

No. 13-1218

**UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT**

W.L. (BILL) ARMSTRONG, et al.,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Colorado
(No. 1:13-cv-00563-RBJ-BNB, Hon. R. Brooke Jackson)

Amicus Curiae Brief of
**Association of American Physicians & Surgeons,
American Association of Pro-Life Obstetricians & Gynecologists,
Christian Medical Association, Catholic Medical Association,
National Catholic Bioethics Center, Physicians for Life, and
National Association of Pro Life Nurses,**
in Support of Plaintiffs-Appellants
and Reversal of the Lower court

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CORPORATE DISCLOSURE STATEMENT

Amici Curiae Association of American Physicians & Surgeons, American Association of Pro-Life Obstetricians & Gynecologists, Christian Medical Association, Catholic Medical Association, the National Catholic Bioethics Center, Physicians for Life, and National Association of Pro Life Nurses have no parent corporations or stock which a publicly held corporation can hold.

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STATEMENT OF INTEREST OF *AMICI CURIAE*¹

Amici curiae are seven national organizations whose members include physicians, bioethicists, and other healthcare professionals who have a profound interest in protecting human life in their roles as healthcare providers, medical experts, and consumers. Generally, *Amici* are sensitive to healthcare disparities and are supportive of a variety of public, private, and charitable efforts that address health care affordability and accessibility. Notwithstanding their support of measures to expand health care affordability and accessibility, *Amici* oppose and object to the requirement imposed on Plaintiffs by Defendants to pay for insurance that covers drugs and devices with life-ending mechanisms of action. This requirement violates Plaintiffs' sincerely held religious beliefs and freedom of conscience.

Amici include the following medical and ethics associations:

Association of American Physicians & Surgeons, Inc. (“AAPS”) is a national association of physicians. Founded in 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the

¹ In accordance with Fed. R. App. P. 29, the Plaintiffs-Appellants and Defendants-Appellees (the parties) have consented to the filing of this *amicus* brief. No party's counsel has authored the brief in whole or in part. No party or party's counsel has contributed money intended to fund preparing or submitting this brief. No person other than *Amici*, their members, or their counsel has contributed money that was intended to fund preparing or submitting this brief.

sanctity of the patient-physician relationship. AAPS has been a litigant in the U.S. Supreme Court and in other appellate courts. *See, e.g., Cheney v. United States Dist. Court*, 542 U.S. 367, 374 (2004) (citing *Association of American Physicians & Surgeons v. Clinton*, 997 F.2d 898 (D.C. Cir. 1993)); *Association of American Physicians & Surgeons v. Mathews*, 423 U.S. 975 (1975). In addition, the U.S. Supreme Court has specifically cited *amicus* briefs submitted by AAPS in high-profile cases. *See, e.g., Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *id.* at 959, 963 (Kennedy, J., dissenting); *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting). Similarly, the Third Circuit cited AAPS in the first paragraph of one of its opinions, ruling in favor of AAPS's position. *See Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006).

American Association of Pro-Life Obstetricians & Gynecologists

(“AAPLOG”) is a non-profit professional medical organization consisting of 2,500 obstetrician-gynecologist members and associates. Significantly, the American College of Obstetricians and Gynecologists (ACOG) has recognized AAPLOG as one of its largest special interest groups. AAPLOG is extremely concerned about the potential long-term adverse consequences of abortion on a woman’s future health and continues to explore data from around the world regarding abortion-associated complications (such as depression, substance abuse, suicide, other pregnancy-associated mortality, subsequent preterm birth, and

placenta previa) in order to provide a realistic appreciation of abortion-related health risks.

Christian Medical Association, founded in 1931, is a nonprofit national organization of Christian physicians and allied healthcare professionals with almost 16,000 members. In addition to its physician members, it also has associate members from a number of allied health professions, including nurses and physician assistants. Christian Medical Association provides up-to-date information on the legislative, ethical, and medical aspects of abortion and its impact on maternal health.

Catholic Medical Association is a nonprofit national organization comprised of almost 2,000 members covering over 75 medical specialties. Catholic Medical Association helps to educate the medical profession and society at large about issues in medical ethics, including abortion and maternal health, through its annual conferences and quarterly journal, *The Linacre Quarterly*.

The National Catholic Bioethics Center, established in 1972, conducts research, consultation, publishing, and education to promote human dignity in health care and the life sciences, and derives its message directly from the teachings of the Catholic Church.

Physicians for Life is a national nonprofit medical organization that exists to draw attention to the issues of abortion, teen pregnancy, and sexually

transmitted diseases. Physicians for Life encourages physicians to educate their patients not only regarding the innate value of human life at all stages of development, but also on the physical and psychological risks inherent in abortion.

National Association of Pro Life Nurses (“NAPN”) is a national not-for-profit nurses’ organization with members in every state. NAPN unites nurses who seek excellence in nurturing for all, including mothers and the unborn. As a professional organization, NAPN seeks to establish and protect ethical values of the nursing profession.

Based on the scientific evidence regarding the post-fertilization destructive effect of certain drugs and devices which are included in the Food and Drug Administration’s definition of “contraception,” and the coercive, unconstitutional actions of Defendants to compel Plaintiffs to cooperate in procuring and providing these drugs and devices contrary to their genuine and authentic beliefs and in violation of their conscience, *Amici* request that this Court reverse the lower court.

