IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

COLORADO CHRISTIAN UNIVERSITY,

Plaintiff,

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

THOMAS PEREZ, Secretary of the United States Department of Labor,

UNITED STATES DEPARTMENT OF LABOR,

JACOB LEW, Secretary of the United States Department of the Treasury, and

UNITED STATES DEPARTMENT OF THE TREASURY,

Defendants.

VERIFIED COMPLAINT

(TRIAL BY JURY DEMANDED)

Plaintiff Colorado Christian University (CCU), by and through its attorneys, alleges and states as follows:

NATURE OF THE ACTION

1. This is a challenge to regulations issued by Defendants under the 2010 Patient Protection and Affordable Care Act that force employee and student health insurance plans to provide free coverage of contraceptive services. The mandated coverage includes "emergency contraceptives," which cause early abortions.

2. CCU is a Christian liberal arts university.

3. Jesus Christ is "the integrating center of Colorado Christian University, intentionally at the core of all that CCU is and does." *See* The Essence of the University, *available at* http://www.ccu.edu/about/essence/ (last visited Aug. 6, 2013).

4. Its mission is to produce graduates who "think critically and creatively, lead with high ethical and professional standards, embody the character and compassion of Jesus Christ, and who thereby are prepared to impact the world." Aug. 6, 2013).

5. In pursuit of this mission, CCU explicitly identifies as one of its strategic objectives to "[i]mpact our culture in support of . . . sanctity of life." *See* Strategic Objectives, *available at* http://www.ccu.edu/strategicobjectives/ (last visited Aug. 6, 2013).

6. CCU's religious convictions concerning the sanctity of life forbid it from participating in, paying for, training others to engage in, or otherwise supporting, or facilitating access to, abortion.

7. CCU publicly speaks out against abortion, including abortion caused by emergency contraceptives.

8. CCU cannot fulfill its mission of preparing students to impact the world by living their Christian values if it violates its own religious convictions by complying with the challenged

regulations and facilitating access to abortion-causing drugs and devices and related counseling and services.

9. CCU qualifies for no exemption from the regulations. While "religious employers" are exempted, Defendants have limited that exemption to protect only "churches, their integrated auxiliaries, and conventions or associations of churches" and "the exclusively religious activities of any religious order."

10. Thousands of other organizations remain exempt from the regulations *for purely secular reasons*. For example, organizations with plans in existence before March 2010 (i.e., "grandfathered" plans), small employers, and other favored organizations are exempt from the challenged regulations.

11. The regulations do offer CCU and other non-exempt religious organizations a so-called "accommodation." But the "accommodation" is meaningless. It would still require CCU to play a central role in the government's scheme and force it to "designate" an agent to pay for the objectionable services on CCU's behalf. This would do nothing to resolve CCU's objections.

12. The supposed "accommodation" also continues to treat CCU as a second-class religious organization, not entitled to the same religious freedom rights as other religious organizations, including any religious universities that are "integrated auxiliaries" to churches.

13. The "accommodation" also creates administrative hurdles and other difficulties for CCU, forcing it to seek out and contract with companies willing to provide the very drugs and services it speaks out against.

14. If CCU does not compromise its religious convictions and comply with the regulations, however, it faces severe penalties that could exceed $12 million each year.

15. By placing CCU in this impossible position, Defendants have violated the Religious Freedom Restoration Act, as well as the Free Exercise, Establishment, and Free Speech Clauses of the First Amendment of the United States Constitution, The Due Process Clause of the Fifth Amendment, and the Administrative Procedure Act.

16. CCU therefore respectfully requests declaratory and permanent injunctive relief.

JURISDICTION AND VENUE

17. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and § 1361. This action arises under the Constitution and laws of the United States. This Court has jurisdiction to render declaratory and injunctive relief under 28 U.S.C. §§ 2201 and 2202, and 42 U.S.C. § 2000bb-1.

18. Venue lies in this district pursuant to 28 U.S.C. § 1391(e). A substantial part of the events or omissions giving rise to the claim occurred in this district, and the Plaintiff is located in this district.

IDENTIFICATION OF PARTIES

19. Plaintiff CCU is a Christian liberal arts university with its main campus in Lakewood, Colorado, with satellite classrooms in five other Colorado cities. Established in 1914, CCU is committed to offering a complete education that develops students intellectually, professionally, and spiritually.

20. Defendants are appointed officials of the United States government and United States governmental agencies responsible for issuing and enforcing the challenged regulations.

21. Defendant Kathleen Sebelius is the Secretary of the United States Department of Health and Human Services ("HHS"). In this capacity, she has responsibility for the operation and management of HHS. Secretary Sebelius is sued in her official capacity only.

22. Defendant HHS is an executive agency of the United States government and is responsible for the promulgation, administration, and enforcement of the challenged regulations.

23. Defendant Thomas Perez is the Secretary of the United States Department of Labor. In this capacity, he has responsibility for the operation and management of the Department of Labor. Secretary Perez is sued in his official capacity only.

24. Defendant Department of Labor is an executive agency of the United States government and is responsible for the promulgation, administration, and enforcement of the challenged regulations.

25. Defendant Jacob Lew is the Secretary of the Department of the Treasury. In this capacity, he has responsibility for the operation and management of the Department. Secretary Lew is sued in his official capacity only.

26. Defendant Department of Treasury is an executive agency of the United States government and is responsible for the promulgation, administration, and enforcement of the challenged regulations.

FACTUAL ALLEGATIONS

I. CCU's Religious Beliefs and Practices Related to Insurance for Abortion.

27. Faith is central to CCU's educational mission. CCU describes itself as a "Christ-centered community" committed to "exemplary academics, spiritual formation, and engagement with the world."

28. Consistent with its religious mission, CCU strives to manifest its Christian faith in all aspects of its administration. All CCU employees profess a Statement of Faith, which establishes "the essential framework" of Christian beliefs "within which members of the University both unite in shared beliefs and explore differences." All undergraduates commit to a Lifestyle Covenant that requires chapel attendance, church attendance, and participation in ministry to the community. Students also commit to refrain from sexual immorality and consumption of alcohol or tobacco on campus.

29. CCU's religious beliefs include traditional Christian teachings on the sanctity of life. Specifically, CCU believes and teaches that each human being bears the image and likeness of God, and therefore that all human life is sacred and precious from the moment of conception. CCU therefore believes and teaches that abortion ends a human life and is a sin.

30. CCU has a sincere religious objection to facilitating access to abortion-causing drugs and devices, including the "emergency contraceptives" Plan B and ella and certain intrauterine devices or IUDs, because they believe those drugs and devices can prevent a human embryo—which CCU understands to include a fertilized egg before implantation—from implanting in the wall of the uterus, thereby causing the death of the embryo.

31. CCU considers artificially preventing implantation of a human embryo to constitute an abortion.

32. Because of its religious convictions concerning the sanctity of life, CCU cannot participate in any scheme to facilitate access to drugs and services that cause abortions.

33. CCU has approximately 350 full-time and 330 part-time employees.

34. It has more than 5,300 graduate and undergraduate students.

35. As part of its commitment to Christian education, CCU promotes both the spiritual and physical well-being and health of its students and employees. This includes providing generous health services and health insurance for its employees and students.

36. CCU's insurance plans do not cover medical abortions or abortion-causing drugs or devices.

37. CCU has no conscientious objection to providing—and, indeed, already provides—insurance coverage for non-abortifacient contraceptive drugs and devices, but it cannot deliberately provide insurance that would facilitate access to abortions of any kind, or to related education and counseling, without violating its deeply held religious convictions.

38. Many, if not all, of CCU's employees and students choose to work at or attend CCU because they share its religious beliefs and wish to help CCU further its mission. CCU would violate their implicit trust in the organization and detrimentally alter its relationship with them if it were to violate its religious beliefs regarding abortion.

II. The Affordable Care Act and Preventive Care Mandate

39. In March 2010, Congress passed, and President Obama signed into law, the Patient Protection and Affordable Care Act, Pub. L. 111-148 (March 23, 2010), and the Health Care and Education Reconciliation Act, Pub. L. 111-152 (March 30, 2010), collectively known as the "Affordable Care Act."

40. The Affordable Care Act regulates the national health insurance market by directly regulating "group health plans" and "health insurance issuers."

41. One provision of the Act mandates that any "group health plan" or "health insurance issuer offering group or individual health insurance coverage" must provide coverage for certain preventive care services. 42 U.S.C. § 300gg-13(a).

42. The services required to be covered include medications, screenings, and counseling given an "A" or "B" rating by the United States Preventive Services Task Force;[1] immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention; and "preventive care and screenings" specific to infants, children, adolescents, and women, as to be "provided for in comprehensive guidelines supported by the Health Resources and Services Administration." 42 U.S.C. § 300gg-13(a)(1)-(4).

43. The statute specifies that all of these services must be provided without "any cost sharing." 42 U.S.C. § 300gg-13(a).

The Interim Final Rule

44. On July 19, 2010, HHS[2] published an interim final rule imposing regulations concerning the Affordable Care Act's requirement for coverage of preventive services without cost sharing. 75 Fed. Reg. 41726, 41728 (2010).

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[1] The list of services that currently have an "A" or "B" rating include medications like aspirin for preventing cardiovascular disease, vitamin D, and folic acid; screenings for a wide range of conditions such as depression, certain cancers and sexually-transmitted diseases, intimate partner violence, obesity, and osteoporitis; and various counseling services, including for breastfeeding, sexually-transmitted diseases, smoking, obesity, healthy dieting, cancer, and so forth. *See* http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm (last visited Aug. 6, 2013); *see also* 75 Fed. Reg. 41726, 41740 (2010).

