention as one of the ten most significant public health achievements of the 20th century. In addition to the IOM, "[n]umerous health care professional associations and other organizations

recommend the use of family planning services as part of preventive care for women." Multiple federal programs promote contraception access.

The Women's Health Amendment, through the HRSA Guidelines, also builds on a network of state contraceptive coverage laws. Twenty-eight states require health plans that include prescription drug coverage to cover contraception. These laws were passed in response to decades of gender discrimination in the provision of health insurance; without contraceptive coverage mandates, women routinely pay more than men for their health care. Similarly, the Equal Employment Opportunity Commission has made clear that Title VII of the Civil Rights Act of 1964, which prohibits discrimination in employment on the basis of sex, requires employers to provide contraceptive coverage when they offer coverage for comparable drugs and devices.

The IOM found, however, that "[d]espite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years." Contraceptive copays can be so expensive that women can pay almost as much out-of-pocket as they would without coverage at all. These high costs have posed a substantial barrier to access and effective use. The cost of contraceptive methods can cause women to have gaps in their use of birth control, or to employ less effective methods with lower upfront costs like condoms, as opposed to long-acting reversible methods like the IUD. Eliminating cost-sharing increases use of these more effective methods.

10. Organizations and Communities of Faith, 9/30/11, pages 1-2

We believe that all women, regardless of income, should have access to medically accurate health education and services that help them stay healthy, prevent and treat HIV and other sexually transmitted diseases and avoid unintended pregnancy. When it comes to their own health care, women face a unique set of challenges because they use more health services than men yet earn less on average than men. As a result, women experience a high level of health care insecurity which leads many women to forgo necessary care because of prohibitive cost-sharing. A recent study by the Kaiser Family Foundation found that one in seven (14 percent) of women with private health insurance and nearly one-third (31 percent) of women covered by Medicaid either postponed or went without needed services in the past year because they could not afford them. Allowing some employers to opt out of fully covering contraceptive services, without patient cost-sharing or co-pay, would preserve an unacceptable, unjust status quo where many women lack access to critical preventive health care services due to cost.

11. Planned Parenthood of California, 9/30/11, page 2

Access to contraception improves health outcomes for women and their children, and provides the foundation for women's full participation in our society.
Contraception enables women to better prevent unintended pregnancy and plan for pregnancy when they do want to have a child. When women plan their pregnancies, they are more likely to seek prenatal care, improving their own health and the health of their children. In addition, the ability to time and space pregnancy allows a woman to identify and address pre-existing conditions, such as diabetes or hypertension, that may complicate pregnancy and compromise

her health. The ability to plan pregnancy also reduces the risk of premature birth and low-birth weight. Given the significant impact of contraception in reducing unintended pregnancy, it is no surprise that access to family planning is directly linked to declines in maternal and infant mortality rates.
Contraception also provides other important health benefits for women, including reducing the risk of endometrial and ovarian cancers, ectopic pregnancy, iron deficiency anemia related to heavy menstruation, osteoporosis, ovarian cysts, and pelvic inflammatory disease. These are important preventive and life-saving benefits that should be made available to every woman. Additionally, the ability to plan for pregnancy has economic implications for women and their families, as well. This has become crystal clear in our health centers as increasing numbers of newly unemployed women and men are seeking contraceptive care.

12. Planned Parenthood Federation of America (PPFA), 9/30/11, pages 1, 4-5

Nationally, ninety-seven percent of Planned Parenthood's services are focused on the preventive care that keeps people healthy, including routine gynecological exams, breast and cervical cancer screenings, contraceptive services, sexually transmitted infection ("STI") testing and treatment, immunizations, and HIV screening and education. At our nearly 800 health centers located nationwide, Planned Parenthood sees approximately three million patients, the vast majority of whom have incomes at or below 150 percent of the Federal Poverty Level. Because of the role we play in communities across the country, Planned Parenthood is all too aware of the critical need to expand health insurance coverage for women's basic preventive services…