ARGUMENT

The Affordable Care Act (ACA) requires that all private insurance plans “provide coverage for and shall not impose any cost sharing requirements for . . . preventive care and screenings [for women].”² Defendants’ regulatory mandate implementing this provision (the “Mandate”) requires that nearly all private health insurance plans fully cover, without co-pay, all drugs and devices labeled by the Food and Drug Administration (FDA) as “contraception.”³

As demonstrated below, the FDA’s definition of “contraception” is broad and *includes drugs and devices with known post-fertilization (i.e., life-ending) mechanisms of action*, including “emergency contraception” such as the abortion-inducing drug *ella*.⁴ It is scientifically undisputed that the life of a human being begins at fertilization. *See* Part I, *infra*. Plaintiffs have a genuine and authentically held religious belief that from the moment of fertilization (*i.e.*, from the moment a human embryo is created) a human being is created and is thus of intrinsic value.

Accordingly, Plaintiffs believe that the destruction of a human embryo at

² 42 U.S.C. § 300gg-13.

³ *See* Health Resources and Services Administration, *Women’s Preventive Services: Required Health Plan Coverage Guidelines* (Aug. 1, 2011), available at <http://www.hrsa.gov/womensguidelines/> (last visited Apr. 22, 2013).

⁴ *See* FDA, *Birth Control Guide* (Aug. 2012), available at <http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM282014.pdf> (last visited Apr. 22, 2013).

any time constitutes the taking of a human life and therefore violates their deeply held religious beliefs. Pls.’ Br. 4. To the extent the Mandate forces employers such as Plaintiffs, who believe that it is immoral for them to “participate in, pay for, facilitate, or otherwise support abortion-inducing drugs and devices,” to provide coverage of drugs and devices which have the effect of destroying a human embryo prior to or following implantation in the womb, the Defendants are violating their religious beliefs and freedom of conscience. Pls.’ Br. 4.

In order to protect their freedom of conscience, Plaintiffs initiated the above-captioned action and moved for a preliminary injunction against the enforcement of the Mandate, on the basis of the Religious Freedom Restoration Act, the First Amendment, and the Administrative Procedure Act. Pls.’ Br. xiii.

Plaintiffs’ request for a preliminary injunction against the enforcement of the Mandate as to them was denied by the United States District Court for the District of Colorado. The district court erroneously held that the Plaintiffs had not demonstrated a reasonable likelihood of success on the merits because the Mandate did not constitute a “substantial burden” on Plaintiffs’ exercise of their sincerely and genuinely held religious beliefs. *Id.* Plaintiffs subsequently appealed to this Court.

Amici curiae have the unique perspective of physicians, bioethicists, and other healthcare professionals who have a profound interest in protecting human

life, which begins at fertilization, and who have an expertise on the life-ending mechanisms of action for certain drugs and devices which the FDA includes in the definition of “contraception.” Given that Defendants ignore or simply disregard Plaintiffs’ objection to paying for and providing the life-ending effect of these drugs and devices, including so-called “emergency contraception,” *Amici curiae* file this brief to elucidate as a matter of well-established science and bioethical considerations why Plaintiffs’ beliefs are reasonable and forcing them to pay for such drugs and devices violates their freedom of conscience, contradicting this nation’s long-standing commitment to that freedom.

I. It is Scientifically Established that a New Human Being Comes into Existence at Fertilization

There is widespread agreement that a new, distinct human being comes into existence during the process of fertilization.⁵ Examples from scientific literature confirm that there is no reasonable scientific disagreement about when life begins:

- “The fusion of sperm and egg membranes *initiates the life* of a sexually reproducing organism.”⁶

⁵ See, e.g., M.L. Condic, *When Does Human Life Begin? A Scientific Perspective* (The Westchester Institute for Ethics & the Human Person Oct. 2008), available at http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf (last visited Apr. 23, 2013); R.P. George & C. Tollefsen, *EMBRYO* 39 (2008).

⁶ H.R. Marsden et al., *Model systems for membrane fusion*, *CHEM. SOC. REV.* 40(3):1572 (Mar. 2011) (emphasis added).

- “The *life cycle of mammals begins* when a sperm enters an egg.”⁷
- “Fertilization is the process by which male and female haploid gametes (sperm and egg) unite to produce *a genetically distinct individual*.”⁸
- “The oviduct or Fallopian tube is the anatomical region where *every new life begins* in mammalian species. After a long journey, the spermatozoa meet the oocyte in the specific site of the oviduct named ampulla, and fertilization takes place.”⁹
- “Fertilization—*the fusion of gametes to produce a new organism*—is the culmination of a multitude of intricately regulated cellular processes.”¹⁰

Even the Defendant’s own definition confirms that human life begins at fertilization. For example, the National Institutes of Health explains that “fertilization” is the process of uniting two gametes (*i.e.*, ovum and sperm) “whereby the somatic chromosome number is restored *and the development of a*

⁷ Y. Okada et al., *A role for the elongator complex in zygotic paternal genome demethylation*, NATURE 463:554 (Jan. 28, 2010) (emphasis added).

⁸ J. Signorelli et al., *Kinases, phosphatases and proteases during sperm capacitation*, CELL TISSUE RES. 349(3):765 (Mar. 20, 2012) (emphasis added).

⁹ P. Coy et al., *Roles of the oviduct in mammalian fertilization*, REPRODUCTION 144(6):649 (Oct. 1, 2012) (emphasis added).