[2] For ease of reading, references to "HHS" in this Complaint refer to all Defendants, unless context indicates otherwise.

45. The interim final rule was enacted without prior notice of rulemaking or opportunity for public comment, because Defendants determined for themselves that "it would be impracticable and contrary to the public interest to delay putting the provisions . . . in place until a full public notice and comment process was completed." 75 Fed. Reg. at 41730.

46. Although Defendants suggested in the Interim Final Rule that they would solicit public comments after implementation, they stressed that "provisions of the Affordable Care Act protect significant rights" and therefore it was expedient that "participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities." *Id*.

47. Defendants stated they would later "provide the public with an opportunity for comment, but without delaying the effective date of the regulations," demonstrating their intent to impose the regulations regardless of the legal flaws or general opposition that might be manifest in public comments. *Id*.

48. In addition to reiterating the Affordable Care Act's preventive services coverage requirements, the Interim Final Rule provided further guidance concerning the Act's restriction on cost sharing.

49. The Interim Final Rule makes clear that "cost sharing" refers to "out-of-pocket" expenses for plan participants and beneficiaries. 75 Fed. Reg. at 41730.

50. The Interim Final Rule acknowledges that, without cost sharing, expenses "previously paid out-of-pocket" would "now be covered by group health plans and issuers" and that those expenses would, in turn, result in "higher average premiums for all enrollees." *Id.*; *see also id*. at 41737 ("Such a transfer of costs could be expected to lead to an increase in premiums.")

51. In other words, the prohibition on cost-sharing was simply a way "to distribute the cost of preventive services more equitably across the broad insured population." 75 Fed. Reg. at 41730.

52. After the Interim Final Rule was issued, numerous commenters warned against the potential conscience implications of requiring religious individuals and organizations to include certain kinds of services—specifically contraception, sterilization, and abortion services—in their health care plans.

53. HHS directed a private health policy organization, the Institute of Medicine (IOM), to make recommendations regarding which drugs, procedures, and services all health plans should cover as preventive care for women.

54. In developing its guidelines, IOM invited a select number of groups to make presentations on the preventive care that should be mandated by all health plans. These were the Guttmacher Institute, the American Congress of Obstetricians and Gynecologists (ACOG), John Santelli, the National Women's Law Center, National Women's Health Network, Planned Parenthood Federation of America, and Sara Rosenbaum.

55. No religious groups or other groups that opposed government-mandated coverage of contraception, sterilization, abortion, and related education and counseling were among the invited presenters.

56. On July 19, 2011, the IOM published its preventive care guidelines for women, including a recommendation that preventive services include "[a]ll Food and Drug Administration approved contraceptive methods [and] sterilization procedures." Institute of

Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, at 102-10 and Recommendation 5.5 (July 19, 2011).

57. FDA-approved contraceptive methods include birth-control pills; prescription contraceptive devices such as IUDs; Plan B (also known as the "morning-after pill"); ulipristal (also known as "ella" or the "week-after pill"); and other drugs, devices, and procedures.

58. Some of these drugs and devices—including the "emergency contraceptives" Plan B and ella and certain IUDs—are known abortifacients, in that they can cause the death of an embryo by preventing it from implanting in the wall of the uterus.

59. Indeed, the FDA's own Birth Control Guide states that both Plan B and ella can work by "preventing attachment (implantation) to the womb (uterus)." FDA, Office of Women's Health, Birth Control Guide at 16-17, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (last visited Aug. 6, 2013) (attached as Exhibit A).

60. On August 1, 2011, thirteen days after IOM issued its recommendations, HRSA issued guidelines adopting them in full. *See* http://www.hrsa.gov/womensguidelines (last visited Aug. 6, 2013).

The "Religious Employers" Exemption

61. That same day, HHS promulgated an additional Interim Final Rule. 76 Fed. Reg. 46621 (published Aug. 3, 2011).

62. This Second Interim Final Rule granted HRSA "*discretion* to exempt certain religious employers from the Guidelines where contraceptive services are concerned." 76 Fed. Reg. 46621, 46623 (emphasis added). The term "religious employer" was restrictively defined as one that (1) has as its purpose the "inculcation of religious values"; (2) "primarily employs persons

who share the religious tenets of the organization"; (3) "serves primarily persons who share the religious tenets of the organization"; and (4) "is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended." 76 Fed. Reg. at 46626 (emphasis added).

63. The fourth of these requirements refers to "churches, their integrated auxiliaries, and conventions or associations of churches" and the "exclusively religious activities of any religious order." 26 U.S.C.A. § 6033.

64. Thus, the "religious employers" exemption was severely limited to formal churches, their integrated auxiliaries, and religious orders whose purpose is to inculcate faith and that hire and serve primarily people of their own faith tradition.

65. HRSA exercised its discretion to grant an exemption for religious employers via a footnote on its website listing the Women's Preventive Services Guidelines. The footnote states that "guidelines concerning contraceptive methods and counseling described above do not apply to women who are participants or beneficiaries in group health plans sponsored by religious employers." *See* http://www.hrsa.gov/womensguidelines (last visited Aug. 6, 2013).

66. Although religious organizations like CCU share the same religious beliefs and concerns as objecting churches, their integrated auxiliaries, and objecting religious orders, HHS deliberately ignored the regulation's impact on their religious liberty, stating that the exemption sought only "to provide for a religious accommodation that respects the unique relationship between a house of worship and its employees in ministerial positions." 76 Fed. Reg. 46621, 46623.

67. Thus, the vast majority of religious organizations with conscientious objections to providing contraceptive or abortifacient services were excluded from the "religious employers" exemption.

68. Like the original Interim Final Rule, the Second Interim Final Rule was made effective immediately, without prior notice or opportunity for public comment.

69. Defendants acknowledged that "while a general notice of proposed rulemaking and an opportunity for public comment is generally required before promulgation of regulations," they had "good cause" to conclude that public comment was "impracticable, unnecessary, or contrary to the public interest" in this instance. 76 Fed. Reg. at 46624.

70. Upon information and belief, after the Second Interim Final Rule was put into effect, over 100,000 comments were submitted opposing the narrow scope of the "religious employers" exemption and protesting the contraception mandate's gross infringement on the rights of religious individuals and organizations.

71. HHS did not take into account the concerns of religious organizations in the comments submitted before the Second Interim Rule was issued.

72. Instead the Second Interim Rule was unresponsive to the concerns, including claims of statutory and constitutional conscience rights, stated in the comments submitted by religious organizations.

The Safe Harbor

73. The public outcry for a broader religious employers exemption continued for many months and, on January 20, 2013, HHS issued a press release acknowledging "the important concerns some have raised about religious liberty" and stating that religious objectors would be

"provided an additional year . . . to comply with the new law." *See* Jan. 20, 2013 Statement by U.S. Department of Health and Human Services Secretary Kathleen Sebelius, *available at* http://www.hhs.gov/news/press/2012pres/01/20120120a.html (last visited Aug. 6, 2013).

74. On February 10, 2012, HHS formally announced a "safe harbor" for non-exempt nonprofit religious organizations that objected to covering free contraceptive and abortifacient services.

75. Under the safe harbor, HHS agreed it would not take any enforcement action against an eligible organization during the safe harbor, which would remain in effect until the first plan year beginning after August 1, 2013.

76. HHS also indicated it would develop and propose changes to the regulations to accommodate the objections of non-exempt, nonprofit religious organizations following August 1, 2013.

77. Despite the safe harbor and HHS's accompanying promises, on February 15, 2012, HHS published a final rule "finalizing, without change," the contraception and abortifacient mandate and narrow religious employers exemption. 77 Fed. Reg. 8725-01 (published Feb. 15, 2012).

The Advance Notice of Proposed Rulemaking

78. On March 21, 2012, HHS issued an Advance Notice of Proposed Rulemaking (ANPRM), presenting "questions and ideas" to "help shape" a discussion of how to "maintain the provision of contraceptive coverage without cost sharing," while accommodating the religious beliefs of non-exempt religious organizations. 77 Fed. Reg. 16501, 16503 (2012).

79. The ANPRM conceded that forcing religious organizations to "contract, *arrange*, or pay for" the objectionable contraceptive and abortifacient servicers would infringe their "religious liberty interests." *Id*. (emphasis added).

80. In vague terms, the ANPRM proposed that the "health insurance issuers" for objecting religious employers could be required to "assume the responsibility for the provision of contraceptive coverage without cost sharing." *Id*.

81. For self-insured plans, the ANPRM suggested that third party plan administrators "assume this responsibility." *Id*.

82. For the first time, and contrary to the earlier definition of "cost sharing," Defendants suggested in the ANPRM that insurers and third party administrators could be prohibited from passing along their costs to the objecting religious organizations via increased premiums. *See id*.

83. "[A]pproximately 200,000 comments" were submitted in response to the ANPRM, 78 Fed. Reg. 8456, 8459, largely reiterating previous comments that the ANPRM's proposals would not resolve conscientious objections, because the objecting religious organizations, by providing a health care plan in the first instance, would still be coerced to arrange for and facilitate access to abortifacient services.

The Notice of Proposed Rulemaking

84. On February 1, 2013, HHS issued a Notice of Proposed Rulemaking (NPRM) purportedly addressing the comments submitted in response to the ANPRM. 78 Fed. Reg. 8456 (published Feb. 6, 2013).

85. The NPRM proposed two changes to the then-existing regulations. 78 Fed. Reg. 8456, 8458-59.

86. First, it proposed revising the religious employers exemption by eliminating the requirements that religious employers have the purpose of inculcating religious values and primarily employ and serve only persons of their same faith. 78 Fed. Reg. at 8461

87. Under this proposal a "religious employer" would be one "that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the [Internal Revenue] Code." 78 Fed. Reg. at 8461.

