No. 14-12696-CC

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ETERNAL WORD TELEVISION NETWORK, INC.,

Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellee.

On Appeal from the United States District Court for the
Southern District of Alabama
(No.1:13-cv-00521-CG-C, Hon. Callie V.S. Granade)

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

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August 4, 2014

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26 and 11th Cir. R. 26.1, I hereby certify that, to the best of my knowledge, except for *Amici* and their counsel set forth below, all persons who may have an interest in the outcome of this case are listed in the Brief for Defendants-Appellants and Response of Plaintiffs-Appellees:

Alabama Physicians for Life

American Association of Pro-Life Obstetricians & Gynecologists

Association of American Physicians & Surgeons, Inc.

Catholic Medical Association

Christian Medical Association

National Association of Catholic Nurses

National Association of Pro Life Nurses

The National Catholic Bioethics Center

Amici Alabama Physicians for Life, Association of American Physicians & Surgeons, American Association of Pro-Life Obstetricians & Gynecologists, Christian Medical Association, Catholic Medical Association, The National Catholic Bioethics Center, National Association of Catholic Nurses and National Association of Pro Life Nurses are not publicly held corporations and have no parent corporations or stock of which a publicly held corporation can hold.

s/ Mailee R. Smith
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STATEMENT OF THE ISSUES

Did the court below err in granting Defendant's motion to dismiss when the mandate unconstitutionally denies Plaintiffs, the Eternal Word Television Network (EWTN), the religious freedom guaranteed under the Religious Freedom Restoration Act and the Free Exercise Clause of the First Amendment?

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

It is undisputed that a new, distinct human organism comes into existence during the process of fertilization—at the moment of sperm-egg fusion— and before implantation. Many drugs and devices labeled by the U.S. Food and Drug Administration as "emergency contraception," however, have post-fertilization mechanisms of action which destroy the life of a human organism. In other words, these drugs and devices work after a new human organism is created (at fertilization). Such "contraceptive" methods may prevent implantation and therefore "pregnancy," as defined by the Defendants and their *amici*, but by preventing implantation these drugs and devices end the life of a unique human being.

Amici curiae are eight national organizations whose members include physicians, bioethicists, and other healthcare professionals who have a profound interest in protecting all stages of human life in their roles as healthcare providers and medical experts. As experts in the medical field, *Amici* file this brief to provide documented scientific analysis that a new human organism undisputedly

[1] In accordance with Fed. R. App. P. 29, 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.

begins at fertilization, and that "emergency contraception" has post-fertilization mechanisms of action which destroy the life of a human organism.

Amici are sensitive to healthcare disparities and support a variety of public and private efforts that address health care affordability and accessibility. *Amici* oppose, however, Defendants' requirement that private insurance plans must cover drugs and devices with post-fertilization (*i.e.*, life-ending) mechanisms of action. Arranging for and facilitating such coverage violates the sincere religious beliefs and freedom of conscience held by Plaintiffs and therefore to the extent that the government coerces their compliance, that coercion is unlawful under the Religious Freedom Restoration Act (RFRA) and unconstitutional as to them.

Amici include the following medical and ethics associations:

Association of American Physicians & Surgeons (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 sanctity of the patient-physician relationship. AAPS has been a litigant before the U.S. Supreme Court and in other appellate courts. *See, e.g.*, *Cheney v. United States Dist. Court*, 542 U.S. 367, 374, 124 S. Ct. 2576 (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, 96 S. Ct. 388 (1975). In addition, the 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, 120 S. Ct. 2597 (2000); *id.* at 959, 963 (Kennedy, J., dissenting); *District of Columbia v. Heller*, 554 U.S. 570, 704, 128 S. Ct. 2783 (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. AAPLOG held the title of "special interest group" within the American College of Obstetricians & Gynecologists (ACOG) for 40 years, from 1973 until 2013, until ACOG discontinued the designation of "special interest group." AAPLOG is 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 in order to provide a realistic appreciation of abortion-related health risks.

Christian Medical Association, founded in 1931, is a non-profit national organization of Christian physicians and allied healthcare professionals with almost 16,000 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 non-profit national organization comprised of over 2,000 members representing 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 bioethics 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.

