Nos. 12-5273 & 12-5291

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

WHEATON COLLEGE; BELMONT ABBEY COLLEGE,

Appellants,

v.

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

Appellees.

On Appeal from the United States District Court for the District of Columbia

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AMICUS CURIAE BRIEF OF ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, CATHOLIC MEDICAL ASSOCIATION, THE NATIONAL CATHOLIC BIOETHICS CENTER, PHYSICIANS FOR LIFE, AND NATIONAL ASSOCIATION OF PRO LIFE NURSES, IN SUPPORT OF APPELLANTS AND REVERSAL OF THE LOWER COURT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26 and L.R. 26.1, the Association of American Physicians & Surgeons, American Association of Pro-Life Obstetricians & Gynecologists, Catholic Medical Association, The National Catholic Bioethics Center, Physicians for Life, and National Association of Pro life Nurses ("*Amici*"), make the following disclosures:

1) *Amici* are not publicly held corporations or other publicly held entities.

2) *Amici* have no parent corporations.

3) No publicly owned corporation or other publicly held entity owns ten (10) percent or more of the stock of *Amici*.

4) *Amici* are physicians, bioethicists, and other healthcare professionals who have a profound interest in defending the sanctity of human life, and who have an expertise on the life-ending mechanisms of action of certain forms of "contraception." (L.R. 26.1(b)).

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Dated October 12, 2012

CERTIFICATE IN SUPPORT OF SEPARATE BRIEF

Under Circuit Rule 29(d), "[a]mici curiae on the same side must join in a single brief to the extent practicable." Counsel for amici certifies that this separate brief is necessary to share the unique perspective of physicians, bioethicists, and other healthcare professionals who have a profound interest in defending the sanctity of human life, and who have an expertise on the life-ending mechanisms of action of certain forms of "contraception." Counsel for amici is not aware of any party or other amicus in this Court that will capture this perspective in depth. Counsel for amici further certifies that the amici have joined together to the extent practicable insofar as this brief features the consolidated views of six medical and bioethics organizations.

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Counsel of Record for *Amici Curiae*

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GLOSSARY

ACA: Affordable Care Act

ANPRM: Advance Notice of Proposed Rulemaking

FDA: Food and Drug Administration

HHS: U.S. Department of Health and Human Services

IUD: Intrauterine Devices

RFRA: Religious Freedom Restoration Act

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae are six national organizations whose members include physicians, bioethicists, and other healthcare professionals who have a profound interest in defending the sanctity of human life in their roles as healthcare providers, medical experts, and consumers. *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. However, *Amici* deeply oppose the requirement imposed by the Appellees on nearly all private insurance plans to cover drugs and devices with life-ending mechanisms of action. This requirement violates Appellants' sincerely held religious beliefs and freedom of conscience.

Amici include the following medical and ethics associations:

Association of American Physicians and Surgeons ("AAPS") is a non-partisan professional association of physicians in all types of practices and specialties across the country. Since 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the

[1] *Amici* have authority to file this brief under Fed. R. App. P. 29 because all parties have consented to its filing. A party's counsel has not authored the brief in whole or in part, nor contributed money that was intended to fund the preparation or submission of the brief. No persons outside of *Amici* or their Counsel have contributed money intended to fund preparation of the brief.

patient-physician relationship and the practice of private medicine. The motto of AAPS is "omnia pro aegroto," meaning "all for the patient."

American Association of Pro-Life Obstetricians and 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, placenta previa, and breast cancer) in order to provide a realistic appreciation of abortion-related health risks.

Catholic Medical Association ("CMA") is a nonprofit national organization comprised of almost 2,000 members covering over 75 medical specialties. CMA 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 (NCBC), 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 ("PFL") is a national nonprofit medical organization that exists to draw attention to the issues of abortion, teen pregnancy, and sexually-transmitted diseases. PFL 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 Prolife 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.