88. HHS emphasized, however, that this proposal "would not expand the universe of employer plans that would qualify for the exemption beyond that which was intended in the 2012 final rules." 78 Fed. Reg. 8456, 8461.

89. In other words, religious organizations like CCU that are not formal churches or religious orders would continue to be excluded from the exemption.

90. Second, the NPRM reiterated HHS's intention to "accommodate" non-exempt, nonprofit religious organizations by making them "designate" their insurers and third party administrators to provide plan participants and beneficiaries with free access to contraceptive and abortifacient drugs and services.

91. The proposed "accommodation" did not resolve the concerns of religious organizations like CCU because it continued to force them to deliberately provide health insurance that would trigger access to abortion-inducing drugs and related education and counseling.

92. In issuing the NPRM, HHS requested comments from the public by April 8, 2013. 78 Fed. Reg. 8457.

93. "[O]ver 400,000 comments" were submitted in response to the NPRM, 78 Fed. Reg. 39870, 39871, with religious organizations again overwhelmingly decrying the proposed

accommodation as a gross violation of their religious liberty because it would conscript their health care plans as the main cog in the government's scheme for expanding access to contraceptive and abortifacient services.

94. CCU submitted comments on the NPRM, stating essentially the same objections stated in this complaint.

95. On April 8, 2013, the same day the notice-and-comment period ended, Defendant Secretary Sebelius answered questions about the contraceptive and abortifacient services requirement in a presentation at Harvard University.

96. In her remarks, Secretary Sebelius stated:

> We have just completed the open comment period for the so-called accommodation, and by August 1st of this year, every employer will be covered by the law with one exception. Churches and church dioceses as employers are exempted from this benefit. But Catholic hospitals, Catholic universities, other religious entities *will be providing coverage* to their employees starting August 1st. . . . [A]s of August 1st, 2013, every employee who doesn't work directly for a church or a diocese *will be included* in the benefit package.

See The Forum at Harvard School of Public Health, A Conversation with Kathleen Sebelius, U.S. Secretary of Health and Human Services, Apr. 8, 2013, *available at* http://theforum.sph.harvard.edu/events/conversation-kathleen-sebelius (Episode 9 at 2:25) (last visited July 12, 2013) (emphases added).

97. It is clear from the timing of these remarks that Defendants gave no consideration to the comments submitted in response to the NPRM's proposed "accommodation."

The Final Mandate

98. On June 28, 2013, Defendants issued a final rule (the "Final Mandate"), which ignores the objections repeatedly raised by religious organizations and continues to co-opt objecting

religious employers into the government's scheme of expanding free access to contraceptive and abortifacient services. 78 Fed. Reg. 39870.

99. Under the Final Mandate, the discretionary "religious employers" exemption, which is still implemented via footnote on the HRSA website, *see* http://www.hrsa.gov/womensguidelines (last visited Aug. 6, 2013), remains limited to formal churches and religious orders "organized and operate[d]" as nonprofit entities and "referred to in section 6033(a)(3)(A)(i) or (iii) of the [Internal Revenue] Code." 78 Fed. Reg. at 39874.

100. All other religious organizations, including CCU, are excluded from the exemption.

101. The Final Mandate creates a separate "accommodation" for certain non-exempt religious organizations. 78 Fed. Reg. at 39874.

102. An organization is eligible for the accommodation if it (1) "[o]pposes providing coverage for some or all of the contraceptive services required"; (2) "is organized and operates as a nonprofit entity"; (3) "holds itself out as a religious organization"; and (4) "self-certifies that it satisfies the first three criteria." 78 Fed. Reg. at 39874.

103. The self-certification must be executed "prior to the beginning of the first plan year to which an accommodation is to apply." 78 Fed. Reg. at 39875.

104. The Final Rule extends the current safe harbor through the end of 2013. 78 Fed. Reg. at 39889.

105. Thus, an eligible organization would need to execute the self-certification prior to its first plan year that begins on or after January 1, 2014, and deliver it to the organization's insurer or, if the organization has a self-insured plan, to the plan's third party administrator. 78 Fed. Reg. at 39875.

106. By the terms of the accommodation, CCU will be required to execute the self-certification and deliver it to its plan's third party administrator before July 1, 2014.

107. By delivering its self-certification to its insurer or third party administrator, CCU would trigger the insurer's or third party administrator's obligation to make "separate payments for contraceptive services directly for plan participants and beneficiaries." 78 Fed. Reg. at 39875-76.

108. CCU would have to identify its employees to the insurer and third party administrator for the distinct purpose of enabling the government's scheme to facilitate free access to contraceptive and abortifacient services.

109. The insurer's and third party administrator's obligation to make direct payments for contraceptive and abortion services would continue only "for so long as the participant or beneficiary remains enrolled in the plan." 78 Fed. Reg. at 39876.

110. Thus CCU would have to coordinate with its insurer and third party administrator regarding when it was adding or removing employees and beneficiaries from its healthcare plan and, as a result, from the contraceptive and abortifacient services payment scheme.

111. Insurers and third party administrators would be required to notify plan participants and beneficiaries of the contraceptive payment benefit "contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment" in a group health plan. 78 Fed. Reg. at 39876.

112. This would also require CCU to coordinate the notices with its insurer and third party administrator.

113. The insurer and third party administrators would be required to provide the contraceptive benefits "in a manner consistent" with the provision of other covered services. 78 Fed. Reg. at 39876-77.

114. Thus, any payment or coverage disputes presumably would be resolved under the terms of CCU's existing plan documents.

115. Thus, even under the accommodation, CCU and every other non-exempt objecting religious organization would continue to play a central role in facilitating free access to contraceptive and abortifacient services.

116. Under the accommodation, issuers "may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), *or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly*, on the eligible organization." 78 Fed. Reg. at 39896 (emphasis added).

117. For all other preventive services, including non-contraceptive preventive services for women, only cost-sharing (*i.e.*, out-of-pocket expense) is prohibited. There is no restriction on passing along costs via premiums or other charges.

118. Defendants state that they "continue to believe, and have evidence to support," that providing payments for contraceptive and abortifacient services will be "cost neutral for issuers," because "[s]everal studies have estimated that the costs of providing contraceptive coverage are balanced by cost savings from lower pregnancy-related costs and from improvements in women's health." 78 Fed. Reg. at 39877.

119. On information and belief, the studies Defendants rely upon to support this claim are severely flawed.

120. Nevertheless, even if the payments were—over time—to become cost neutral, it is undisputed that there will be up-front costs for making the payments. *See, e.g.,* 78 Fed. Reg. at 39877-78 (addressing ways insurers can cover up-front costs).

121. Moreover, if cost savings arise that make insuring an employer's employees cheaper, the savings would have to be passed on to employers through reduced premiums, not retained by insurance issuers.

122. HHS suggests that, to maintain cost neutrality, issuers may simply ignore this fact and "set the premium for an eligible organization's large group policy as if no payments for contraceptive services had been provided to plan participants." 78 Fed. Reg. at 39877.

123. This encourages issuers to artificially inflate the eligible organization's premiums.

124. Under this methodology—even assuming its legality—the eligible organization would still bear the cost of the required payments for contraceptive and abortifacient services in violation of its conscience, as if the accommodation had never been made.

125. Defendants have suggested that "[a]nother option" would be to "treat the cost of payments for contraceptive services . . . as an administrative cost that is spread across the issuer's entire risk pool, excluding plans established or maintained by eligible organizations." 78 Fed. Reg. at 39878.

126. There is no legal authority for forcing third parties to pay for services provided to eligible organizations under the accommodation.

127. Furthermore, under the Affordable Care Act, Defendants lack authority in the first place to coerce insurers to directly purchase contraceptive and abortifacient services for an eligible organization's plan participants and beneficiaries.

128. Thus, the accommodation fails to protect objecting religious organizations for lack of statutory authority.

129. For all these reasons, the accommodation does nothing to relieve non-exempt religious organizations with insured plans from being co-opted as the central cog in the government's scheme to expand access to free contraceptive and abortifacient services.

130. Religious organizations with self-insured plans managed by a third party administrator would be similarly enmeshed in the government's scheme.

131. Defendants acknowledge "there is no obligation for a third party administrator to enter into or remain in a contract with the eligible organization if it objects to any of these responsibilities." 78 Fed. Reg. at 39880.

132. Thus, the burden remains on the objecting religious organization to find a third party administrator that will agree to providing free access to the same contraceptive and abortifacient services the religious organization cannot directly provide.

133. CCU's religious beliefs preclude it from soliciting, contracting with, or designating a third party to provide these services.

134. Moreover, the Final Mandate requires that, even if the third party administrator consents, the religious organization—via its self-certification—must expressly designate the third party administrator as "an ERISA section 3(16) plan administrator and claims administrator solely for the purpose of providing payments for contraceptive services for participants and beneficiaries." 78 Fed. Reg. at 39879.

135. The self-certification must specifically notify the third party administrator of its "obligations set forth in the[] final regulations, and will be treated as a designation of the third

party administrator(s) as plan administrator and claims administrator for contraceptive benefits pursuant to section 3(16) of ERISA." 78 Fed. Reg. at 39879.

136. Because the designation makes the third party administrator a plan administrator with fiduciary duties, the payments for contraceptive and abortifacient services would be payments made under the objecting religious organization's plan.

137. Because CCU would be required to identify and designate a third party administrator willing to administer the contraceptive and abortifacient services, CCU's religious beliefs preclude it from complying with the accommodation.