Alabama Physicians for Life (APFL) is a non-profit medical organization that exists to draw attention to the issues of abortion and "contraception." APFL encourages physicians to educate their patients not only regarding the innate value of human life at all stages of development, but also on the risks inherent in abortion.

National Association of Pro Life Nurses (NAPN) is a national non-profit nurses' organization with members in every state. NAPN unites nurses who seek

excellence in nursing for all, including mothers and the unborn. NAPN seeks to establish and protect ethical values of the nursing profession.

National Association of Catholic Nurses is a national non-profit organization that gives nurses of different backgrounds the opportunity to promote moral principles within the Catholic context in nursing and to stimulate desire for professional development. The organization focuses on educational programs, spiritual nourishment, patient advocacy, and integration of faith and health.

Based on the destructive, post-fertilization effect of "emergency contraception" and the coercive, unconstitutional actions of Defendants requiring Plaintiffs to violate their religious beliefs and consciences, *Amici* urge this Court to reverse the lower court.

SUMMARY OF THE ARGUMENT

The Affordable Care Act (ACA) requires that non-grandfathered private health 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 these private health insurance plans fully cover, without co-pay, all drugs and devices labeled by the Food and Drug Administration (FDA) as "contraception," including "emergency contraception."[3] It is scientifically undisputed that the life of a new human organism begins at fertilization. *See* Part I, *infra*. However, the FDA's definition of "contraception" is broad and includes as "emergency contraception" drugs and devices with known post-fertilization (*i.e.*, life-ending) mechanisms of action.[4] *See* Part II, *infra*. As such, forcing employers to provide coverage of such life-ending drugs violates the conscientious beliefs of Plaintiffs and Americans across the nation.

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[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), http://www.hrsa.gov/womensguidelines/. All internet sites last visited May 12, 2014.

[4] *See* FDA, *Birth Control Guide* (Aug. 2012), http://www.co.burke.nc.us/vertical/sites/%7BDF44FA7A-21E3-466A-A30D-00122906F160%7D/uploads/FDA_Birth_Control_Guide-_Updated_August_2012.pdf.

Defendants exercised their discretion to create exemptions in their regulatory scheme for churches and the integrated auxiliaries, and conventions or associations of churches. However, Defendants demand that certain religious non-profit employers, including Plaintiffs, which share the same religious objections as those churches which were granted exemptions, must comply with the Mandate through what it terms an "accommodation." *See* Part III, *infra*.

When the life-ending mechanisms of action of "emergency contraception" are understood, it is clear that forcing Plaintiffs to facilitate coverage for such drugs and devices violates their religious rights protected under the First Amendment and contradicts this nation's long-standing commitment to the freedom of conscience. *See* Part III, *infra*.

ARGUMENT

I. It is Undisputed that a New Human Organism is Created at Fertilization.

It is undisputed that a new, distinct human organism comes into existence during the process of fertilization, which begins at the time of sperm-egg fusion and well before implantation.[5] Scientific literature is replete with statements

[5] *See, e.g.*, Condic, *When Does Human Life Begin? A Scientific Perspective* (The Westchester Institute for Ethics & the Human Person Oct. 2008), http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf; George & Tollefsen, EMBRYO 39 (2008).

regarding the beginning of human life as follows:

- "The fusion of sperm and egg membranes ***initiates the life*** of a sexually reproducing organism."[6]

- "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]

Defendants' own definition attests to the fact that life begins at fertilization. According to the National Institutes of Health, "fertilization" is the "process of

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

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

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

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

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

union" of two gametes (*i.e.*, ovum and sperm) "whereby the somatic chromosome number is restored *and the development of a **new individual** is initiated*."[11] Thus, in the context of human life, a new individual human organism is initiated at the union of ovum and sperm.

One textbook similarly explains the following:

> 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 organism 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 distract from the objections of Plaintiffs to arranging for the coverage of life-ending drugs by arguing over terminology concerning when "pregnancy" begins rather than when life begins (at fertilization). Relying on a definition of pregnancy that begins at "implantation," the Defendants and their *amici* argue that "emergency contraceptives" are not "abortifacients." However, this is a nonresponse to the concern that a drug or

[11] National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2014), http://www.merriam-webster.com/medlineplus/fertilization (emphasis added).