¹⁰ M.R. Marcello et al., *Fertilization*, ADV. EXP. BIOL. 757:321 (2013) (emphasis added).

new individual is initiated.”¹¹

One textbook similarly explains it this way:

Human development begins at fertilization when a male gamete or sperm (spermatozoon) unites with a female gamete or oocyte (ovum) to produce a single cell—a zygote. This highly specialized, totipotent cell marked *the beginning of each of us as a unique individual.*¹²

Thus, a new human being is created *before* the developing embryo implants in the uterus—*i.e.*, before that time at which some people consider a woman “pregnant.”

Defendants and their *Amici* have at times tried to blur the distinction between fertilization and implantation by focusing only on when “pregnancy” begins rather than on the scientific significance of fertilization. What Plaintiffs—and *Amici*—conscientiously oppose is not simply the termination of a “pregnancy,” but the ending of human life itself. “Emergency contraception” has a post-fertilization effect, meaning it can end the life of an already-developing human being prior to implantation (*i.e.*, pregnancy).¹³ See Part II, *infra*. Thus, to force

¹¹ National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2013), available at <http://www.merriam-webster.com/medlineplus/fertilization> (last visited Apr. 23, 2013) (emphasis added).

¹² K.L. Moore & T.V.N. Persaud, *THE DEVELOPING HUMAN* 16 (7th ed. 2003) (emphasis added).

¹³ Generally, the life of the human organism is ended because implantation is prevented.

Plaintiffs to provide coverage of such life-ending drugs is a violation of Plaintiffs' constitutionally guaranteed freedom of conscience. *See* Part III, *infra*.

II. Drugs and Devices Defined as “Emergency Contraception” by the FDA, including Ulipristal Acetate (*ella*), have Post-Fertilization Mechanisms of Action.

Drugs and devices with post-fertilization (*i.e.*, life-ending) mechanisms of action are included in the FDA definition of “contraception.” Although these drugs or devices may end a developing, distinct human being’s life by preventing implantation, they are labeled by the FDA as “contraception.”

Referring to such drugs as “contraception” or “emergency contraception” is misleading in that it infers the *prevention* of fertilization. The FDA’s current criterion in categorizing a drug as “contraception” is whether the drug can work by preventing “*pregnancy*”—which the FDA defines as beginning at “implantation,” not fertilization.¹⁴ Thus, drugs that interfere with implantation—which occurs *after* fertilization and the creation of a new human being—are categorized as “contraception.” Moreover, as further discussed below, with the approval of the drug *ella* in 2010, the FDA’s definition of “contraception” now encompasses a drug or device that can destroy a human life even *after* implantation.

¹⁴ For an overview of how the definition of “pregnancy” has changed, *see* C. Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of Conception and Pregnancy*, FRC INSIGHT PAPER (Apr. 2009), *available at* <http://downloads.frc.org/EF/EF09D12.pdf> (last visited Apr. 22, 2013).

In promoting the Mandate, Defendant Kathleen Sebelius, the Secretary of Health and Human Services (HHS), admitted that the FDA’s definition of “contraception” is not limited to a drug’s ability to *prevent* fertilization, but extends to *blocking the implantation* of an already developing human embryo: “The Food and Drug Administration has a category [of drugs] that prevent fertilization *and implantation*. That’s really the scientific definition.”¹⁵ Secretary Sebelius stated that under the new Mandate, “[t]hese covered prescription drugs are specifically those that are designed to *prevent implantation*.”¹⁶ In other words, Defendants know and readily admit that these drugs work after fertilization has occurred.

In his most recent study on “emergency contraception,” Dr. James Trussell, whose research concerning “contraception” has been cited by the FDA, states: “To make an informed choice, women must know that [emergency contraception pills] . . . may at times inhibit implantation. . . .”¹⁷ In other words, Dr. Trussell, although

¹⁵ K. Wallace, *Health and Human Services Secretary Kathleen Sebelius Tells iVillage “Historic” New Guidelines Cover Contraception, Not Abortion* (Aug. 2, 2011), available at <http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception-not-abortion/4-a-369771> (last visited Apr. 22, 2013) (emphasis added).

¹⁶ *Id.* (emphasis added).

¹⁷ J. Trussell et al., *Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy* (Office of Population Research at Princeton University June 2010).

an advocate of “emergency contraception,”¹⁸ believes that the scientific difference between a drug that prevents fertilization of an egg and one that may also prevent implantation of a unique human organism is significant enough that it must be disclosed to a potential user.

Strikingly, Dr. Warren Wallace, a physician at Northwestern University Medical School who has “prescribed emergency contraceptives,” and who was called to testify in support of a law restricting rights of conscience protections for the prescription of “emergency contraception,” testified under oath that “there is a new unique human life before” the implantation of an embryo.¹⁹

Moreover, a new drug classified by the FDA as “emergency contraception”—Ulipristal Acetate (*ella*)—is actually an abortion-inducing drug, because it can kill an embryo *after* implantation. The post-fertilization mechanisms of action of each common type of “emergency contraception” are discussed in more detail below. An understanding of these mechanisms of action demonstrates that Defendants and their *Amici* erroneously reject Plaintiffs’ concerns as if they were irrelevant or insubstantial.

¹⁸ See Profile of Dr. James Trussell, *available at* <https://www.princeton.edu/~trussell/> (last visited Apr. 22, 2013).

¹⁹ Transcript of Bench Trial at 91-92, 111, *Morr-Fitz, Inc. v. Quinn*, 2012 IL App (4th) 110398 (Ill. App. Ct. Sept. 20, 2012).