138. The Final Rule sets forth complex means through which a third party administrator may seek to recover its costs incurred in making payments for contraceptive and abortifacient services.

139. The third party administrator must identify an issuer who participates in the federal exchanges established under the Affordable Care Act and who would be willing to make payments on behalf of the third party administrator.

140. Cooperating issuers would then be authorized to obtain refunds from the user fees they have paid to participate in the federal exchange as a means of being reimbursed for making payments for contraceptive and abortifacient services on behalf of the third party administrator.

141. Issuers would be required to pay a portion of the refund back to the third party administrator to compensate it for any administrative expenses it has incurred.

142. These extreme machinations, ostensibly employed only to shift the *cost* of the Final Mandate, are severely flawed.

143. CCU has already had to change its third party administrator to comply with the administrative burdens imposed by the Affordable Care Act.

144. It reasonably anticipates that the fees it pays will increase correspondingly.

145. There is no way to ensure that the cost of administering the contraceptive and abortifacient services would not be passed on to CCU through the third party administrator's fees.

146. Moreover, taking the user fees intended for funding the federal exchanges and using them to provide contraceptive and abortifacient services to employees not participating in the federal exchanges would violate the statute authorizing the user fees. *See* 78 Fed. Reg. at 15412; 31 U.S.C. § 9701.

147. In sum, for both insured and self-insured organizations, the accommodation is nothing more than a shell game that attempts to disguise the religious organization's role as the central cog in the government's scheme for expanding access to contraceptive and abortifacient services.

148. Despite the accommodation's convoluted machinations, a religious organization's decision to offer health insurance and its self-certification continue to serve as the sole triggers for creating access to free contraceptive and abortifacient services.

149. CCU cannot participate in or facilitate the government's scheme in this manner without violating its religious convictions.

CCU's Health Care Plan and Its Religious Objections

150. The plan year for CCU's student healthcare plan begins on July 31 of each year.

151. The Final Mandate declares that the rules concerning contraceptive and abortifacient services will "apply to student health insurance coverage arranged by an eligible organization

that is an institution of higher education in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer." 78 Fed. Reg. at 39897.

152. Thus, beginning on or about July 31, 2014, CCU faces the choice of either including free coverage for contraceptive and abortifacient services in its student health plan or else forcing its insurance issuer to provide the exact same services.

153. The plan year for CCU's employee healthcare plan begins on July 1 of each year.

154. CCU's employee health care plan is self-insured.

155. Thus, beginning on or about July 1, 2014, CCU faces the choice of either including free coverage for contraceptive and abortifacient services in its employee health plan or else "designating" its third party administrator to provide the exact same services.

156. Although CCU has no objection to including, and already does include, free coverage for non-abortifacient contraceptive services, its religious convictions forbid it from including free coverage for abortifacient services in either its employee or student healthcare plans.

157. CCU's religious convictions equally forbid it from designating its third party administrator as a plan administrator with obligations to provide free access to abortifacient services.

158. From CCU's perspective, forcing its insurance issuer or "designating" its third party administrator to provide free access to abortifacient services is no different than directly providing that access.

159. CCU's religious convictions forbid it from participating in any way in the government's scheme to provide free access to abortifacient services through CCU's health care plans.

160. CCU is not eligible for the religious employers exemption because it is not an organization "described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended." 76 Fed. Reg. 46621, 46626.

161. Neither CCU's student healthcare plan nor its employee healthcare plan meets the definition of a "grandfathered" plan.

162. Because CCU refuses to comply with the Final Mandate and refuses to force its insurer or third party administrator to carry out the Final Mandate by submitting a self-certification, it faces crippling fines of $100 each day, for "each individual to whom such failure relates." 26 U.S.C. § 4980D(b)(1).

163. Dropping its insurance plans would place CCU at a severe competitive disadvantage in its efforts to recruit and retain employees and students.

164. CCU would also face fines of $2000 per year for each of its employees for dropping its insurance plans.

165. Although the government has recently announced that it will postpone implementing the annual fine of $2000 per employee for organizations that drop their insurance altogether, the postponement is only for one year, until 2015. This postponement does not delay the crippling daily fines under 26 U.S.C. § 4980D.

166. CCU's Christian faith compels it to promote the spiritual and physical well-being of its students and employees by providing them with generous health services.

167. The Final Mandate forces CCU to violate its religious beliefs or incur substantial fines for either excluding objectionable coverage without designating its third party administrator and insurance issuer, or terminating its employee and student health insurance coverage altogether.

168. The Final Mandate forces CCU to deliberately provide health insurance that would facilitate free access to emergency contraceptives, including Plan B and ella, regardless of the ability of insured persons to obtain these drugs from other sources.

169. The Final Mandate forces CCU to facilitate government-dictated education and counseling concerning abortion that directly conflicts with its religious beliefs and teachings.

170. Facilitating this government-dictated speech directly undermines the express speech and messages concerning the sanctity of life that CCU seeks to convey.

The Lack of a Compelling Government Interest

171. The government lacks any compelling interest in coercing CCU to facilitate access to abortifacient services.

172. The required abortifacient drugs, devices, and related services are already widely available at non-prohibitive costs.

173. There are multiple ways in which the government could provide access without co-opting religious employers and their insurance plans in violation of their religious beliefs.

174. For example, it could pay for the objectionable services through its existing network of family planning services funded under Title X, through direct government payments, or through tax deductions, refunds, or credits.

175. The government could also simply exempt all religious organizations, just as it has already exempted nonprofit religious employers referred to in Section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code.

176. HHS claims that its "religious employers" exemption does not undermine its compelling interest in making contraceptive and abortifacient services available for free to women because "houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people who are of the same faith and/or adhere to the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan." 78 Fed. Reg. at 39887.

177. CCU's employees and students all commit to a Statement of Faith or Lifestyle Covenant confirming that they adhere to the same basic Christian beliefs as CCU, including its beliefs concerning the sanctity of life.

178. Because of CCU's express mission of promoting the sanctity of life and opposing all abortions, including those caused by abortifacient drugs and devices, CCU's employees and students are just as likely as employees of exempt organizations to adhere to the same values, and thus are less likely than other people to use the objectionable drugs, devices, and services.

179. In one form or another, the government also provides exemptions for grandfathered plans, 42 U.S.C. § 18011; 75 Fed. Reg. 41,726, 41,731 (2010), small employers with fewer than 50 employees, 26 U.S.C. § 4980H(c)(2)(A), and certain religious denominations, 26 U.S.C. § 5000A(d)(2)(a)(i) and (ii) (individual mandate does not apply to members of "recognized religious sect or division" that conscientiously objects to acceptance of public or private

insurance funds); 26 U.S.C. § 5000A(d)(2)(b)(ii) (individual mandate does not apply to members of "health care sharing ministry" that meets certain criteria).

180. These broad exemptions further demonstrate that the government has no compelling interest in refusing to include religious organizations like CCU within its religious employers exemption.

181. Employers who follow HHS guidelines may continue to use grandfathered plans indefinitely.

182. Indeed, HHS has predicted that a majority of large employers, employing more than 50 million Americans, will continue to use grandfathered plans through at least 2014, and that a third of medium-sized employers with between 50 and 100 employees may do likewise. 75 Fed. Reg. 34538 (June 17, 2010); *See also* http://web.archive.org/web/20130620171510/http://www.healthcare.gov/news/ factsheets/2010/06/keeping-the-health-plan-you-have-grandfathered.html (archived version) (last visited Aug. 7, 2013); https://www.cms.gov/CCIIO/Resources/Files/factsheet_grandfather_amendment.html (noting that amendment to regulations "will result in a small increase in the number of plans retaining their grandfathered status relative to the estimates made in the grandfathering regulation").

183. According to the United States census, more than 20 million individuals are employed by firms with fewer than 20 employees. http://www.census.gov/econ/smallbus.html.

184. It is reasonable to presume that millions more are employed by firms with between 20 and 50 employees.

185. The government's recent decision to postpone the employer mandate—i.e., the annual fine of $2000 per employee for not offering any insurance—also demonstrates that there is no

compelling interest in coercing universal compliance with the Final Mandate concerning contraceptive and abortifacient services, since employers can now simply drop their insurance without any penalty, at least for one additional year.

186. These broad exemptions also demonstrate that the Final Mandate is not a generally applicable law entitled to judicial deference, but rather is constitutionally flawed.

187. The government's willingness to exempt various secular organizations and postpone the employer mandate, while adamantly refusing to provide anything but the narrowest of exemptions for religious organizations also shows that the Final Mandate is not neutral, but rather discriminates against religious organizations because of their religious commitment to promoting the sanctity of life.

188. Indeed, the Final Mandate was promulgated by government officials, and supported by non-governmental organizations, who strongly oppose religious teachings and beliefs regarding marriage and family.

189. Defendant Sebelius, for example, has long been a staunch supporter of abortion rights and a vocal critic of religious teachings and beliefs regarding abortion and contraception.

190. On October 5, 2011, six days after the comment period for the original interim final rule ended, Defendant Sebelius gave a speech at a fundraiser for NARAL Pro-Choice America. She told the assembled crowd that "we are in a war."

191. She further criticized individuals and entities whose beliefs differed from those held by her and the others at the fundraiser, stating: "Wouldn't you think that people who want to reduce the number of abortions would champion the cause of widely available, widely affordable contraceptive services? Not so much."

192. On July 16, 2013, Secretary Sebelius further compared opponents of the Affordable Care Act generally to "people who opposed civil rights legislation in the 1960s," stating that upholding the Act requires the same action as was shown "in the fight against lynching and the fight for desegregation." *See* http://www.hhs.gov/secretary/about/speeches/sp20130716.html (last visited Aug. 7, 2013).