These women use contraception because it enables them to better prevent unintended pregnancy and plan for pregnancy when they do want to have a child. When women plan their pregnancies, they are more likely to seek prenatal care, improving their own health and the health of their children. Access to family planning is directly linked to declines in maternal and infant mortality rates. In addition to the primary purpose of allowing women to plan and prepare for pregnancy, other health benefits of contraception include reduced risk of endometrial and ovarian cancers, ectopic pregnancy, iron deficiency anemia related to heavy menstruation, osteoporosis, ovarian cysts, and pelvic inflammatory disease. It is for all of these reasons that the Institute of Medicine recommended that HHS include the full range of contraceptive methods and counseling as a women's preventive service that must be covered by health plans without cost-sharing. The religious employer refusal in the Preventive Services Rule will limit the number of women who can reap these benefits.

To be clear, Section 2713 – and in fact, no provision of law – requires any individual who is opposed to contraception to obtain or use it. That decision is left to the individual. However, the Rule's religious employer refusal makes it more difficult for women to decide to use contraception because they will not have it paid for by their insurance. There can be no doubt that individuals are sensitive to prices for health services. In fact, a May 2007 report by the Commonwealth Fund found that more than half of women delayed or avoided preventive care because of cost. Additionally, an October 2010 survey showed that 34 percent of all women voters, and 55 percent of women between the ages of 18 and 34, have struggled with the cost of prescription birth control. Thus, those women left out by the religious employer refusal will be

much less likely to access contraception. They will not only lose the health benefits of contraception; they will also be at much greater risk of unintended pregnancy.

13. Society for Adolescent Health and Medicine (SAHM), 9/30/11, page 3

Although adolescent pregnancy rates in the United States have decreased significantly over the past decade, births to adolescents remain both an individual and public health issue. An unintended pregnancy may have significant implications for an adolescent's physical and emotional health. As advocates for the health and well-being of all young people, SAHM strongly supports the recommendation that adolescents postpone consensual sexual activity until they are fully ready for the emotional, physical, and financial consequences of sex. We recognize, however, that some young people will choose not to postpone sexual activity. As adolescent health care providers, we have a responsibility to help teens reduce risks and negative health consequences associated with adolescent sexual behaviors, including unintended pregnancies and sexually transmitted infections. SAHM strongly encourages the use of contraception—including emergency contraception—by adolescents when prescribed and counseled by a provider in an appropriate and recommended manner.

14. Shriver Center, 9/30/11, page 2

The inclusion of contraception as a service that is required to be covered with no cost-sharing presents a tremendous step forward in improving the health status of women and their families. Contraceptive care and counseling allows women to control the timing, number, and spacing of births, leading to improved health and mortality outcomes for themselves and their children. The ability to determine the timing of a pregnancy can prevent a range of pregnancy complications that can endanger a woman's health, including gestational diabetes, high blood pressure, and placental problems, among others. In addition, an unintended pregnancy may have significant implications for a woman's health. A preexisting health condition such as diabetes, hypertension, or coronary artery disease may be worsened by a pregnancy. A planned pregnancy allows a woman to take steps so she is sufficiently healthy to undergo pregnancy and childbirth.
In general, cost plays a major role in a woman's ability to secure access to contraception and to choose the contraceptive method that is right for her. A 2009 survey by the Guttmacher Institute found that because of the economic recession, 23% of women report having difficulty paying for birth control and 24% have put off a gynecology or birth control visit because of cost. There is evidence that cost and lack of insurance coverage pose barriers to obtaining a postpartum tubal ligation, even among women who express a desire for the procedure.