ARGUMENT

Appellant Belmont Abbey College is a Benedictine college where "obedience to the teachings of the Catholic Church is central to the College's identity and mission." Therefore, "the College sincerely believes that Catholic teachings regarding . . . the protection of nascent human life **forbid it from providing employees with insurance coverage for contraceptives, abortion-inducing drugs,** sterilizations, or related education and counseling."[2]

[2] Pl.'s Opp'n to Defs' Mot. to Dismiss 3-4, ECF No. 24 (emphasis added).

Appellant Wheaton College is a Christian liberal arts college which "holds and follows traditional Christian beliefs about the sanctity of life." Further, "it is a violation of Wheaton's teachings for it to **deliberately provide insurance coverage for, fund, sponsor, underwrite, or otherwise facilitate access to abortion- inducing drugs, abortion procedures, and related services."** This specifically includes coverage for "emergency contraceptive drugs popularly known as Plan B and Ella."[3]

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]."[4] The Appellees' regulatory mandate (the "Mandate") implementing this provision 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."[5] The FDA's definition of "contraception" is broad and **includes drugs and devices with known life-ending mechanisms of action, including the abortion-inducing drug *ella*.**[6]

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[3] Mem. of Law in Supp. of Mot. for Prelim. Inj. 6-7, ECF No. 4-1, *quoting* Ryken Decl. ¶ 14, 15, 17 (emphasis added).
[4] 42 USCS § 300gg-13 (2012).
[5] *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 Oct. 1, 2012).
[6] *See* FDA *Birth Control Guide* (Aug. 2012), *available at* http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM282014.pdf (last visited Oct. 1, 2012).

Neither Belmont Abbey College nor Wheaton College meet the criteria for a narrow religious employer exemption to the Mandate,[7] nor are their private insurance plans "grandfathered," and therefore temporarily exempted.[8] Consequently, **beginning January 1, 2013, both Appellants are required to comply with the Mandate**—which includes the provision of insurance coverage for life-ending drugs and devices—in violation of their sincerely held religious beliefs and freedom of conscience.

I. DRUGS AND DEVICES DEFINED AS "EMERGENCY CONTRACEPTION" BY THE FDA, INCLUDING ULIPRISTAL ACETATE (*ELLA*), HAVE LIFE-ENDING 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" (a term which connotes simply preventing fertilization or conception) because the FDA's relevant criterion is whether they can work by preventing "pregnancy," defined as beginning at "implantation," not fertilization.[9] Moreover, as will be discussed

[7] *See* Pl.'s Opp'n to Defs.' Mot. to Dismiss 5, ECF No. 24; Pl.'s Mem. of Law in Opp'n to Mot. to Dismiss 16, ECF No.18.
[8] Pl.'s Opp'n to Defs.' Mot. to Dismiss 12, ECF 24; Pl.'s Mem. of Law in Opp'n to Mot. to Dismiss 6, ECF No. 18.
[9] For an overview of how the definition of pregnancy has "changed," *see* Christopher Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their*

below, with the approval of the drug *ella* in 2010, the FDA definition of "contraception" now encompasses a drug or device that can end a life *after* implantation.

Promoting the Mandate, Appellee Kathleen Sebelius, the Secretary of Health and Human Services (HHS), has 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."[10] Secretary Sebelius stated that under the new mandate, "[t]hese covered prescription drugs are specifically those that are designed to prevent implantation."[11]

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]

Definitions of Conception and Pregnancy, FRC INSIGHT PAPER (April 2009), *available at* http://downloads.frc.org/EF/EF09D12.pdf (last visited Oct. 2, 2012).

[10] Kelly Wallace, *Health and Human Services Secretary Kathleen Sebelius Tells iVillage "Historic" New Guidelines Cover Contraception, Not Abortion*, IVILLAGE, Aug. 2, 2011, *available at* http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception-not-abortion/4-a-369771 (last visited June 12, 2012).

[11] *Id.*

. . . may at times inhibit implantation. . . ."[12] In other words, Dr. Trussell, although an advocate of "emergency contraception,"[13] believes that the scientific difference between a drug that prevents fertilization and one that may also prevent implantation 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 pertaining to the prescription of "emergency contraception," testified under oath that "there is a new unique human life before" implantation of an embryo.[14]

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.