193. Consequently, on information and belief, CCU alleges that the purpose of the Final Mandate, including the restrictively narrow scope of the religious employers exemption, is to discriminate against religious organizations that oppose contraception and abortion.

CLAIMS

COUNT I

Violation of the Religious Freedom Restoration Act
Substantial Burden

194. CCU incorporates by reference all preceding paragraphs.

195. CCU's sincerely held religious beliefs prohibit it from deliberately providing health insurance that would facilitate access to abortion-inducing drugs or services or related education and counseling. CCU's compliance with these beliefs is a religious exercise.

196. The Final Mandate creates government-imposed coercive pressure on CCU to change or violate its religious beliefs.

197. The Final Mandate chills CCU's religious exercise.

198. The Final Mandate exposes CCU to substantial fines for its religious exercise.

199. The Final Mandate exposes CCU to substantial competitive disadvantages, in that it will no longer be permitted to offer health insurance.

200. The Final Mandate imposes a substantial burden on CCU's religious exercise.

201. The Final Mandate furthers no compelling governmental interest.

202. The Final Mandate is not narrowly tailored to any compelling governmental interest.

203. The Final Mandate is not the least restrictive means of furthering Defendants' stated interests.

204. The Final Mandate and Defendants' threatened enforcement of the Final Mandate violate CCU's rights secured to it by the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*

205. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT II

Violation of the First Amendment to the United States Constitution
Free Exercise Clause
Substantial Burden

206. CCU incorporates by reference all preceding paragraphs.

207. CCU's sincerely held religious beliefs prohibit it from deliberately providing health insurance that would facilitate access to abortion or related education and counseling. CCU's compliance with these beliefs is a religious exercise.

208. Neither the Affordable Care Act nor the Final Mandate is neutral.

209. Neither the Affordable Care Act nor the Final Mandate is generally applicable.

210. Defendants have created categorical and individualized exemptions to the Final Mandate.

211. The Final Mandate furthers no compelling governmental interest.

212. The Final Mandate is not the least restrictive means of furthering Defendants' stated interests.

213. The Final Mandate creates government-imposed coercive pressure on CCU to change or violate its religious beliefs.

214. The Final Mandate chills CCU's religious exercise.

215. The Final Mandate exposes CCU to substantial fines for its religious exercise.

216. The Final Mandate exposes CCU to substantial competitive disadvantages, in that it will no longer be permitted to offer health insurance.

217. The Final Mandate imposes a substantial burden on CCU's religious exercise.

218. The Final Mandate is not narrowly tailored to any compelling governmental interest.

219. The Final Mandate and Defendants' threatened enforcement of the Final Mandate violate CCU's rights secured to it by the Free Exercise Clause of the First Amendment of the United States Constitution.

220. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT III

Violation of the First Amendment to the United States Constitution
Free Exercise Clause
Intentional Discrimination

221. CCU incorporates by reference all preceding paragraphs.

222. CCU's sincerely held religious beliefs prohibit it from deliberately providing health insurance that would facilitate access to abortion or related education and counseling. CCU's compliance with these beliefs is a religious exercise.

223. Despite being informed in detail of these beliefs beforehand, Defendants designed the Final Mandate and its religious employers exemption to the Final Mandate to target religious organizations like CCU because of their religious beliefs.

224. Defendants promulgated both the Final Mandate and its religious employers exemption to suppress the religious exercise of CCU and others.

225. The Final Mandate and Defendants' threatened enforcement of the Final Mandate thus violate CCU's rights secured to it by the Free Exercise Clause of the First Amendment of the United States Constitution.

226. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT IV

Violation of the First Amendment to the United States Constitution
Free Exercise and Establishment Clauses
Discrimination Among Religions

227. CCU incorporates by reference all preceding paragraphs.

228. The Free Exercise Clause and Establishment Clause of the First Amendment mandate the equal treatment of all religious faiths and institutions without discrimination or preference.

229. This mandate of equal treatment protects organizations as well as individuals.

230. The Final Mandate's narrow exemption for "religious employers" but not others discriminates among religions on the basis of religious views or religious status.

231. The Final Mandate and Defendants' threatened enforcement of the Final Mandate thus violate CCU's rights secured to it by the First Amendment of the United States Constitution.

232. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT V

Violation of the First Amendment to the United States Constitution Establishment Clause Selective Burden/Denominational Preference (*Larson v. Valente*)

233. CCU incorporates by reference all preceding paragraphs.

234. By design, defendants imposed the Final Mandate on some religious organizations but not on others, resulting in a selective burden on CCU.

235. The Final Mandate and Defendants' threatened enforcement of the Final Mandate therefore violate CCU's rights secured to it by the Establishment Clause of the First Amendment of the United States Constitution.

236. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT VI

Interference in Matters of Internal Religious Governance Free Exercise Clause and Establishment Clause

237. Plaintiffs repeat and reallege each of the foregoing allegations in this Complaint.

238. The Free Exercise Clause and the Establishment Clause protect the freedom of religious organizations to decide for themselves, free from state interference, matters of internal governance as well as those of faith and doctrine.

239. Under these Clauses, the Government may not interfere with a religious organization's internal decisions concerning the organization's religious structure, leadership, or doctrine.

240. Under these Clauses, the Government may not interfere with a religious organization's internal decision if that interference would affect the faith and mission of the organization itself.

241. CCU has made an internal decision, dictated by its Christian faith, that the health plans it makes available to its employees and students may not subsidize, provide, or facilitate access to abortifacient drugs, devices, or related services.

242. The Final Mandate interferes with CCU's internal decisions concerning its structure and mission by requiring it to subsidize, provide, and facilitate practices that directly conflict with its Christian beliefs

243. The Final Mandate's interference with CCU's internal decisions affects its faith and mission by requiring it to subsidize, provide, and facilitate practices that directly conflict with its religious beliefs.

244. Because the Final Mandate interferes with CCU's internal decision making in a manner that affects its faith and mission, it violates the Establishment Clause and Free Exercise Clause of the First Amendment.

245. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT VII

Religious Discrimination
Violation of the First and Fifth Amendments to the United States Constitution
Establishment Clause and Due Process

246. CCU incorporates by reference all preceding paragraphs.

247. By design, defendants imposed the Final Mandate on some religious organizations but not on others, resulting in discrimination among religious objectors.

248. Religious liberty is a fundamental right.

249. The "religious employer" exemption protects many religious objectors, but not CCU.

250. The "accommodation" provides no meaningful protection for CCU.

251. The Final Mandate and Defendants' threatened enforcement of the Final Mandate therefore violate CCU's rights secured to it by the Establishment Clause of the First Amendment and the Due Process Clause of the Fifth Amendment to the United States Constitution.

252. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT VIII

Violation of the Fifth Amendment to the United States Constitution Due Process and Equal Protection

253. CCU incorporates by reference all preceding paragraphs.

254. The Due Process Clause of the Fifth Amendment mandates the equal treatment of all religious faiths and institutions without discrimination or preference.

255. This mandate of equal treatment protects organizations as well as individuals.

256. The Final Mandate's narrow exemption for "religious employers" but not others discriminates among religions on the basis of religious views or religious status.

257. The Final Mandate and Defendants' threatened enforcement of the Final Mandate thus violate CCU's rights secured to it by the Fifth Amendment of the United States Constitution.

258. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT IX

Violation of the First Amendment to the United States Constitution
Freedom of Speech
Compelled Speech

259. CCU incorporates by reference all preceding paragraphs.

260. CCU teaches that abortion violates its religious beliefs.

261. The Final Mandate would compel CCU to facilitate activities that CCU teaches are violations of its religious beliefs.

262. The Final Mandate would compel CCU to facilitate access to government-dictated education and counseling related to abortion.

263. Defendants' actions thus violate CCU's right to be free from compelled speech as secured to it by the First Amendment of the United States Constitution.

264. The Final Mandate's compelled speech requirement is not narrowly tailored to a compelling governmental interest.

265. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT X

Violation of the First Amendment to the United States Constitution
Freedom of Speech
Expressive Association

266. CCU incorporates by reference all preceding paragraphs.

267. CCU teaches that abortion violates its religious beliefs.

268. The Final Mandate would compel CCU to facilitate activities that it teaches are violations of its religious beliefs.

269. The Final Mandate would compel CCU to facilitate access to government-dictated education and counseling related to abortion.

270. Defendants' actions thus violate CCU's right of expressive association as secured to it by the First Amendment of the United States Constitution.

271. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT XI

Violation of the First Amendment to the United States Constitution
Free Exercise Clause and Freedom of Speech
Unbridled Discretion

272. CCU incorporates by reference all preceding paragraphs.

273. By stating that HRSA "may" grant an exemption to certain religious groups, the Final Mandate vests HRSA with unbridled discretion over which organizations can have their First Amendment interests accommodated.

274. Defendants have exercised unbridled discretion in a discriminatory manner by granting an exemption via footnote in a website for a narrowly defined group of "religious employers" but not for other religious organizations like CCU.

275. Defendants have further exercised unbridled discretion by indiscriminately waiving enforcement of some provisions of the Affordable Care Act while refusing to waive enforcement of the Final Mandate, despite its conflict with the free exercise of religion.

276. The Defendants' actions therefore violate CCU's right not to be subjected to a system of unbridled discretion when engaging in speech or when engaging in religious exercise, as secured to it by the First Amendment of the United States Constitution.

277. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT XII

Violation of the Administrative Procedure Act
Lack of Good Cause and Improper Delegation

278. CCU incorporates by reference all preceding paragraphs.

279. The Affordable Care Act expressly delegates to HRSA, an agency within Defendant HHS, the authority to establish guidelines concerning the "preventive care" that a group health plan and health insurance issuer must provide.

280. Given this express delegation, Defendants were required to engage in formal notice-and-comment rulemaking in a manner prescribed by law before issuing the guidelines that group health plans and insurers must cover. Proposed regulations were required to be published in the Federal Register and interested persons were required to be given an opportunity to participate in the rulemaking through the submission of written data, views, or arguments.

281. Defendants promulgated the "preventive care" guidelines without engaging in formal notice-and-comment rulemaking in a manner prescribed by law. Defendants, instead, wholly delegated their responsibilities for issuing preventive care guidelines to a non-governmental entity, the IOM.

282. The IOM did not permit or provide for the broad public comment otherwise required under the APA concerning the guidelines that it would recommend. The dissent to the IOM report noted both that the IOM conducted its review in an unacceptably short time frame, and that the review process lacked transparency.

283. Within two weeks of the IOM issuing its guidelines, Defendant HHS issued a press release announcing that the IOM's guidelines were required under the Affordable Care Act.

284. Defendants have never explained why they failed to enact these "preventive care" guidelines through notice-and-comment rulemaking as required by the APA.

285. Defendants' stated reasons that public comments were unnecessary, impractical, and opposed to the public interest are false and insufficient, and do not constitute "good cause."

286. Without proper notice and opportunity for public comment, Defendants were unable to take into account the full implications of the regulations by completing a meaningful "consideration of the relevant matter presented."

287. Defendants did not consider or respond to the voluminous comments they received in opposition to the interim final rule or the NPRM.

288. Therefore, Defendants have taken agency action not in observance with procedures required by law, and CCU is entitled to relief pursuant to 5 U.S.C. § 706(2)(D).

289. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT XIII

Violation of the Administrative Procedure Act
Arbitrary and Capricious Action

290. CCU incorporates by reference all preceding paragraphs.

291. In promulgating the Final Mandate, Defendants failed to consider the constitutional and statutory implications of the Final Mandate on CCU and similar organizations.

292. Defendants' explanation for its decision not to exempt CCU and similar religious organizations from the Final Mandate runs counter to the evidence submitted by religious organizations during the comment period.

293. Defendant Secretary Sebelius, in remarks made at Harvard University on April 8, 2013, essentially conceded that Defendants completely disregarded the religious liberty concerns submitted by thousands of religious organizations and individuals.

294. Thus, Defendants' issuance of the interim final rule was arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A) because the rules fail to consider the full extent of their implications and they do not take into consideration the evidence against them.

295. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT XIV

Violation of the Administrative Procedure Act
Agency Action Without Statutory Authority

296. CCU incorporates by reference all preceding paragraphs.

297. Defendant's authority to enact regulations under the Affordable Care Act is limited to the authority expressly granted them by Congress.

298. Defendants lack statutory authority to coerce insurance issuers and third party administrators to pay for contraceptive and abortifacient services for individuals with whom they have no contractual or fiduciary relationship.

299. Defendants lack statutory authority to prevent insurance issuers and third party administrators from passing on the costs of providing contraceptive and abortifacient services via higher premiums or other charges that are not "cost sharing."

300. Defendants lack statutory authority to allow user fees from the federal exchanges to be used to purchase contraceptive and abortifacient services for employees not participating in the exchanges.

301. Because the Final Mandate's "accommodation" for non-exempt, nonprofit religious organizations lacks legal authority, it is arbitrary and capricious and provides no legitimate protection of objecting organization's First Amendment rights.

302. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT XV

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law
Weldon Amendment
Religious Freedom Restoration Act
First Amendment to the United States Constitution

303. CCU incorporates by reference all preceding paragraphs.

304. The Final Mandate is contrary to the provisions of the Weldon Amendment of the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009, Public Law 110 329, Div. A, Sec. 101, 122 Stat. 3574, 3575 (Sept. 30, 2008).

305. The Weldon Amendment provides that "[n]one of the funds made available in this Act [making appropriations for Defendants Department of Labor and Health and Human Services] may be made available to a Federal agency or program . . . if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions."

306. The Final Mandate requires issuers, including CCU, to deliberately provide health insurance that facilitates access to all Federal Drug Administration-approved contraceptives.

307. Some FDA-approved contraceptives cause abortions.

308. As set forth above, the Final Mandate violates RFRA and the First Amendment.

309. Under 5 U.S.C. § 706(2)(A), the Final Mandate is contrary to existing law, and is in violation of the APA.

310. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

COUNT XVI

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law
Affordable Care Act

311. CCU incorporates by reference all preceding paragraphs.

312. The Final Mandate is contrary to the provisions of the Affordable Care Act.

313. Section 1303(b)(1)(A) of the Affordable Care Act states that "nothing in this title"—*i.e.*, title I of the Act, which includes the provision dealing with "preventive services"—"shall be construed to require a qualified health plan to provide coverage of [abortion] services . . . as part of its essential health benefits for any plan year."

314. Section 1303 further states that it is "the issuer" of a plan that "shall determine whether or not the plan provides coverage" of abortion services.

315. Under the Affordable Care Act, Defendants do not have the authority to decide whether a plan covers abortion; only the issuer does.

316. The Final Mandate requires issuers, including CCU, to deliberately provide health insurance that would facilitate access to coverage of all Federal Drug Administration-approved contraceptives.

317. Some FDA-approved contraceptives cause abortions.

318. Under 5 U.S.C. § 706(2)(A), the Final Mandate is contrary to existing law, and is in violation of the APA.

319. Absent injunctive and declaratory relief against the Final Mandate, CCU has been and will continue to be harmed.

PRAYER FOR RELIEF

Wherefore, CCU requests that the Court:

a. Declare that the Final Mandate and Defendants' enforcement of the Final Mandate against CCU violate the First Amendment of the United States Constitution;

b. Declare that the Final Mandate and Defendants' enforcement of the Final Mandate against CCU violate the Fifth Amendment of the United States Constitution;

c. Declare that the Final Mandate and Defendants' enforcement of the Final Mandate against CCU violate the Religious Freedom Restoration Act;

d. Declare that the Final Mandate was issued in violation of the Administrative Procedure Act;

e. Issue a permanent injunction prohibiting Defendants from enforcing the Final Mandate against CCU and other religious organizations that object to facilitating access to contraceptives (including abortifacient contraceptives), sterilization procedures, and related education and counseling;

f. Award CCU the costs of this action and reasonable attorney's fees; and

g. Award such other and further relief as it deems equitable and just.

Respectfully submitted this 7th day of August, 2013.

JURY DEMAND

CCU requests a trial by jury on all issues so triable.

/s/ *Eric S. Baxter*
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VERIFICATION OF COMPLAINT ACCORDING TO 28 U.S.C. § 1746

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on Aug. 6, 2013

/s/ *William L. Armstrong*
William L. Armstrong*
President, Colorado Christian University

**I certify that I have the signed original of this document, which is available for inspection at any time by the Court or a party to this action.*

EXHIBIT A

Office of Women's Health

Birth Control Guide

This guide gives the basic facts about the different kinds of FDA-approved medicines and devices for birth control. Ask your doctor to tell you about all of the risks and benefits of using these products.

If you do not want to get pregnant, there are many birth control options to choose from. No one product is best for everyone. The only sure way to avoid pregnancy and sexually transmitted infections (STIs or STDs) is not to have any sexual contact (abstinence). This guide lists FDA-approved products for birth control. Talk to your doctor, nurse, or pharmacist about the best method for you.

There are different kinds of medicines and devices for birth control:

To Learn More:

This guide should not be used in place of talking to your doctor or reading the label for your product. The product and risk information may change. To get the most recent information for your birth control go to:

Drugs
Go to http://www.accessdata.fda.gov/scripts/cder/drugsatfda
(type in the name of your drug)

Devices
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/LSTSimpleSearch.cfm
(type in the name of your device)

Some things to think about when you choose birth control:

- Your health
- How often you have sex.
- How many sexual partners you have.
- If you want to have children in the future.
- If you will need a prescription or if you can buy the method over-the-counter.
- The number of pregnancies expected per 100 women who use a method for 1 year. For comparison, about 85 out of 100 sexually active women who do not use any birth control can expect to become pregnant in a year.
- This booklet lists pregnancy rates of **typical use**. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent).
- For more information on the chance of getting pregnant while using a method, please see Trussell, J. (2011). "Contraceptive failure in the United States." Contraception 83(5):397-404.

Tell your doctor, nurse, or pharmacist if you:

- Smoke.
- Have liver disease.
- Have blood clots.
- Have family members who have had blood clots.
- Are taking any other medicines, like antibiotics.
- Are taking any herbal products, like St. John's Wort.

To avoid pregnancy:

- No matter which method you choose, it is important to follow all of the directions carefully. If you don't, you raise your chance of getting pregnant.
- The best way to avoid pregnancy and sexually transmitted infections (STIs) is to practice total abstinence (do not have any sexual contact).

BARRIER METHODS

Block sperm from reaching the egg

Male Condom

(Latex or Polyurethane)

What is it?

- A thin film sheath placed over the erect penis.

How do I use it?

- Put it on the erect penis right before sex.
- Pull out before the penis softens.
- Hold the condom against the base of the penis before pulling out.
- Use it only once and then throw it away.

How do I get it?

- You do not need a prescription.
- You can buy it over-the-counter.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, 18 may get pregnant.
- The most important thing is that you use a condom every time you have sex.

Some Risks

- Irritation
- Allergic reactions (If you are allergic to latex, you can try condoms made of polyurethane).