15. National Women's Law Center (NWLC), 9/30/11, page 3

The inclusion of contraception as a service that is required to be covered with no cost-sharing presents a tremendous step forward in improving the health status of women and their families. Contraceptive care and counseling allow women to control the timing, number, and spacing of births, leading to improved health and mortality outcomes for themselves and their children. Planned pregnancies—which for most women require contraception—improve women's health. The ability to determine the timing of a pregnancy can prevent a range of pregnancy complications that can endanger a woman's health, including gestational diabetes, high blood

pressure, and placental problems, among others. In addition, an unintended pregnancy may have significant implications for a woman's health. A preexisting health condition such as diabetes, hypertension, or coronary artery disease may be worsened by a pregnancy. A planned pregnancy allows a woman to take steps so she is sufficiently healthy to undergo pregnancy and childbirth. Planned pregnancies not only improve women's health, but improve the health of their children. Women who wait for some time after delivery before conceiving their next child lower the risk of adverse perinatal outcomes, including low birth weight, preterm birth, and small-for-size gestational age. And a planned pregnancy affords women an opportunity to make behavioral changes that lead to better birth outcomes.

16. National Partnership for Women & Families (NPWF), 9/30/11, page 5

Since the burdens of pregnancy fall entirely on women and most contraceptive methods are available only to women, failure to provide equal access to contraception constitutes discrimination on the basis of sex. Furthermore, access to contraception is vital to gender equality as it is only when women can control their fertility that they are able to participate equally in society.

17. Americans United for Separation of Church and State (AUSCS) 9/30/11. Page 6

If there were a substantial burden, it surely would be overcome by a compelling state interest. As stated above, courts have already concluded that the state's interest in "fostering equality between the sexes, and in providing women with better healthcare" is sufficient to justify the law.

18. Advocates for Youth 9/30/11, page 1

According to the recent report "TECHsex USA: Youth Sexuality and Reproductive Health in the Digital Age," birth control is one of the most important health issues for women. The United States has one of the highest teen pregnancy rates in the developed world with 71.5 pregnancies per 1000 women ages 15-19. That number is nearly three times that of Germany or France and four times the rate in the Netherlands. Among teens between the ages of 15-17 who become pregnancy, almost 90 percent of those pregnancies are unintended. In 20-24 year olds, more than half of all pregnancies are unintended. According to the Guttmacher Institute, unintended pregnancies cost the United States $11.1 billion in 2006.

19. New York Alliance for Women's Health, pages 1-2

The Institute of Medicine's report *Clinical Preventive Services for Women: Closing the Gaps* concluded that contraceptive services are fundamental preventive health care for women. The Committee of IOM experts who produced the report conducted a comprehensive review of the evidence and recommended that contraceptive coverage should include the full range of contraception approved by the Food and Drug Administration. The evidence further shows that cost-sharing requirements, like copayments, make people, especially low-income people, less likely to get health services, including preventive care and prescription drugs. In 2009, 30 percent of sexually active low- and middle-income women reported having put off a gynecology

or birth control visit to save money; one-quarter of those who used the contraceptive pill reported saving money by using the method inconsistently. Additionally, research shows that in states that made it easier for low-income women to afford contraception by extending Medicaid family planning coverage to more people, there was a dramatic drop in the incidence of short birth intervals (a year or less between babies) for women in the program. Shorter times between a birth and a subsequent pregnancy make preterm birth and low birth weight more likely, which has serious negative consequences for the babies' health.

20. NARAL Pro-Choice America, 9/30/11, pages 1-2

Currently, an estimated 36 million women in the United States are in need of contraception. For many women, contraception has been simply too expensive. One in three women has struggled with the cost of prescription birth control at some point, and research shows that even small cost-sharing requirements can put contraception out of reach. Moreover, costs associated with birth control obstruct women's ability to access highly effective contraceptive methods, such as intrauterine contraceptives (IUCs), leading them to use methods with higher failure rates. Conversely, removal of cost barriers such as co-pays or deductibles results in a shift toward the most effective contraceptive methods. Requiring no-cost coverage of family planning services is a critical step toward increasing the use of highly effective contraception and reducing unintended pregnancy rates.