[12] Moore & Persaud, THE DEVELOPING HUMAN 16 (7th ed. 2003) (emphasis added).

device can work to destroy human life after fertilization but before implantation by blocking the implantation of a developing human embryo. Such drugs might not end a "pregnancy" under Defendants' definition, but it does end the life of a unique human being. What Plaintiffs—and *Amici*—conscientiously oppose is not simply the ending of a "pregnancy," but the voluntary ending of human life itself at any time following fertilization when such a termination is not necessary to save the life of the mother.

II. Drugs and Devices Defined by the FDA as "Emergency Contraception" Have Post-Fertilization Mechanisms of Action.

Drugs and devices with post-fertilization mechanisms of action (*i.e.*, life-ending) are included in the FDA definition of "contraception," including "emergency contraception." Even though these drugs and devices may end a developing, distinct human being's life by preventing implantation, they are included in the FDA's definition of "contraception." Referring to such drugs as "contraception" is deceiving in that the term implies to the public only the *prevention of fertilization*. However, the endpoint which defines a drug as a "contraceptive" for the FDA is the ability to prevent a "pregnancy"—which in operational terms means preventing detection of a positive pregnancy test at the end of a woman's cycle, nearly ten days to two weeks after embryo formation.

Thus, because the FDA's criterion in categorizing a drug as "contraception" is whether a drug can work by preventing "*pregnancy*"—which the FDA defines as

beginning at "implantation," not fertilization—drugs that interfere with *implantation*, which occurs days *after* fertilization and the creation of a new human organism, are categorized as "contraception."[13]

There is no dispute among the parties that at least some of the drugs and devices included in the definition of "contraception" have post-fertilization mechanisms of action (*i.e*. life-ending) and can prevent implantation of an already-developing human embryo. For example, in *Burwell v. Hobby Lobby*, the U.S. Supreme Court noted:

> [Plaintiffs] have a sincere religious belief that life begins at conception. They therefore object on religious grounds to providing health insurance that covers methods of birth control that, as HHS acknowledges, may result in the destruction of an embryo.

No. 13-354 (U.S. June 30, 2014), slip op. at 32.

Additional statements by Defendants and their *amici* further demonstrate that there is no dispute as to the post-fertilization mechanism of action of some "contraceptives." For example, when promoting the Mandate, Kathleen Sebelius, then the Secretary of Health and Human Services (HHS), admitted that the FDA's definition of "contraception" extends to *blocking the implantation* of an already developing human embryo: "The Food and Drug Administration has a category [of

[13] For an overview of how the definition of "pregnancy" has changed, *see* Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of Conception and Pregnancy*, 9 NAT'L CATHOLIC BIOETHICS QUARTERLY 542 (2009).

drugs] that prevent fertilization *and implantation*. That's really the scientific definition."[14] Secretary Sebelius stated that under the new Mandate, "[t]hese covered prescription drugs are specifically those that are designed to *prevent implantation*."[15] Defendants know and admit that these drugs work after fertilization.

In a study on "emergency contraception," Dr. James Trussell, who has appeared as an *amicus* supporting the Defendants in numerous related cases, [16] states: "To make an informed choice, women must know that [emergency contraception pills] . . . may at times inhibit implantation. . . ."[17] Although an advocate of "emergency contraception," Dr. Trussell believes that the scientific

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[14] Wallace, *Health and Human Services Secretary Kathleen Sebelius Tells iVillage "Historic" New Guidelines Cover Contraception, Not Abortion* (Aug. 2, 2011), http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception-not-abortion/4-a-369771 (emphasis added).

[15] *Id.* (emphasis added).

[16] For example, an *amicus* brief filed by Physicians for Reproductive Health, American College of Obstetricians & Gynecologists, Dr. James Trussell, and other medical organizations and individuals was filed in the U.S. Supreme Court case *Burwell v. Hobby Lobby*. That brief was filled with semantic arguments, such as when "pregnancy" begins and whether a drug can be considered an "abortifacient;" however, such semantic arguments miss the mark. When "pregnancy" begins is not the scientific benchmark at issue here. The relevant scientific benchmark is when the life of a human organism begins—and that is undisputedly at fertilization.