A. Plan B can prevent implantation.

In 1999, the FDA first approved the distribution of “emergency contraception,” specifically the drug known as “Plan B,” by prescription. In 2006, the FDA extended the drug’s approval to over-the-counter sales for women 18 years of age and over.²⁰ Although called “contraception,” the FDA’s labeling acknowledges that Plan B can prevent implantation of an already-developing human embryo.²¹ Further, the FDA states on its website:

Plan B acts primarily by stopping the release of an egg from the ovary (ovulation). It may prevent the union of sperm and egg (fertilization). *If fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation).*²²

²⁰ On March 23, 2009, a federal district court in New York ruled that Plan B must be made available over-the-counter to 17-year-old minors and directed the FDA to reconsider its policies regarding minors’ access. *See Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009). The Obama Administration did not appeal and the FDA indicated intent to comply with the ruling. However, in December 2011, the Obama Administration announced that it would not extend the drug’s over-the-counter status to minors under 17 years of age. A new case, *Tummino v. Hamburg* (E.D.N.Y. 12-763), challenging this decision by the FDA, was filed by the Center for Reproductive Rights in 2012. On April 10, 2013, the federal court ordered the FDA to make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days.

²¹ Plan B Approved Labeling, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_P_RNTLBL.pdf (last visited Apr. 22, 2013).

²² FDA, *FDA’s Decision Regarding Plan B: Questions and Answers* (updated Apr. 30, 2009), *available at* <http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm> (last visited Apr. 22, 2013) (emphasis added).

The same explanation is provided by Duramed Pharmaceuticals, the manufacturer of Plan B One-Step. Duramed states that Plan B One-Step “works primarily by”: 1) preventing ovulation; 2) possibly preventing fertilization by altering tubal transport of sperm and/or egg; 3) *altering the endometrium, which may inhibit implantation.*²³

Under Defendants’ Mandate, there can be no dispute that Plaintiffs are forced to pay for Plan B, despite its life-ending effect on already-formed unique human beings and in violation of Plaintiffs’ genuinely held religious beliefs.

B. Ulipristal Acetate (*ella*) can prevent implantation or kill an implanted embryo.

In 2010, the FDA approved the drug Ulipristal Acetate (*ella*) as another “emergency contraceptive.” Importantly, *ella* is not an “improved” version of Plan B; instead, the chemical make-up of *ella* is similar to the abortion drug RU-486 (brand name Mifeprex). Like RU-486, *ella* is a selective progesterone receptor modulator (SPRM)—“[t]he mechanism of action of ulipristal (*ella*) in human ovarian and endometrial tissue is identical to that of its parent compound

²³ Duramed Pharmaceuticals, *How Plan B One-Step Works* (2010), available at <http://www.planbonestep.com/plan-b-prescribers/how-plan-b-works.aspx> (last visited Apr. 22, 2013) (emphasis added).

mifepristone.”²⁴ This means that though *labeled* as “contraception,” *ella* works the same way as RU-486. By blocking progesterone—a hormone necessary to build and maintain the uterine wall during pregnancy—a SPRM can either prevent a developing human embryo from implanting in the uterus, or it can kill an implanted embryo by essentially starving it to death. Put another way, *ella can abort a pregnancy*, no matter whether you define “pregnancy” as beginning at fertilization or at implantation.²⁵

Studies confirm that *ella* is harmful to a human embryo.²⁶ The FDA’s own labeling notes that *ella* may “affect implantation,”²⁷ and contraindicates (or advises against) use of *ella* in the case of known or suspected pregnancy. A study funded by *ella*’s manufacturer, HRA Pharma, explains that SPRMs (drugs that block the

²⁴ D.J. Harrison & J.G. Mitroka, *Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health*, 45 ANNALS PHARMACOTHERAPY 115 (Jan. 2011).

²⁵ See C. Gacek, *Conceiving Pregnancy*, *supra*.

²⁶ European Medicines Agency, *Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone 16* (2009), available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf (last visited Apr. 22, 2013).

²⁷ *ella* Labeling Information (Aug. 13, 2010), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (last visited Apr. 22, 2013).

hormone progesterone) “including ulipristal acetate” can “impair implantation.”²⁸

While the study theorizes that the dosage used in its trial “might be too low to inhibit implantation,”²⁹ it states affirmatively that “an additional postovulatory mechanism of action,” *e.g.* impairing implantation, “cannot be excluded.”

There can be little doubt that *ella* has the effect of destroying a human embryo. Notably, at the FDA advisory panel meeting for *ella*, Dr. Scott Emerson, a professor of Biostatistics at the University of Washington and a panelist, raised the point that the low pregnancy rate for women who take *ella* four or five days after intercourse suggests that the drug *must* have an “abortifacient” quality.³⁰

²⁸ A.F. Glasier *et. al*, *Ulipristal acetate versus levonorgestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis*, 375 THE LANCET 555 (Jan. 2010).

²⁹ In the Glasier study, “follow-up was done 5-7 days after expected menses. If menses had occurred and a pregnancy test was negative, participation [in the study] ended. If menses had not occurred, participants returned a week later.” Considering that implantation must occur *before* menses, the study could not, and did not attempt to, measure an impact on an embryo prior to implantation or even shortly after implantation. *ella* was not given to anyone who was known to already be pregnant (upon enrollment participants were given a pregnancy test and pregnant women were excluded from the study). The only criterion for *ella* “working” was that a woman was not pregnant in the end. Whether that was achieved through blocking implantation, or killing the embryo after implantation, was not determinable.

³⁰ See Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs (June 17, 2010), *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterial>

In short, *ella* goes beyond that of any other “contraceptive” approved by the FDA at the time of the Affordable Care Act’s enactment. By including *ella* as “contraception,” the FDA has removed, not simply blurred, the line between “contraception” and “abortion” drugs because *ella* can work by ending an “established” pregnancy.