21. Sexual and Reproductive Health Rights Organizations, 9/30/11, page 1

Access to preventive services, such as birth control, education and counseling, and expanded health screening, will help women control, track, and better manage their life-long health. Women face a unique set of healthcare challenges because they use more health services than men1 yet earn less on average than men. As a result, women face a high level of health care insecurity which leads many women to forgo necessary care because of prohibitive patient cost-sharing. A recent study by the Kaiser Family Foundation found that one in seven women with private health insurance and nearly one-third of women covered by Medicaid either postponed or went without needed services in the past year because they could not afford it. The IOM report found that contraceptive services are "appropriate medical care" for women of childbearing age on numerous grounds.4 Requiring insurance providers to fully cover, without patient deductibles or co-pays, preventive services such as contraception, screenings, education, and counseling will go a long way to expanding women's access to health care services. These services are so critical to women's health and well-being that they should be available to all women without exception.

22. National Campaign to Prevent Teen & Unplanned Pregnancy, 9/20/11, page 2

In addition to improving economic and social well-being, contraception improves the health of women and children. Family planning, through the use of contraception, reduces maternal mortality. It also reduces the risk of low birth weight, prematurity and infant mortality. Family planning is a precondition to pre-conception care which the Centers for Disease Control and Prevention have gone to great lengths to define as having major medical benefits for both maternal and infant health, such as a reduced incidence of uncontrolled gestational diabetes and of neural tube defects. Preconception care assumes a scenario in which a woman is planning to get pregnant but is not yet pregnant, which in the vast majority of cases presumes she and her

partner are using contraception effectively. Consider that a woman who has become pregnant unintentionally is more likely to expose her child to harmful substances including tobacco, alcohol or caffeine while pregnant. A woman with an unintended pregnancy is also more likely to delay prenatal care until the second trimester, in part because she is less likely to realize that she is pregnant in the early weeks of pregnancy. The likelihood of breastfeeding varies accordingly to intention of pregnancy—only 36-40 percent of infants are breastfed if the pregnancy was unplanned, compared to 60-61 percent if it was planned. Finally, access to contraception helps to reduce abortion.

23. National Council of Jewish Women, 9/23/11, page 2

Making contraception widely available and affordable, as the new women's preventive health benefits are intended to do, will allow women to be the decision makers about the preventive care services they wish to access.

24. Catholics for Choice 9/30/11, page 1,2,3

The proposed refusal clause leaves too many women without affordable access to the healthcare they need. We know that each and every woman—her health and her conscience—matters. Similarly, we know that social justice is not served by excluding some from opportunities available to others. Our Catholic faith values the well-being of all women, regardless of their financial circumstances or whom they work for, and respects each woman's conscience and ability to make her own moral decisions. It is simply unjust to leave even one woman without access in order to gain coverage for a few. Restricting access for select groups is in fact counter to the ultimate goal of the Affordable Care Act, which is to expand healthcare access for all Americans…

The proposed refusal clause is an affront to religious freedom**.** Our faith also compels us to respect religious pluralism and religious freedom. In keeping with our Catholic tradition, we must also advocate for each woman's ability to follow her own conscience about which healthcare services are best for her and for her family, regardless of where or if she works. Religious freedom is an expansive rather than restrictive idea. It is not about telling people what they can and cannot believe or practice, but about giving people the space to follow their own conscience in what they believe or practice. The protections extend to one's personal religious beliefs and practices, but they do not give entire institutions or individuals license to obstruct or coerce the exercise of another's conscience.

The proposed refusal clause goes against Catholic ideals of conscience, workers' rights and social justice. Our faith compels us to listen to our own consciences in matters of moral decision-making and to respect the rights of others to do the same. This deference for the primacy of conscience extends to all women and to their personal decisions about which family planning methods are best for them and their families.