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[12] J. Trussell et al., *Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy*, Office of Population Research at Princeton University (June 2010).
[13] *See* Profile of Dr. James Trussell, *available at* https://www.princeton.edu/~trussell/ (last visited Oct. 2, 2012).
[14] 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 "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.[15] Although called "contraception," the FDA's labeling acknowledges that Plan B can prevent implantation of a human embryo.[16] 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).**[17]

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

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[15] 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. Mar. 23, 2009). The Obama Administration did not appeal and the FDA has indicated intent to comply with the ruling. However, the Obama Administration announced in December 2011 that it would not extend the drug's over-the-counter status to minors under 17 years of age.

[16] Plan B Approved Labeling, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf (last visited Sept. 30, 2012).

[17] 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 Sept. 30, 2012) (emphasis added).

altering tubal transport of sperm and/or egg; 3) **altering the endometrium, which may inhibit implantation**.[18]

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. 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 mifepristone."[19] 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 it to death. Put another way**, *ella* can abort a pregnancy**, no matter whose definition of "pregnancy" is used.[20]

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[18] 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 Sept. 30, 2012) (emphasis added).

[19] 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).

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

Studies confirm that *ella* is harmful to a human embryo.[21] The FDA's own labeling notes that *ella* may "affect implantation,"[22] 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 hormone progesterone) "including ulipristal acetate" can "impair implantation."[23] While the study theorizes that the dosage used in its trial "might be too low to inhibit implantation,"[24] it states affirmatively that "an additional postovulatory mechanism of action," *e.g.* impairing implantation, "cannot be excluded."

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[21] European Medicines Agency, *Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone*, at 16 (2009), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf (last visited Sept. 30, 2012).

[22] *ella* Labeling Information (Aug. 13, 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (last visited Oct. 2, 2012).

[23] Glasier *et. al*, *Ulipristal acetate versus levongestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis*, 375 THE LANCET 555 (Jan. 2010).

[24] 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; 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 even ending implantation, was not determinable.

In fact, *ella*'s deadliness is confirmed by its high "effectiveness." 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 taking *ella* four or five days after intercourse suggests that the drug *must* have an "abortifacient" quality.[25]

In short, *ella*'s deadliness goes beyond that of any other "contraceptive" approved by the FDA at the time of the ACA's enactment. Without diminishing the legitimate and serious objections to the deceptive approval of other life-ending drugs and devices, it should be acknowledged that by approving *ella* as "contraception" the FDA has removed, not simply blurred, the line between "contraception" and "abortion" drugs. The FDA-approved "contraceptive" *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

[25] *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/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf (last visited Sept. 30, 2012).

no physician or pharmacist to examine the patient, explain the risks in person, or verify the identity and intentions of the purchaser.

It is also known that Planned Parenthood, which participated in the development of *ella* and is already promoting the drug, frequently uses drugs off-label. Planned Parenthood's Dr. Vanessa Cullins practically boasted to the FDA advisory panel considering whether to approve *ella* of her organization's (off-label) use of Plan B past the FDA-permitted time for use.[26] Dr. Cullins' proffered rationale that Planned Parenthood's misuse was based on a desire to give women "every opportunity" to "prevent" a pregnancy raises the concern that Planned Parenthood may likewise dispense *ella* after the FDA's permitted time for use, because of the extended opportunity it provides to ensure there is no pregnancy, whether or not implantation has already occurred.

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

Copper Intrauterine Devices (IUDs) are being heavily pushed for use as "emergency contraception." IUDs are acknowledged to work not only by preventing conception, but by blocking implantation.[27] In his study on "emergency

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[26] *See* Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs, *supra*.

[27] *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 Sept. 30, 2012). HHS describes among the mechanisms of action for copper IUDs: "If fertilization

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.**"[28] Put another way, IUDs are so effective because they do not just prevent conception, but can "work" by killing an already developing human embryo.