Further, though “indicated” for contraceptive use, mandated coverage for *ella* opens the door to off-label and intended-abortion usage of the drug being funded by nearly all health insurance plans. Already, *ella* is available for sale online, where a purchaser need only fill out a questionnaire to obtain the drug with no physician or pharmacist to examine the patient, explain the risks in person, or verify the identity and intentions of the purchaser.

Thus, contrary to their religious and moral beliefs, Plaintiffs are required to pay for *ella*—an abortion-inducing drug—under Defendants’ Mandate.

C. Other accepted forms of “contraception,” such as Intrauterine Devices, may also prevent implantation.

Copper Intrauterine Devices (IUDs) are being heavily promoted as yet another form of “emergency contraception.” IUDs are acknowledged to work not only by preventing conception, but by blocking the implantation of a human

s/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf (last visited Apr. 22, 2013).

embryo post fertilization.³¹ In his study on “emergency contraceptives,” Dr. Trussell concludes that, “[i]ts very high effectiveness implies that emergency insertion of a copper IUD *must* be able to prevent pregnancy *after fertilization*.”³² Put another way, IUDs are so effective because they do not just prevent conception, but can “work” by destroying an already developing human embryo.

Once again, under Defendants’ Mandate and contrary to their religious and moral beliefs, Plaintiffs are required to pay for devices that can kill human embryos.

III. The Mandate Violates Sincerely Held Religious Beliefs and Freedom of Conscience.

As discussed above, Plaintiffs are required under the Mandate to provide insurance coverage for drugs and devices with life-ending mechanisms of action, including “emergency contraception.” This Court is well aware that Plaintiffs have made clear their conscientious objection to paying for such life-ending drugs. If Plaintiffs do not comply with Defendants’ Mandate, they will face potentially

³¹ See Department of Health and Human Services, *Birth Control Methods* (Nov. 21, 2011), available at <http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf> (last visited Apr. 22, 2013). HHS describes among the mechanisms of action for copper IUDs: “If fertilization does occur, the IUD keeps the fertilized egg from implanting in the lining of the uterus.” For hormonal IUDs the guide states, “It also affects the ability of a fertilized egg to successfully implant in the uterus.”

³² See J. Trussell, *Emergency Contraception*, *supra* (emphasis added).

ruinous penalties.³³ Clearly, Plaintiffs are being forced to choose between following their religious and conscientious beliefs, and complying with the law. It is exactly this type of coercive dichotomy that violates the U.S. Constitution's guarantee of freedom of conscience.

Freedom of conscience is a fundamental right that has been respected and protected since the founding of our Nation. Since that time, the federal government has upheld the paramount importance of this historic right which has been affirmed by both by the United States Supreme Court and the United States Congress. In short, our Nation's history and tradition as well as its jurisprudence affirm that a person cannot be forced to commit an act that is against his or her moral, religious, or conscientious beliefs—including payment for such an act—and this history, tradition and jurisprudence unequivocally support Plaintiffs in this case.

³³ See 26 U.S.C. § 4980H(a), (c)(1). Employers who fail to provide all coverage required by the Mandate face onerous annual fines of \$2,000 per full-time employee. See also 26 U.S.C. § 4980D(b). Failing to provide certain required coverage may subject group health plans to a fine of \$100 a day per individual. See also 42 U.S.C. § 300gg-22(b)(2)(C)(i) and Cong. Research Serv., RL 7-5700 (asserting that the Secretary of HHS' authority to impose a \$100 per day per individual penalty for failure to provide coverage applies to insurers who violate the "preventive care" provision). See also 29 U.S.C. § 1132(a)(1)(B) and Cong. Research Serv., RL 7-5700 (asserting that the Secretary of Labor's authority to fine group health plans extends to violations of the "preventive care" provision).

A. Freedom of Conscience is a fundamental right affirmed by our Founders.

The First Amendment guarantees that Congress shall make no law prohibiting the free exercise of religion. U.S. Const. amend. I. At the very root of that promise is the guarantee that the government cannot force a person to commit an act in violation of his or her religion.³⁴

The signers to the religion provisions of the First Amendment were united in a desire to protect the “liberty of conscience.” Having recently shed blood to throw off a government which dictated and controlled their religion and practices, a government which guaranteed freedom of conscience was foremost in their hearts and minds.³⁵

The most often quoted Founder and author of the Declaration of Independence, Thomas Jefferson, made it clear that freedom of conscience is not to be subordinate to the interests of government:

³⁴ See generally M.W. McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 HARV. L. REV. 1409 (1990).

³⁵ The Founders often used the terms “conscience” and “religion” synonymously. T. Berg, *Free Exercise of Religion*, in THE HERITAGE GUIDE TO THE CONSTITUTION 310 (2005). Thus, adoption of the “religion” clauses does not mean that the Founders were ignoring freedom of conscience. The two were inextricably intertwined.

[O]ur rulers can have authority over such natural rights only as we have submitted to them. The rights of conscience we never submitted, we could not submit. We are answerable for them to our God.³⁶

Jefferson also stated that no provision in the Constitution “ought to be dearer to man than that which protects the rights of conscience against the enterprises of civil authority.”³⁷

Jefferson also maintained that forcing a person to *contribute* to—much like forcing Plaintiffs to pay for—a cause to which he or she abhorred was “tyrannical.”³⁸ This belief formed the basis of Jefferson’s bill in Virginia, which prohibited the compelling of a man to furnish money for the propagation of opinions to which he was opposed.³⁹ Jefferson—who considered it “tyrannical” to force a person to contribute monetarily to a position he disagreed with—would likely be aghast at a law requiring payment for a drug that is conscientiously objectionable to that person.