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

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. He has also stated that these post-fertilization effects "should certainly be [acknowledged and] celebrated, because without them the [contraceptive] method would not provide as much benefit as they do."[18] In other words, if fertilization has occurred, the method provides "benefit" by preventing implantation.

Moreover, a drug classified by the FDA as "emergency contraception"—Ulipristal Acetate (*ella*)—is actually an abortion-inducing drug, because it can kill a human embryo *after* implantation. An understanding of these post-fertilization mechanisms of action, discussed below, further demonstrates that "emergency contraception" can end the life of an already developing human organism.

A. Plan B can prevent implantation.

In 1999, the FDA approved the distribution of the drug known as Plan B. Although called "emergency contraception," the FDA's labeling acknowledges that Plan B can prevent implantation of an already-developing human embryo.[19]

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[18] Raymond et al., *Embracing post-fertilisation methods of family planning: a call to action*, J. FAM. PLAN. REPROD. HEALTH CARE (2013).

[19] Plan B Approved Labeling, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf.

Further, the FDA states on its website, "[i]f fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation)."[20] The same explanation is provided by Duramed Pharmaceuticals, the manufacturer of Plan B One-Step.[21]

Under Defendants' Mandate, Plaintiffs are forced to pay for Plan B, despite its life-ending effect on already formed unique human organisms, in violation of their 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

[20] FDA, *FDA's Decision Regarding Plan B: Questions and Answers* (updated Apr. 30, 2009), http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm.

[21] Duramed Pharmaceuticals, *How does Plan B One-Step work?* (2010), http://www.planbonestep.com/faqs.aspx (explaining that Plan B can work "by preventing attachment (implantation) to the uterus (womb)").

mifepristone."[22] 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—an SPRM can either prevent a developing human embryo from implanting in the uterus, or it can kill an implanted embryo by essentially starving him or her to death. Put another way**,** *ella can abort a pregnancy*, whether you define "pregnancy" as beginning at fertilization or at implantation.[23]

Studies confirm that *ella* is harmful to an embryo.[24] The FDA-approved labeling notes that *ella* may "affect implantation"[25] and contraindicates use of *ella* in the case of known or suspected pregnancy. A study funded by *ella*'s manufacturer explains that SPRMs (drugs that block the hormone progesterone), "including ulipristal acetate," can "impair implantation."[26] While the study

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[22] Harrison & 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).

[23] *See* Gacek, *Conceiving Pregnancy*, *supra*.

[24] European Medicines Agency, *Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone* 16 (2009), http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf.

[25] *ella* Labeling Information (Aug. 13, 2010), http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.

[26] Glasier et. al, *Ulipristal acetate versus levongestrel for emergency*

theorizes that the dosage used in its trial "might be too low to inhibit implantation,"[27] it states affirmatively that "an additional postovulatory mechanism of action," *e.g.*, impairing implantation, "cannot be excluded."

Thus, *ella* has the potential to destroy a human embryo.

In his most recent study on "emergency contraceptives," Dr. Trussell has noted that "trials of [*ella*] showed no statistically significant effect of treatment delay" (*i.e.* reduced efficiacy) for up to 120 hours (the time frame that the trials studied).[28] Dr. Trussell further articulates that an emergency contraceptive "could not be effective on average when started after 96 hours (four days) without a post-

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contraception: a randomized non-inferiority trial and meta-analysis, 375 THE LANCET 555 (Jan. 2010).

[27] 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.

[28] Trussell et al., "Emergency Contraception: A last chance to prevent unintended pregnancy" (Office of Population Research at Princeton University December 2013).

fertilization effect; the reason is that with increasing delay, a greater proportion of women would be too near to ovulation."[29]

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]

In short, *ella* goes beyond any other "contraceptive" approved by the FDA at the time of the Affordable Care Act's enactment. By approving *ella* as "contraception," the FDA 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 the funding (through health insurance) of purposeful, off-label abortion usage of the drug. Already, *ella* is available for sale online, where a purchaser need only fill out a questionnaire to obtain the drug, with no physician or

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[29] *Id.*

[30] *See* Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs (June 17, 2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf.