II. THE APPELLEES' MANDATE REQUIRING APPELLANTS TO SPONSOR HEALTH-INSURANCE PLANS THAT PAY FOR DRUGS AND DEVICES WITH KNOWN LIFE-ENDING MECHANISMS OF ACTION VIOLATE APPELLANTS' SINCERELY HELD RELIGIOUS BELIEFS AND FREEDOM OF CONSCIENCE.

As discussed above, Appellants are required under the Mandate to provide insurance coverage for "emergency contraception"—drugs and devices with life-ending mechanisms of action. Because Appellants do not meet the criteria for the narrow religious employer exemption to the Mandate, nor are their private insurance plans "grandfathered," and therefore temporarily exempted, they must provide coverage or face heavy penalties.[29]

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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."

[28] *See* Trussell, *Emergency Contraception, supra* (emphasis added).

[29] *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 Appellees' narrowly defined exemption to such an extreme Mandate has no precedent in federal law. In fact, contrary to the ACA's explicit language stating that "[n]othing in this Act shall be construed to have any effect on Federal laws regarding – (i) conscience protection…,"[30] the Mandate's inclusion of abortion-inducing drugs violates the animating principles of long-standing federal laws protecting conscience rights.

Freedom of conscience is a fundamental right that has been revered since the founding of our nation. The First Amendment promises that Congress shall make no law prohibiting the free exercise of religion.[31] 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.[32] As Thomas Jefferson wrote, "[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of civil authority."[33] Jefferson also stated,

> The rights of conscience we never submitted [to rulers], we could not submit. We are answerable for them to our God. The legitimate powers of government extend to such acts only as are injurious to others.[34]

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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).

[30] 42 USCS § 18023 (2012).

[31] U.S. CONST. amend. I.

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

[33] Thomas Jefferson to New London Methodists (1809).

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

Likewise, James 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…. It is the duty of every man to render to the Creator such homage, and such only, as he believes to be acceptable to him.[35]

Indeed, it cannot be disputed that the right of conscience lies at the very core of the free exercise clause of the First Amendment.

Congress first addressed the issue of conscience protections just weeks after the U.S. Supreme Court decision in *Roe v. Wade*.[36] In 1973, Congress passed the first of the Church Amendments (named for its sponsor, Senator Frank Church).[37] The Amendment provides that the receipt of funding through three federal programs cannot be used as a basis to compel a hospital or individual to participate in an abortion or sterilization procedure to which the hospital or individual has a moral or religious objection.

In addition, §§ c(2) and (d) of the Church Amendment provide broad protection ensuring that no "individual shall be required to perform or assist in the performance of any part of a health service program or research activity" funded in whole or in part by the federal government if doing so "would be contrary to his

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[35] James Madison, *Memorial and Remonstrance Against Religious Assessments* ¶ 15 (reprinted in *Everson v. Bd. of Ed.*, 330 U.S. 1, 64 (Rutledge, J., dissenting)).
[36] 410 U.S. 113 (1973).
[37] 42 U.S.C. 300a-7 (2012).

religious beliefs or moral convictions." Thus, the protections of the Church Amendment are broad and are not limited to abortion and sterilization.

Taken together, the original and subsequent Church Amendments protect healthcare providers from discrimination by recipients of HHS funds on the basis of their objection, stemming from their religious beliefs or moral convictions, to performing or participating in *any* lawful health service or research activity.

In addition, the Hyde-Weldon Amendment, first enacted in 2005, provides that no federal, state, or local government agency or program that receives funds in the Labor/Health and Human Services appropriations bill may discriminate against a healthcare provider because the provider refuses to provide, pay for, provide coverage of, or refer for abortion.[38]

Further, the Mandate's application to the Appellants violates the Religious Freedom Restoration Act (RFRA).[39] To abide by RFRA, the Mandate (which burdens the exercise of religion) would have to be both "in furtherance of a compelling governmental interest" and "the least restrictive means of furthering that compelling governmental interest." The Appellees fail to offer a "compelling" interest for the Mandate. Moreover, the Mandate and the proposals in the ANPRM, addressed below, clearly are not the "least restrictive" means to accomplish the

[38] Consolidated Appropriations Act 2008, Pub. L. No. 110-161, §508(d), 121 Stat. 1844, 2209 (2007).
[39] 42 U.S.C. §§ 2000bb et seq (2012).