³⁶ Thomas Jefferson, *Notes on Virginia* (1785).

³⁷ Thomas Jefferson, Letter to New London Methodists (1809).

³⁸ J.P. Boyd, *THE PAPERS OF THOMAS JEFFERSON* 545 (1950) (quoting Jefferson, *A Bill for Establishing Religious Freedom*).

³⁹ Thus, not only is Jefferson the author of the Declaration of Independence, but he is also the author of one of this Nation’s first statutes granting the right to refuse to participate or to act because of conscientious convictions. Jefferson was so proud of this accomplishment that he had “Author of the ... Statute of Virginia Religious Freedom...” etched on his gravestone.

James Madison, was also concerned that the freedom of conscience of Americans be protected. In *Memorial and Remonstrance against Religious Assessments*, Madison stated:

The Religion then of every man must be left to the conviction and conscience of every man; and it is the right of every man to exercise it as these may dictate. This right is in its nature *unalienable right*.⁴⁰

In fact, Madison described conscience as “the most sacred of all property.”⁴¹

Madison also amended the Virginia Declaration of Rights to state that all men are entitled to full and free exercise of religion, “according to the dictates of conscience.”

Madison understood that if man cannot be loyal to himself, to his conscience, then a government cannot expect him to be loyal to less compelling obligations or rules, statutes, judicial orders, and professional duties. If the government demands that he betray his conscience, the government has eliminated the only moral basis for obeying any law. Madison considered it “the particular glory of this country, to have secured the rights of conscience which in other nations are least understood or most strangely violated.”⁴²

⁴⁰ James Madison, *Memorial and Remonstrance Against Religious Assessments* ¶ 15 (emphasis added).

⁴¹ B.F. Milton, *THE QUOTABLE FOUNDING FATHERS: A TREASURY OF 2,500 WISE AND WITTY QUOTATIONS* 36-37 (2005).

⁴² James Madison, *Speech Delivered in Congress* (Dec. 22, 1790).

President George Washington maintained that “the establishment of Civil and Religious Liberty was the Motive that induced me to the field of battle,” and he advised Americans to “labor to keep alive in your breast that little spark of celestial fire called conscience.”⁴³ President Washington also maintained that the government should accommodate religious persons:

The conscientious scruples of all men should be treated with great delicacy and tenderness: and it is my wish and desire, that the laws may always be extensively accommodated to them, as a due regard for the protection and essential interests of the nation may justify and permit.⁴⁴

John Adams stated that “no subject shall be hurt, molested, or restrained, in his person, liberty, or estate, for worshipping God in the manner most agreeable to the dictates of his own conscience.”⁴⁵ Samuel Adams wrote that the liberty of conscience is an original right.⁴⁶

⁴³ M. Novak & J. Novak, WASHINGTON’S GOD 111(2006); Milton, *supra*.

⁴⁴ George Washington, Letter to the Religious Society Called Quakers (1879).

⁴⁵ John Adams, *A Declaration of the Rights of the Inhabitants of the Commonwealth of Massachusetts*, in REPORT FROM COMMITTEE BEFORE THE CONVENTION OF DELEGATES (1779).

⁴⁶ H.A. Cushing, THE WRITINGS OF SAMUEL ADAMS 350-59 (vol. II, 1906).

Forcing Plaintiffs to pay for drugs and devices to which they are conscientiously opposed eviscerates the very purpose for which this Nation was founded and formed. As Thomas Jefferson charged us:

[W]e are bound, you, I, every one, to make common cause, even with error itself, to maintain the common right of freedom of conscience. *We ought with one heart and one hand hew down the daring and dangerous efforts of those who would seduce the public opinion to substitute itself into ... tyranny over religious faith....*⁴⁷

B. Freedom of Conscience is a fundamental right affirmed by the United States Supreme Court.

The United States Supreme Court has consistently ruled in favor of protecting the freedom of conscience of every American. Further, the Court has held that laws cannot abridge expressions protected by the First Amendment simply because a corporation is the source of protected conduct. *See First National Bank of Boston v. Bellotti*, 435 U.S. 765 (1978); *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310 (2010). In fact, the Court's decisions affirming the freedom of conscience are too numerous to discuss here, and thus a few examples must suffice.

The Supreme Court has held that “[f]reedom of conscience and freedom to adhere to such religious organization or form of worship as the individual may choose *cannot be restricted by law.*” *Cantwell v. Conn.*, 310 U.S. 296, 303 (1940) (emphasis added). While the “freedom to believe” is absolute, the “freedom to

act” is not; however, “in every case,” regulations on the freedom to act cannot “unduly infringe the protected freedom.” *Id.* at 303-04.