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 conscientious beliefs, Plaintiffs are required to pay for *ella*—an abortion-inducing drug—under Defendants' Mandate.

C. Intrauterine Devices can also prevent implantation.

Copper Intrauterine Devices (IUDs) are heavily promoted as another form of "emergency contraception." IUDs, however, can operate to block the implantation of a human embryo after 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—they can kill an already developing human embryo.

Clearly, under Defendants' Mandate, Plaintiffs are required to pay for devices that can kill human embryos, contrary to their religious and conscientious beliefs.

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[31] *See* Department of Health and Human Services, *Birth Control Methods* (Nov. 21, 2011), http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf ("If fertilization does occur, the IUD keeps the fertilized egg from implanting in the lining of the uterus.").

[32] *See* Trussell et al., *Emergency Contraception, supra* (emphasis added).

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

There can be no genuine dispute that the Mandate includes drugs and devices with life-ending mechanisms of action, including "emergency contraception." Plaintiffs have made clear their conscientious and religious objections to paying or arranging for such life-ending drugs, but they are being forced to choose between either following their religious and conscientious beliefs or 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 paramount importance of this historic right has been affirmed by our Founders, by the U.S. Supreme Court, and by Congress. In short, history, tradition, and 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 the Plaintiffs.

A. HHS' "accommodation" for religious non-profits requires their compliance with the Mandate.

The very explanation HHS gave in its final rule for how the "accommodation" will work exposes the fallacy of its claim that under the "accommodation" these religious groups "would not contract, arrange, pay, or refer

for [the coverage that violates its religious beliefs]." 78 Fed. Reg. 39870, 39878 (2013). HHS notes that "plan participants and beneficiaries" on an accommodated plan do *not* have "two separate health insurance policies." *Id.* at 39876. Rather, the insurance issuer (the insurance company for the religious organization) will make what HHS calls "separate payments" for the objectionable coverage. *Id.* at 39874. These payments are directly linked to the insurance plan they are supposedly separate from. There is no opt-in or opt-out.

The payments are automatically made for the "accommodated" plan's participants and beneficiaries and start and end with a person's enrollment in the "accommodated" plan – not a moment before and not a moment after. HHS also acknowledges that "issuers typically do not receive enrollee information prior to enrollment." *Id*. at 39881. Put another way, the relationship between the issuer making the "separate payments" and the plan enrollees is completely dependent on the supposedly "accommodated" organization's plan.

In its final rule, HHS explains that these payments can be envisioned as "cost neutral" for the insurance issuer "because they would be insuring the same set of individuals under both the group health insurance policies and [the separate payments]." *Id.* at 39877. Even accepting HHS' assumption that providing no-co-pay coverage of contraceptives (use of which is already ubiquitous) would result in fewer pregnancies and at least equally lower costs on the "accommodated" group

health plan, the math only works if these contraceptive payments are considered in conjunction with the supposedly separate health plan provided by the religious employer.

The "accommodation" effectively requires a religious non-profit to arrange for and facilitate coverage for the drugs and devices it objects to. Thus, for religious non-profits such as Plaintiffs, it substantially burdens their religious beliefs in a manner similar to that of the plaintiffs in *Burwell v. Hobby Lobby*. Importantly, the U.S. Supreme Court held that "[b]y requiring [Plaintiffs] and their companies to arrange for such coverage, the HHS mandate demands that they engage in conduct that seriously violates their religious beliefs." *Hobby Lobby*, slip op. at 32. Likewise, if a non-profit religious employer does not "yield to this demand, the economic consequences will be severe." *Id*.

Notably, HHS has expressly exempted churches and their auxiliaries with the same religious objections as Plaintiffs from compliance with the Mandate. Concurring in *Burwell v. Hobby Lobby*, Justice Kennedy noted that the Religious Freedom Restoration Act "is inconsistent with the insistence of an agency such as HHS on distinguishing between different religious believers—burdening one while accommodating the other—when it may treat them both equally by offering both of them the same accommodation." *Hobby Lobby*, slip op. at 3 (Kennedy, J., concurring).