Appellees' stated interest of increasing "access" to contraception. Furthering that goal does not require forcing the Appellants to facilitate, pay for, and participate in health insurance plans covering drugs and devices to which they have religious objections.

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 the Appellants 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 objections (or face heavy penalties).

III. THE "SAFE HARBOR" AND ADVANCED NOTICE OF PROPOSED RULEMAKING (ANPRM) DO NOT ADEQUATELY PROTECT APPELLANTS' FREEDOM OF CONSCIENCE.

A. The "Temporary Enforcement Safe Harbor" is Wholly Insufficient.

In response to a dramatic outpouring of concerns regarding the Mandate, Appellee Secretary Sebelius acknowledged in January 2012 that there are "important concerns" about "religious liberty." Nonetheless, the Appellees did not change the Mandate[40] or broaden its exception; rather, they decided to "add an

[40] Regulations adopting the Mandate with its narrow religious employer exemption were published in final form, without change on February 15, 2012. *See* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed.

additional element to the final rule"— that "(n)onprofit employers who, based on religious beliefs, do not currently provide contraceptive coverage [including coverage for life-ending drugs and devices] in their insurance plan, **will be provided an additional year**, until August 1, 2013, **to comply with the new law."**[41]

Secretary Sebelius stated that the "extension" for nonprofit groups with a religious-based objection to providing coverage for "contraception" was "the appropriate balance" for "respecting religious freedom."[42] However, putting an

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Reg. 8725-01, 8729 (published Feb. 15, 2012) (to be codified at 26 CFR pt. 54; 29 CFR pt. 2590; 45 CFR pt. 147).

[41] *See* January 20, 2012 Statement of HHS Secretary Kathleen Sebelius, *available at* http://www.hhs.gov/news/press/2012pres/01/20120120a.html (last visited Oct. 1, 2012).

[42] The "balance" should clearly be weighted in favor of freedom of conscience since there is no constitutional right to subsidized life-ending drugs and devices. *See Harris v. McRae,* 448 U.S. 297 (1980). Even the ACLU's "Reproductive Freedom Project," dedicated to promoting abortion and "contraception," acknowledges that "access" to contraception is not a constitutional right. *See Religious Refusals and Reproductive Rights*, American Civil Liberties Union (ACLU) Reproductive Freedom Project (2007), *available at* http://www.aclu.org/pdfs/reproductiverights/finalreport.pdf (last visited Oct. 2, 2012). Addressing a pharmacist's or pharmacy's decision not to participate in contraception, ACLU literature states it "does not violate a woman's federal constitutional rights. The U.S. Constitution imposes no limitations on nongovernmental institutions like privately owned pharmacies. Even if the refusal takes place in a state-owned pharmacy, a woman has no federal constitutional right to receive contraception."

expiration date on the freedom of conscience is not a "balance;" it is a denial of rights guaranteed by the First Amendment.[43]

Further, Appellants may not qualify for the "safe harbor," or may face the threat of private ERISA lawsuits during the "safe harbor" period (the "safe harbor" only applies to *government* enforcement of the Mandate).[44] Regardless, the end result will be the same for Appellants as for all other employers—**under federal law**, **they are required to provide insurance coverage for life-ending drugs and devices and will ultimately face government enforcement of the Mandate.**

B. The March 2012 Advance Notice Of Proposed Rulemaking (ANPRM) indicates that the government may merely modify *how* Appellants will be allowed to satisfy the Mandate, and therefore will not protect the Appellants' conscience rights.