In the 1940s, the Supreme Court considered regulations requiring public school students to recite the pledge to the American flag. Initially, the Court ruled against a group of Jehovah’s Witnesses who sought to have their children exempted from reciting the pledge. *Minersville Sch. Dist. v. Gobitis*, 310 U.S. 586 (1940).⁴⁸ However, in just three short years, the Supreme Court reversed this decision. In *West Virginia State Board of Education v. Barnette*, the Supreme Court considered another public school policy requiring students to recite the pledge against their religious convictions. 319 U.S. 624 (1943). The majority opinion stated:

If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to

⁴⁸ Even though *Gobitis* was ultimately decided incorrectly, Justice Frankfurter, writing the majority opinion, did expound upon the balance between the interest of the schools and the interest of the students. He saw that the claims of the parties must be reconciled so as to “prevent either from destroying the other.” *Gobitis*, 310 U.S. at 594. Because the liberty of conscience is so fundamental, “every possible leeway” must be given to the claims of religious faith. *Id.* On the other hand, Justice Frankfurter stated, similarly to what Defendants have argued here, that “[t]he mere possession of religious convictions which contradict the relevant concerns of a political society does not relieve the citizen from the discharge of political responsibilities.” *Id.* at 594-95. However, such conclusions were ultimately overthrown in *Barnette*, and as such this Court should reject any similar arguments that “religious convictions which contradict the relevant concerns of a political society” must submit to an overreaching authority.

confess by word or act their faith therein.... We think the action of the local authorities in compelling the flag statute and pledge transcends constitutional limitations on their power and invades the sphere of intellect and spirit which it is the purpose of the *First Amendment to our Constitution* to reserve from all official control.”

Id. at 642 (emphasis in original). In other words, the Supreme Court ruled it unconstitutional to force public school children to perform an act that was against their religious beliefs. The Supreme Court also held: “[F]reedom to differ is not limited to things that do not matter much.... The test of its substance is the right to differ as to things that touch the heart of the existing order.” *Id.*⁴⁹

Barnette has been affirmed on numerous occasions, including in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), where the Supreme Court stated:

It is conventional constitutional doctrine that where reasonable people disagree the government can adopt one position or the other. *That theorem, however, assumes a state of affairs in which the choice does not intrude upon a protected liberty.* Thus, while some people might disagree about whether or not the flag should be saluted, or disagree about the proposition that it may not be defiled, *we have ruled that a State may not compel or enforce one view or the other.*

Id. at 851 (citing *Barnette*, 319 U.S. 624) (other citations omitted) (emphasis added).

⁴⁹ “The very purpose of a *Bill of Rights* was to withdraw certain subjects from the vicissitudes of political controversy, to place them beyond the reach of majorities and officials and to establish them as legal principles to be applied by the courts. One’s ... freedom of worship and assembly, and other fundamental rights may not be submitted to vote; they depend on the outcome of no elections.” *Barnette*, 319 U.S. at 638 (emphasis in original).

To force parents and children to choose between their religious beliefs and their public education was a clear violation of the plaintiffs' First Amendment rights. Likewise, forcing Plaintiffs to choose between their religious, moral, or conscientious convictions and the potential of heavy fines—or going out of business altogether—and complying with the Mandate is an unconstitutional exercise of state power.

In the 1960s and 1970s, the Supreme Court continued to protect Americans' freedom of conscience. In a notable example, the Supreme Court protected men who were conscientiously opposed to war. Section 6(j) of the Universal Military Training and Service Act contained a conscience clause exempting men from the draft who were conscientiously opposed to military service because of “religious training and belief.”⁵⁰ In *United States v. Seeger* and *Welsh v. United States*, the Supreme Court extended draft exemptions to “all those whose consciences, spurred by deeply held moral, ethical, or religious beliefs, would give them no rest or peace if they allowed themselves to become part of an instrument of war.” *Welsh*, 398 U.S. 333, 344 (1970) (affirming *Seeger*, 380 U.S. 163 (1965)).

Welsh acknowledged that § 6(j) protected persons with “intensely personal” convictions—even when other persons found those convictions

⁵⁰ Section 6(j) was not a “new” idea or exemption. Early colonial charters and state constitutions spoke of freedom of conscience as a right, and during the Revolutionary War, many states granted exemptions from conscription to Quakers, Mennonites, and others with religious beliefs against war.

“incomprehensible” or “incorrect.” *Welsh*, 398 U.S. at 339. Seeger and Welsh “held deep conscientious scruples against taking part in wars where people were killed. Both strongly believed that killing in war was wrong, unethical, and immoral, and their consciences forbade them to take part in such an evil practice.”

Id. at 337. Important here is Welsh’s statement:

I believe that human life is valuable in and of itself; in its living; therefore I will not injure or kill another human being.... I cannot, therefore conscientiously comply with the Government’s insistence that I assume duties which I feel are immoral and totally repugnant.

Id. at 343 (quoting Welsh).

While the draft cases were related to a statutory exemption not at issue here, the holdings of these cases demonstrate a strong commitment by the Court to protect freedom of conscience. Like Welsh, Plaintiffs believe that human life is valuable—at all stages and in all situations. They cannot injure or kill another human being, but, as discussed *supra*, “emergency contraception” has the potential to terminate the lives of unborn children. Being forced to pay for the termination of a human life is just as objectionable as being forced to participate in the termination of the human life. Indeed, paying for the act *is* participation in the act.

Just one year after *Welsh*, the Supreme Court stated the following in a case requiring bar applicants to make certain statements about their personal beliefs:

And we have made it clear that: “This conjunction of liberties is not peculiar to religious activity and institutions alone. The *First*

Amendment gives freedom of mind the same security as freedom of conscience.”

Baird v. State Bar of Ariz., 401 U.S. 1, 6 (1971) (emphasis in the original). Indeed, “freedom of conscience” is referenced explicitly throughout Supreme Court jurisprudence. *See, e.g., Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 506 n.2 (1969) (specifically referencing “constitutionally protected freedom of conscience”).