Ultimately, it is for the Plaintiffs, not the Defendants or the courts, to determine whether what HHS has styled as an "accommodation" burdens their religious beliefs. The U.S. Supreme Court squarely addressed this point in *Burwell v. Hobby Lobby*, holding that Plaintiffs "sincerely believe that providing the insurance coverage demanded by the HHS regulations lies on the forbidden side of the line, and it is not for us to say that their religious beliefs are mistaken or insubstantial." *Hobby Lobby*, slip op. at 34. Here, as in *Hobby Lobby*, it is not for Defendants or the courts to determine what "lies on the forbidden side of the line" for Plaintiffs' religious beliefs regarding complicity with life-ending drugs and devices.

B. 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.[33]

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

[33] *See generally* McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 HARV. L. REV. 1409 (1990).

throw off a government which dictated and controlled their religion and practices, guaranteeing freedom of conscience was of utmost importance.[34]

Thomas Jefferson made it clear that freedom of conscience is not to be subordinate to the government:

> [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.[35]

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."[36]

Likewise, James Madison, considered the Father of the Bill of Rights, was deeply concerned that the freedom of conscience of Americans be protected. 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 *an unalienable right*.[37]

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[34] The Founders often used the terms "conscience" and "religion" synonymously. 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.

[35] Jefferson, *Notes on Virginia* (1785).

[36] Jefferson, Letter to New London Methodists (1809).

[37] Madison, *Memorial and Remonstrance Against Religious Assessments* ¶ 15 (1785) (emphasis added).

In fact, Madison described the conscience as "the most sacred of all property."[38] 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, statutes, judicial orders, or 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."[39]

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

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[38] Milton, THE QUOTABLE FOUNDING FATHERS: A TREASURY OF 2,500 WISE AND WITTY QUOTATIONS 36-37 (2005).

[39] Madison, Speech Delivered in Congress (Dec. 22, 1790).

fire called conscience."[40] 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.[41]

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."[42] Patriot leader Samuel Adams wrote that the liberty of conscience is an original right.[43]

Forcing Plaintiffs to arrange for and facilitate coverage for drugs and devices which have the effect of ending human life and 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*

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[40] Novak & Novak, WASHINGTON'S GOD 111(2006); Milton, *supra*.

[41] Washington, Letter to the Religious Society Called Quakers (1789).

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

[43] Cushing, THE WRITINGS OF SAMUEL ADAMS 350-59 (vol. II, 1906).

> *dangerous efforts of those who would seduce the public opinion to substitute itself into … tyranny over religious faith….*"[44]

C. Freedom of Conscience is a fundamental right affirmed the U.S. Supreme Court.

The Supreme Court has consistently ruled in favor of protecting the freedom of conscience of every American. "Freedom of conscience" is referenced explicitly throughout Supreme Court jurisprudence *See, e.g.*, *Baird v. State Bar of Ariz.*, 401 U.S. 1, 6, 91 S. Ct. 702 (1971) ("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."); *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 506 n.2, 89 S. Ct. 733 (1969) (referencing "constitutionally protected freedom of conscience").

The Court has stated that "*[f]reedom of conscience … cannot be restricted by law*." *Cantwell v. Conn.*, 310 U.S. 296, 303, 60 S. Ct. 900 (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 Court considered regulations requiring public school students to recite the pledge to the American flag, ultimately vindicating the

[44] Jefferson, Letter to Edward Dowse, Esq. (Apr. 19, 1803) (emphasis added).

students' freedom of conscience. In *West Virginia State Board of Education v. Barnette*, the Court 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 confess by word or act their faith therein…. [L]ocal authorities [may not] transcend [] constitutional limitations on their power and invade[] the sphere of intellect and spirit which it is the purpose of the *First Amendment to our Constitution* to reserve from all official control.

Barnette, 319 U.S. 624, 642, 63 S. Ct. 1178 (1943) (emphasis in original). The Court also stated, "[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.*[45] Based upon these principles, the Court ruled it unconstitutional to force public school children to perform an act that was against their religious beliefs.

Barnette has been affirmed on numerous occasions, including in *Planned Parenthood v. Casey*, 505 U.S. 833, 112 S. Ct. 2791 (1992), where the Court stated:

> It is conventional constitutional doctrine that where reasonable people disagree the government can adopt one position or the other. *That*

[45] "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).