Each woman's ability to prevent unintended pregnancies, regulate healthcare conditions, prevent sexually transmitted diseases and, in some cases, to avoid potentially life-threatening pregnancies matters, and there is no acceptable religious or political justification to the contrary.

25. Reproductive Health Technologies Project et al., 9/30/11, page 1

According to the U.S. Centers for Disease Control's website, ―Unintended pregnancy is associated with an increased risk of morbidity for women, and with health behaviors during pregnancy that are associated with adverse effects. For one, a woman facing an unintended pregnancy may delay prenatal care. Furthermore, 40% of unintended pregnancies end in abortion. Providing women with increased access to contraceptive services in preventive services under this interim final rule is a critical step to decreasing the high incidence of unintended pregnancy in the United States.

26. American Association of University Women (AAUW), 9/30/11, page 2

The IOM report found that contraceptive services are "appropriate medical care" for women of childbearing age on numerous grounds. Requiring insurance providers to fully cover, without patient deductibles or co-pays, preventive services such as contraception, screenings, education, and counseling will go a long way to expanding women's access to health care services. Family planning fosters self-sufficiency, improves health, and educates people on ways to protect themselves and their families from the spread of sexually transmitted infections. In a country where half of all pregnancies are unintended and the rate of sexually transmitted infections is one of the highest in the industrialized world, expanding Americans' ability to access preventive health care is sound public policy. Access to preventive services, such as contraception, education and counseling, and expanded health screening, will help women control, track, and better manage their life-long health. These services are so critical to women's health and well-being that they should be available to all women without exception.

27. Northwest Health Law Advocates, 9/30/11, pages 1-2

The inclusion of contraception as a covered service without cost-sharing is a particularly important step in improving women's health status for two reasons:

- Contraceptive care and counseling allows women to control the timing, number, and spacing of births, leading to improved health and mortality outcomes for themselves and their children. The ability to determine the timing of a pregnancy can prevent a range of pregnancy complications that may endanger a woman's health, including gestational diabetes, high blood pressure, and placental problems. In addition, an unintended pregnancy may have significant implications for a woman's health. A preexisting health condition such as diabetes, hypertension, or coronary artery disease may be worsened by a pregnancy. A planned pregnancy allows a woman to take steps so she is sufficiently healthy to undergo pregnancy and childbirth.

- Cost plays a major role in a woman's ability to secure access to contraception and to choose the contraceptive method that is right for her. A 2009 survey by the Guttmacher Institute found that because of the economic recession, 23% of women report having difficulty paying for birth control and 24% have put off a gynecology or birth control visit because of cost. There is evidence that cost and lack of insurance coverage pose barriers to obtaining a postpartum tubal ligation, even among women who express a desire for the procedure.

28. National Organization for Women NYC (NOW NYC), pages 1-2

We believe no woman should be denied the coverage she needs for contraceptive services, because this is an essential women's preventive health service, as amply documented by the recent Institute of Medicine report.
The Institute of Medicine's report *Clinical Preventive Services for Women: Closing the Gaps* concluded that contraceptive services are fundamental preventive health care for women. The Committee of IOM experts who produced the report conducted a comprehensive review of the evidence and recommended that contraceptive coverage should include the full range of contraception approved by the Food and Drug Administration. The evidence further shows that cost-sharing requirements, like co-payments, make people, especially low-income people, less likely to get health services, including preventive care and prescription drugs. In 2009, 30 percent of sexually active low- and middle-income women reported having put off a gynecology or birth control visit to save money; one-quarter of those who used the contraceptive pill reported saving money by using the method inconsistently. Additionally, research shows that in states that made it easier for low-income women to afford contraception by extending Medicaid family planning coverage to more people, there was a dramatic drop in the incidence of short birth intervals (a year or less between babies) for women in the program. Shorter times between a birth and a subsequent pregnancy make preterm birth and low birth weight more likely, which has serious negative consequences for the babies' health.