Does it protect me from sexually transmitted infections (STIs)?

- Except for abstinence, latex condoms are the best protection against HIV/AIDS and other STIs.

Female Condom

What is it?

- A lubricated, thin polyurethane pouch that is put into the vagina.

How do I use it?

- Put the female condom into the vagina right before sex.
- Use it only once and then throw it away.

How do I get it?

- You do not need a prescription.
- You can buy it over-the-counter.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 21 may get pregnant.
- The most important thing is that you use a condom every time you have sex.

Some Risks

- Irritation
- Allergic reactions

Does it protect me from sexually transmitted infections (STIs)?

- May give some protection against STIs, but more research is needed.
- Not as effective as male latex condoms.

BARRIER METHODS

Block sperm from reaching the egg

Diaphragm with Spermicide

Spermicides containing N9 can irritate the vagina and rectum. It may increase the risk of getting the AIDS virus (HIV) from an infected partner.

What is it?

- A dome-shaped flexible disk with a flexible rim.
- Made from latex rubber or silicone.
- It covers the cervix.

How do I use it?

- You need to put spermicidal jelly on the inside of the diaphragm before putting it into the vagina.
- You must put the diaphragm into the vagina before having sex.
- You must leave the diaphragm in place at least 6 hours after having sex.
- It can be left in place for up to 24 hours. You need to use more spermicide every time you have sex.

How do I get it?

- You need a prescription.
- A doctor or nurse will need to do an exam to find the right size diaphragm for you.
- You should have the diaphragm checked after childbirth or if you lose more than 15 pounds. You might need a different size.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 12 may get pregnant.

Some Risks

- Irritation, allergic reactions, and urinary tract infection.
- If you keep it in place longer than 24 hours, there is a risk of toxic shock syndrome. Toxic shock is a rare but serious infection.

Does it protect me from sexually transmitted infections (STIs)? No.

Sponge with Spermicide

Spermicides containing N9 can irritate the vagina and rectum. It may increase the risk of getting the AIDS virus (HIV) from an infected partner.

What is it?

- A disk-shaped polyurethane device with the spermicide nonoxynol-9.

How do I use it?

- Put it into the vagina before you have sex.
- Protects for up to 24 hours. You do not need to use more spermicide each time you have sex.
- You must leave the sponge in place for at least 6 hours after having sex.
- You must take the sponge out within 30 hours after you put it in. Throw it away after you use it.

How do I get it?

- You do not need a prescription.
- You can buy it over-the-counter.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, 12 to 24 may get pregnant.
- It may not work as well for women who have given birth. Childbirth stretches the vagina and cervix and the sponge may not fit as well.

Some Risks

- Irritation
- Allergic reactions
- Some women may have a hard time taking the sponge out.
- If you keep it in place longer than 24-30 hours, there is a risk of toxic shock syndrome. Toxic shock is a rare but serious infection.

Does it protect me from sexually transmitted infections (STIs)? No.

BARRIER METHODS

Block sperm from reaching the egg

Cervical Cap with Spermicide

Spermicides containing N9 can irritate the vagina and rectum. It may increase the risk of getting the AIDS virus (HIV) from an infected partner.

What is it?

- A soft latex or silicone cup with a round rim, which fits snugly around the cervix.

How do I use it?

- You need to put spermicidal jelly inside the cap before you use it.
- You must put the cap in the vagina before you have sex.
- You must leave the cap in place for at least 6 hours after having sex.
- You may leave the cap in for up to 48 hours.
- You do NOT need to use more spermicide each time you have sex.

How do I get it?

- You need a prescription.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 17 to 23 may get pregnant.
- It may not work as well for women who have given birth. Childbirth stretches the vagina and cervix and the cap may not fit as well.

Some Risks

- Irritation, allergic reactions, and abnormal Pap test.
- You may find it hard to put in.
- If you keep it in place longer than 48 hours, there is a risk of toxic shock syndrome. Toxic shock is a rare but serious infection.

Does it protect me from sexually transmitted infections (STIs)? No

Spermicide Alone

Spermicides containing N9 can irritate the vagina and rectum. It may increase the risk of getting the AIDS virus (HIV) from an infected partner.

What is it?

- A foam, cream, jelly, film, or tablet that you put into the vagina.

How do I use it?

- You need to put spermicide into the vagina 5 to 90 minutes before you have sex.
- You usually need to leave it in place at least 6 to 8 hours after sex; do not douche or rinse the vagina for at least 6 hours after sex.
- Instructions can be different for each type of spermicide. Read the label before you use it.

How do I get it?

- You do not need a prescription.
- You can buy it over-the-counter.

Chance of getting pregnant with typical use

(Number of pre

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 28 may get pregnant.
- Different studies show different rates of effectiveness.

Some Risks

- Irritation
- Allergic reactions
- Urinary tract infection
- If you are also using a medicine for a vaginal yeast infection, the spermicide might not work as well.

Does it protect me from sexually transmitted infections (STIs)? No.

HORMONAL METHODS

Prevent pregnancy by interfering with ovulation and possibly fertilization of the egg

Oral Contraceptives (Combined Pill)
"The Pill"

What is it?

- A pill that has 2 hormones (estrogen and progestin) to stop the ovaries from releasing eggs.
- It also thickens the cervical mucus, which keeps the sperm from getting to the egg.

How do I use it?

- You should swallow the pill at the same time every day, whether or not you have sex.
- If you miss 1 or more pills, or start a pill pack too late, you may need to use another method of birth control, like a condom.

How do I get it?

- You need a prescription.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 9 may get pregnant.

Some Side Effects

- Changes in your cycle (period)
- Nausea
- Breast tenderness
- Headache

Less Common Serious Side Effects

- It is not common, but some women who take the pill develop high blood pressure.
- It is rare, but some women will have blood clots, heart attacks, or strokes.

Does it protect me from sexually transmitted infections (STIs)? No.

Oral Contraceptives (Progestin-only)
"The Mini Pill"

What is it?

- A pill that has only 1 hormone, a progestin.
- It thickens the cervical mucus, which keeps sperm from getting to the egg.
- Less often, it stops the ovaries from releasing eggs.

How do I use it?

- You should swallow the pill at the same time every day, whether or not you have sex.
- If you miss 1 or more pills, or start a pill pack too late, you may need to use another method of birth control, like a condom.

How do I get it?

- You need a prescription.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 9 may get pregnant.

Some Risks

- Irregular bleeding
- Headache
- Breast tenderness
- Nausea
- Dizziness

Does it protect me from sexually transmitted infections (STIs)? No.

HORMONAL METHODS

Prevent pregnancy by interfering with ovulation and possibly fertilization of the egg

Oral Contraceptives (Extended/Continuous Use)

"The Pill"

What is it?

- A pill that has 2 hormones (estrogen and progestin) to stop the ovaries from releasing eggs.
- It also thickens the cervical mucus, which keeps sperm from getting to the egg.
- These pills are designed so women have fewer or no periods.

How do I use it?

- You should swallow the pill at the same time every day, whether or not you have sex.
- If you miss 1 or more pills, or start a pill pack too late, you may need to use another method of birth control, like a condom.

How do I get it?

- You need a prescription.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 9 may get pregnant.

Some Risks

- Risks are similar to other oral contraceptives with estrogen and progestin.
- You may have more light bleeding and spotting between periods than with 21 or 24 day oral contraceptives.
- It may be harder to know if you become pregnant, since you will likely have fewer periods or no periods.

Does it protect me from sexually transmitted infections (STIs)? No.

Patch

What is it?

- This is a skin patch you can wear on the lower abdomen, buttocks, or upper arm or back.
- It has hormones (estrogen and progestin) that stop the ovaries from releasing eggs.
- It also thickens the cervical mucus, which keeps sperm from getting to the egg.

How do I use it?

- You put on a new patch and take off the old patch once a week for 3 weeks (21 total days).
- Don't put on a patch during the fourth week. Your menstrual period should start during this patch-free week.
- If the patch comes loose or falls off, you may need to use another method of birth control, like a condom.

How do I get it?

- You need a prescription.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, about 9 may get pregnant.

Some Risks

- It will expose you to higher levels of estrogen compared to most combined oral contraceptives.
- It is not known if serious risks, such as blood clots and strokes, are greater with the patch because of the greater exposure to estrogen.

Does it protect me from sexually transmitted infections (STIs)? No.

HORMONAL METHODS

Prevent pregnancy by interfering with ovulation and possibly fertilization of the egg

Vaginal Contraceptive Ring

What is it?

- It is a flexible ring that is about 2 inches around.
- It releases 2 hormones (progestin and estrogen) to stop the ovaries from releasing eggs.
- It also thickens the cervical mucus, which keeps sperm from getting to the egg.

How do I use it?

- You put the ring into your vagina.
- Keep the ring in your vagina for 3 weeks and then take it out for 1 week. Your menstrual period should start during this ring-free week.
- If the ring falls out and stays out for more than 3 hours, replace it but use another method of birth control, like a condom, until the ring has been in place for 7 days in a row.
- Read the directions and talk to your doctor, nurse or pharmacist about what to do.

How do I get it?

- You need a prescription.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

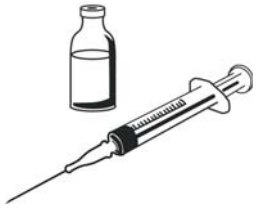
- Out of 100 women who use this method, about 9 may get pregnant.

Some Side Effects and Risks

- Vaginal discharge, discomfort in the vagina, and mild irritation.
- Other risks are similar to oral contraceptives (combined pill).

Does it protect me from sexually transmitted infections (STIs)? No.