The Appellees' now propose to create new regulations that will "accommodate" a religious organization that "objects to the coverage of contraceptive services (including life-ending drugs and devices) for religious reasons and that is not exempt under the final regulations published February 15,

[43] It is unsettling that when testifying before the House Education and Workforce Committee, Secretary Sebelius (who noted "I am not a lawyer and I do not pretend to understand the nuances of the constitutional balancing tests") stated that she relied on "discussions" with attorneys, but seemed to indicate that no legal memorandum was ever created addressing the fact that the fundamental constitutional guarantee of "religious freedom," which HHS appears to at least understand, hangs in the balance. *See* Sebelius Interview, *available at* http://www.youtube.com/watch?v=NnO7qa7fMRc&feature=plcp (last visited Oct. 1, 2012).

[44] *See* Pl.'s Opp'n to Defs.' Mot. to Dismiss 13, ECF No. 24; Pl.'s Mem. of Law in Opp'n to Mot. to Dismiss 10-15, ECF No.18.

2012."[45] However, the Appellees' Advance Notice of Proposed Rulemaking (ANPRM) fails to promise timely or sufficient conscience protection for the Appellants.

The definition that HHS applies to the term "accommodation" in the ANPRM makes clear that it is not a conscience protection, but rather the forced compliance of these insurance plans:

> [T]he term 'accommodation' is used to refer to an arrangement under which contraceptive coverage is provided without cost sharing to the participants and beneficiaries covered under a plan…[46]

While stating that its proposed "accommodation" will "effectively exempt the religious organization from the requirement to cover contraceptive services," the proposal does not, in fact, "effectively" do so.[47]

Under the ANPRM's "accommodation," insurance providers "must offer…insurance coverage that does not include coverage for contraceptive services" to those eligible for the accommodation. Yet, simultaneously, "the issuer must additionally provide to the participants and beneficiaries covered under the plan separate health insurance coverage consisting solely of coverage for

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[45] Certain Preventive Services Under the Affordable Care Act, 77 Fed. Reg. 16501 (proposed Mar. 21, 2012) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147).
[46] *Id.* at 16503.
[47] *Id.*

contraceptive services....without charge to the organization, group health plan, or plan participants or beneficiaries."[48]

In other words, the "accommodation" still requires that employers, including the Appellants, facilitate objectionable insurance coverage or be subject to a penalty. The objecting employer must arrange for health insurance and, according to the ANPRM, the plan participants and beneficiaries will be automatically enrolled ("without an application or enrollment process") in contraceptive coverage without cost-sharing.[49]

Further, much of the ANPRM and the "accommodation" are dedicated to purportedly accomplishing an economic impossibility: providing the mandated drugs and devices at no cost to either the employer providing the insurance plan or the employee participating in the insurance plan. Such a feat would defy basic economic reality. The mandated drugs and devices are not without cost. Someone has to pay for them. The idea that these costs will in no way be passed on to the "accommodated" employers, such as, arguably, the Appellants, in the form of higher premiums, is clearly suspect.[50]

In sum, the ANPRM will not protect Appellants from complicity in providing for their employees insurance coverage for or access to life-ending drugs

[48] *Id.* at 16505-06.
[49] *Id.* at 16505.
[50] *See* discussion in 77 Fed. Reg. 1605-16507.

and devices. It is merely another attempt by Appellees to obfuscate the true nature of the Mandate—it is an unprecedented requirement on religious employers, including the Appellants, to choose between violating their sincerely held religious beliefs (by providing insurance coverage for life-ending drugs and devices) or facing stiff government penalties.

CONCLUSION

The judgments of the District court dismissing Belmont Abbey College's case and Wheaton College's case should be reversed and remanded, and the court's denial of Wheaton College's motion for preliminary injunction should be reversed and remanded.

Respectfully submitted,

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I hereby certify that on October 12, 2012, a true and correct copy of the foregoing Brief was electronically filed with the Clerk of Court through the CM/ECF system. An electronic copy will be served on the following parties who are registered in the system:

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