C. Freedom of Conscience is a fundamental right also affirmed by the Congress.

Congress likewise has considered and passed a number of measures expressing the federal government’s commitment to protecting the freedom of conscience. Congress first addressed the issue of conscience protections just weeks after the U.S. Supreme Court handed down its decision in *Roe v. Wade*. In 1973, Congress passed the first of the Church Amendments (named for its sponsor, Senator Frank Church).⁵¹ Taken together, the original and subsequent Church Amendments protect healthcare providers from discrimination by recipients of U.S. Department of Health and Human Services (HHS) funds on the basis of their objection, because of religious belief or moral conviction, to performing or participating in *any* lawful health service or research activity.

⁵¹ 42 U.S.C. 3001-7.

In 1996, Section 245 of the Public Health Service Act, known as the Coats Amendment (named for its sponsor, Senator Daniel Coats), was enacted to prohibit the federal government and state or local governments that receive federal financial assistance from discriminating against individual and institutional healthcare providers, including participants in medical training programs, who refused to, among other things, receive training in abortions; require or provide such training; perform abortions; or provide referrals or make arrangements for such training or abortions.⁵² The measure was prompted by a 1995 proposal from the Accreditation Council for Graduate Medical Education to mandate abortion training in all obstetrics and gynecology residency programs.

The most recent federal conscience protection, the Hyde-Weldon Amendment, was first enacted in 2005 and provides that no federal, state, or local government agency or program that receives funds under the Labor, Health and Human Services (LHHS) appropriations bill may discriminate against a healthcare provider because the provider refuses to provide, pay for, provide coverage of, or

⁵² 42 U.S.C. 238n.

refer for abortion.⁵³ The Amendment is subject to annual renewal and has survived multiple legal challenges brought by pro-abortion groups.⁵⁴

Congress has also acted to provide specific conscience protections in the provision of contraceptives. For example, in 2000, Congress passed a law requiring the District of Columbia to include a conscience clause in any contraceptive mandate, protecting religious beliefs and moral convictions. *See* Title III, § 127 of Division C (D.C. Appropriations) of the Consolidated Appropriations Resolution of 2003, Pub. L. No. 108-7, 117 Stat. 11, 126-27 (2000). Similarly, in 1999, Congress prohibited health plans participating in the federal employees' benefits program from discriminating against individuals who refuse to prescribe contraceptives. *See* Title VI, § 635(c) of Division J (Treasury and General Government Appropriations) of the Consolidated Appropriations Resolution of 2003, Pub. L. No. 108-7, 117 Stat. 11, 472 (1999).

These laws highlight the deeply held desire of the American people to protect individuals and employers from mandates or other requirements forcing them to choose between their consciences and/or religious and moral beliefs, and

⁵³ Consolidated Appropriations Act of 2008, Pub. L. No. 110-161, §508(d), 121 Stat. 1844, 2209 (2007).

⁵⁴ Many similar conscience provisions related to federal funding have been passed over the last 45 years. *See, e.g.*, 42 U.S.C. § 300a-7(b), (c)(1) (1973); 42 U.S.C. § 300a-7(c)(2), (d) (1974); 42 U.S.C. § 300a-7(e) (1979); 42 U.S.C. § 1395w-22(j)(3)(B) (1997); 48 C.F.R. § 1609.7001(c)(7) (1998); Pub. L. No. 108-25, 117 Stat. 711, at 733 (2003).

aptly demonstrate that the actions of Defendants ignore the longstanding national commitment to protect the freedom of conscience.⁵⁵

In contrast to the principles of federal laws which recognize a right not to be coerced into participating in abortion, sterilization, and other services “contrary to [] religious or moral convictions,” the Mandate leaves employers such as Plaintiffs with no option but to offer health insurance plans that cover abortion-inducing drugs, sterilization, and other “contraceptive” items and services to which they have religious or conscientious objections (or face heavy penalties).

⁵⁵ In addition, 47 states provide some degree of statutory protection to healthcare providers who conscientiously object to certain procedures. *See Rights of Conscience Overview*, in DEFENDING LIFE 2012: BUILDING A CULTURE OF LIFE, DECONSTRUCTING THE ABORTION INDUSTRY, at 565 (2012), available at <http://www.aul.org/wp-content/uploads/2012/04/maps-11.pdf> (last visited Apr. 22, 2013). Thus, Defendants’ actions run contradictory to the laws and clear intent of the vast majority of states to protect the freedom of conscience. Some states—including Louisiana and Mississippi—extend this protection to public and/or private payers (*i.e.*, health insurers).

CONCLUSION

Plaintiffs' opposition to payment for life-ending drugs and devices is not attenuated and is supported by scientific evidence and bioethical analysis. Being forced to pay for drugs that can end a human life amounts to forced participation in the act itself. Such a coercive policy runs contrary to the history, tradition and jurisprudence of this Nation and violates Plaintiffs' freedom of conscience. As such, this Court should reverse the lower court and enjoin Defendants from enforcing the Mandate as to the Plaintiffs.

Respectfully submitted,

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AND PRIVACY REDACTIONS**

I hereby certify that a copy of the foregoing *Amicus Curiae* Brief as submitted in digital form via the court's ECF system is an exact copy of the written document filed with the Clerk and has been scanned for viruses with AVG Antivirus (last updated 8.6.2013) and, according to the program, is free of viruses. In addition, I certify all required privacy redactions have been made.

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Counsel of Record for Amici Curiae

Dated: August 7, 2013

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2013, I electronically filed the foregoing *Amicus Curiae* Brief with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the CM/ECF system. I further certify that one of the participants in the case is not a CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid, to the following non-CM/ECF participant:

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