> *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).

In the context of an obligatory flag salute and pledge, the Court has established the principle that to force parents and children to choose between their religious beliefs and their public education is a clear violation of their First Amendment rights. Likewise, forcing Plaintiffs to choose between adhering to their religious, moral, or conscientious convictions and complying with the Mandate is an unconstitutional exercise of state power.

The Court has also 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."[46] In *United States v. Seeger* and *Welsh v. United States*, the 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

[46] Section 6(j) did not embody a "new" idea. 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.

part of an instrument of war." *Welsh*, 398 U.S. 333, 344, 90 S. Ct. 1792 (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 "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.

The holdings in these cases demonstrate a strong commitment by the Supreme Court to protect freedom of conscience. Like Welsh, Plaintiffs believe that human life is valuable—at all stages and in all situations. As discussed *supra*, "emergency contraception" has the potential to kill developing human embryos. Being forced to arrange for and facilitate for the termination of a human life is just as objectionable as being forced to participate in the termination of human life in war.

D. Freedom of Conscience is a fundamental right affirmed by Congress.

Congress likewise has considered and passed numerous measures expressing the federal government's commitment to protecting the freedom of conscience. Congress addressed the issue of conscience just weeks after the Supreme Court decided *Roe v. Wade*. In 1973, Congress passed the first of the Church Amendments.[47] 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.

In 1996, Section 245 of the Public Health Service Act, known as the Coats Amendment, 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.[48] The measure was prompted by a 1995 proposal from the Accreditation Council for Graduate Medical

[47] 42 U.S.C. § 300-7.

[48] 42 U.S.C. § 238n.

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 refer for abortion.[49] The Amendment is subject to annual renewal and has survived multiple legal challenges.[50]

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 protecting religious beliefs and moral convictions in any contraceptive mandate.[51] Similarly, in 1999, Congress prohibited health plans participating in the federal employees'

[49] Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209 (2007).

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

[51] *See* Pub. L. No. 108-7, 117 Stat. 11, 126-27 (2000).

benefits program from discriminating against individuals who refuse to prescribe contraceptives.[52]

These laws highlight the commitment of the American people to protect individuals and employers from mandates or other requirements forcing them to violate their consciences and/or religious and moral beliefs, and demonstrate that Defendants' Mandate ignores the longstanding national commitment to protect the freedom of conscience.[53]

[52] *See* Pub. L. No. 108-7, 117 Stat. 11, 472 (1999).

[53] Defendants' actions also run contrary to the laws and clear intent of the vast majority of states that protect the freedom of conscience. At least 47 states provide some degree of statutory protection to healthcare providers who conscientiously object to certain procedures. Some states—including Louisiana and Mississippi—extend this protection to public and/or private payers (*i.e.*, health insurers). *See Rights of Conscience Overview*, in DEFENDING LIFE 2013: DECONSTRUCTING ROE: ABORTION'S NEGATIVE IMPACT ON WOMEN (2013), http://www.aul.org/wp-content/uploads/2013/04/06-Freedom-of-Conscience.pdf.

CONCLUSION

It is undisputed that a new human organism is created at fertilization. Being forced to arrange and facilitate coverage for drugs and devices that can end a human life after fertilization but before implantation amounts to forced participation in the act of ending a human life itself. Plaintiffs have a genuine and authentic conscientious objection to arranging for and facilitating insurance coverage for such drugs and devices. The Defendants' Mandate requiring the provision of such drugs and devices is a coercive policy which runs contrary to the history, tradition, and jurisprudence of this Nation and violates Plaintiffs' freedom of conscience and is therefore unconstitutional.

For the forgoing reasons, this Court should affirm the preliminary injunction entered by the lower court.

Respectfully submitted,

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Dated: August 4, 2014

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s/ Mailee R. Smith
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Dated: August 4, 2014

CERTIFICATE OF DIGITAL SUBMISSION, VIRUS SCAN, AND PRIVACY REDACTIONS

I hereby certify that August 4, 2014, I electronically filed the foregoing *Amicus Curiae* Brief with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

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I hereby certify that on August 4, 2014, 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.

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