Shot/Injection



What is it?

- A shot of the hormone progestin, either in the muscle or under the skin.

How does it work?

- The shot stops the ovaries from releasing eggs.
- It also thickens the cervical mucus, which keeps the sperm from getting to the egg.

How do I get it?

- You need 1 shot every 3 months from a health care provider.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, including women who don't get the shot on time, 6 may get pregnant.

Some Risks

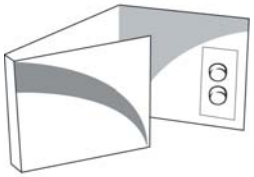
- You may lose bone density if you get the shot for more than 2 years in a row.
- Bleeding between periods
- Headaches
- Weight gain
- Nervousness
- Abdominal discomfort

Does it protect me from sexually transmitted infections (STIs)? No.

EMERGENCY CONTRACEPTION

May be used if you did not use birth control or if your regular birth control fails. It should not be used as a regular form of birth control.

Plan B, Plan B One-Step and Next Choice (Levonorgestrel)



What is it?

- These are pills with the hormone progestin.
- They help prevent pregnancy after birth control failure or unprotected sex.

How does it work?

- It works mainly by stopping the release of an egg from the ovary. It may also work by preventing fertilization of an egg (the uniting of sperm with the egg) or by preventing attachment (implantation) to the womb (uterus).
- For the best chance for it to work, you should take the pill(s) as soon as possible after unprotected sex.
- You should take emergency contraception within 3 days after unprotected sex.

How do I get it?

- You can get Plan B, Plan B One-Step and Next Choice without a prescription if you are 17 years or older.
- If you are younger than 17, you need a prescription.

Chance of getting pregnant with typical use

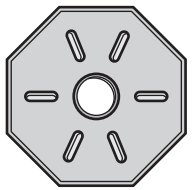
- 7 out of every 8 women who would have gotten pregnant will not become pregnant after taking Plan B, Plan B One-Step, or Next Choice.

Some Risks

- Nausea
- Vomiting
- Abdominal pain
- Fatigue
- Headache

Does it protect me from sexually transmitted infections (STIs)? No.

Ella (ulipristal acetate)



What is it?

- A pill that blocks the hormone progesterone.
- It helps prevent pregnancy after birth control failure or unprotected sex.

How does it work?

- It works mainly by stopping or delaying the ovaries from releasing an egg. It may also work by changing the lining of the womb (uterus) that may prevent attachment (implantation).
- For the best chance for it to work, you should take the pill as soon as possible after unprotected sex.
- You should take Ella within 5 days after having unprotected sex.

How do I get it?

- You need a prescription.

Chance of getting pregnant with typical use

- 6 or 7 out of every 10 women who would have gotten pregnant will not become pregnant after taking Ella.

Some Risks

- Headache
- Nausea
- Abdominal pain
- Menstrual pain
- Tiredness
- Dizziness

Does it protect me from sexually transmitted infections (STIs)? No.

IMPLANTED METHODS

Inserted/implanted into the body and can be kept in place for several years

Copper IUD

What is it?

- A T-shaped device that is put into the uterus by a healthcare provider.

How does it work?

- The IUD prevents sperm from reaching the egg, from fertilizing the egg, and may prevent the egg from attaching (implanting) in the womb (uterus).
- It does not stop the ovaries from making an egg each month.
- The Copper IUD can be used for up to 10 years.
- After the IUD is taken out, it is possible to get pregnant.

How do I get it?

- A doctor or other healthcare provider needs to put in the IUD.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, less than 1 may get pregnant.

Some Side Effects

- Cramps
- Irregular bleeding

Uncommon Risks

- Pelvic inflammatory disease
- Infertility

Rare Risk

- IUD is stuck in the uterus or found outside the uterus.
- Life-threatening infection

Does it protect me from sexually transmitted infections (STIs)? No.

IUD with progestin

What is it?

- A T-shaped device that is put into the uterus by a healthcare provider.

How does it work?

- It may thicken the mucus of your cervix, which makes it harder for sperm to get to the egg, and also thins the lining of your uterus.
- After a doctor or other healthcare provider puts in the IUD, it can be used for up to 5 years.
- After the IUD is taken out, it is possible to get pregnant.

How do I get it?

- A doctor or other healthcare provider needs to put in the IUD.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, less than 1 may get pregnant.

Some Side Effects

- Irregular bleeding
- No periods
- Abdominal/pelvic pain
- Ovarian cysts

Uncommon Risks

- Pelvic inflammatory disease
- Infertility

Rare Risk

- IUD is stuck in the uterus or found outside the uterus.
- Life-threatening infection

Does it protect me from sexually transmitted infections (STIs)? No.

IMPLANTED METHODS

Inserted/implanted into the body and can be kept in place for several years

Implantable Rod

What is it?

- A thin, matchstick-sized rod that contains the hormone progestin.
- It is put under the skin on the inside of your upper arm.

How does it work?

- It stops the ovaries from releasing eggs.
- It thickens the cervical mucus, which keeps sperm from getting to the egg.
- It can be used for up to 3 years.

How do I get it?

- After giving you local anesthesia, a doctor or nurse will put it under the skin of your arm with a special needle.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, less than 1 may get pregnant.

Some Side Effects

- Changes in bleeding patterns
- Weight gain
- Breast and abdominal pain

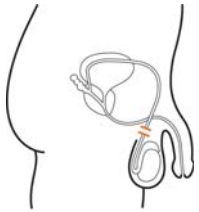
Does it protect me from sexually transmitted infections (STIs)? No.

PERMANENT METHODS

For people who are sure they never want to have a child or do not want any more children.

Sterilization Surgery for Men Vasectomy

This method is for men who are sure they never want to have a child or do not want any more children. If you are thinking about reversal, vasectomy may not be right for you. Sometimes it is possible to reverse the operation, but there are no guarantees. Reversal involves complicated surgery that might not work.



What is it?

- This is a surgery a man has only once.
- It is permanent.

How does it work?

- A surgery blocks a man's vas deferens (the tubes that carry sperm from the testes to other glands).
- Semen (the fluid that comes out of a man's penis) never has any sperm in it.
- It takes about 3 months to clear sperm out of a man's system. You need to use another form of birth control until a test shows there are no longer any sperm in the seminal fluid.

How do I get it?

- A man needs to have surgery.
- Local anesthesia is used.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women whose partner has had a vasectomy, less than 1 may get pregnant.

Some Risks

- Pain
- Bleeding
- Infection

Does it protect me from sexually transmitted infections (STIs)? No.

The success of reversal surgery depends on:

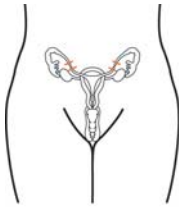
- The length of time since the vasectomy was performed.
- Whether or not antibodies to sperm have developed.
- The method used for vasectomy
- Length and location of the segments of vas deferens that were removed or blocked.

PERMANENT METHODS

For people who are sure they never want to have a child or do not want any more children.

Sterilization Surgery for Women

Surgical Implant (also called trans-abdominal surgical sterilization)



What is it?

- A device is placed on the outside of each fallopian tube.

How does it work?

- One way is by tying and cutting the tubes — this is called tubal ligation. The fallopian tubes also can be sealed using an instrument with an electrical current. They also can be closed with clips, clamps or rings. Sometimes, a small piece of the tube is removed.
- The woman's fallopian tubes are blocked so the egg and sperm can't meet in the fallopian tube. This stops you from getting pregnant.
- This is a surgery a woman has only once.
- It is permanent.

How do I get it?

- This is a surgery you ask for.
- You will need general anesthesia.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, less than 1 may get pregnant.

Some Risks

- Pain
- Bleeding
- Infection or other complications after surgery
- Ectopic (tubal) pregnancy

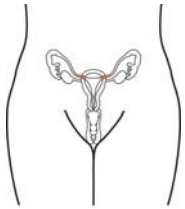
Does it protect me from sexually transmitted infections (STIs)? No.

Can it be reversed?

Reversals require complicated surgery. Even though tubes can sometimes be rejoined, there are no guarantees. For many women, reversals are not possible because there is not enough of their tubes left to reconnect.

Sterilization Implant for Women

Transcervical Surgical Sterilization Implant



What is it?

- Small flexible, metal coil that is put into the fallopian tubes through the vagina.
- The device works by causing scar tissue to form around the coil. This blocks the fallopian tubes and stops you from getting pregnant.

How does it work?

- The device is put inside the fallopian tube with a special catheter.
- You need to use another birth control method during the first 3 months. You will need an X-ray to make sure the device is in the right place.
- It is permanent.

How do I get it?

- The devices are placed into the tubes using a camera placed in the uterus.
- Once the tubes are found, the devices are inserted.
- Since it is inserted through the vagina, no skin cutting (incision) is needed.
- You may need local anesthesia.

Chance of getting pregnant with typical use

(Number of pregnancies expected per 100 women who use this method for 1 year)

- Out of 100 women who use this method, less than 1 may get pregnant.

Some Risks

- Mild to moderate pain after insertion
- Ectopic (tubal) pregnancy

Does it protect me from sexually transmitted infections (STIs)? No.

http://www.fda.gov/birthcontrol

To Learn More:

This guide should not be used in place of talking to your doctor or reading the label for your product. The product and risk information may change. To get the most recent information for your birth control go to:

Drugs

Go to http://www.accessdata.fda.gov/scripts/cder/drugsatfda
(type in the name of your drug)

Devices

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/LSTSimpleSearch.cfm
(type in the name of your device)

UPDATED AUGUST 2012

TAKE TIME TO CARE ... For yourself, for those who need you.