No. 12-3238

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

STATE OF NEBRASKA, et al.,

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

On Appeal from the United States District Court for the District of Nebraska
(No. 12-03035, Hon. Warren K. Urbom)

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, PHYSICIANS FOR LIFE, AND NATIONAL ASSOCIATION OF PRO LIFE NURSES,
IN SUPPORT OF APPELLANTS
AND REVERSAL OF THE LOWER COURT

Mailee R. Smith
Counsel of Record for Amici Curiae
Americans United for Life
655 15th St. NW, Suite 410
Washington, D.C. 20005
Telephone: 202-289-1478
Facsimile: 202-289-1473

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 of which a publicly held corporation can hold.

/s/ Mailee R. Smith
Mailee R. Smith
Counsel of Record for Amici Curiae
Americans United for Life
655 15th St. NW, Suite 410
Washington, D.C. 20005
Telephone: 202-289-1478
Facsimile: 202-289-1473

Dated: November 13, 2012

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

FEDERAL REGULATIONS

OTHER SOURCES

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 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 Defendants on nearly all private insurance plans to cover drugs and devices with life-ending mechanisms of action. This requirement violates 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 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*

[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 the brief.

& 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 expressly made use of *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). The Third Circuit cited AAPS in the first paragraph of one of its opinions, which ruled 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.

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] The 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 life-ending mechanisms of action,**

[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 Oct. 1, 2012).

including the abortion-inducing drug *ella*.[4] As such, the Mandate violates the conscientious beliefs not just of the Plaintiffs, but of Americans across the nation.

The court below wrongfully based its decision, in part, on a "safe harbor"—allowing non-profit employers one year to come into compliance with the Mandate—and potential rule-making that will *allegedly* provide further accommodation to those opposed to life-ending drugs and devices. But as demonstrated below, this "safe harbor" and Advanced Notice of Proposed Rulemaking (ANPRM) are wholly inadequate and do not protect the freedom of conscience. As such, the "safe harbor" and the ANPRM cannot form the basis for a decision on either standing or ripeness in this case.

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."

[4] *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).

Yet referring to such drugs as "contraception" is deceiving in that it connotes the prevention of *fertilization* or *conception*. But the FDA's current criterion in categorizing something as "contraception" is whether a drug can work by preventing "*pregnancy*"—which the FDA defines as beginning at "implantation," not fertilization.[5] Thus, drugs that interfere with implantation—which occurs after fertilization—are being categorized as "contraception." Moreover, as will be 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 end a life *after* implantation.

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."[6] Secretary

---

[5] 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 Oct. 2, 2012).

[6] 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 June 12, 2012).

Sebelius stated that under the new Mandate, "[t]hese covered prescription drugs are specifically those that are designed to prevent implantation."[7]

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. . . ."[8] In other words, Dr. Trussell, although an advocate of "emergency contraception,"[9] 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 pertaining to the

---

[7] *Id.*

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

[9] *See* Profile of Dr. James Trussell, *available at* https://www.princeton.edu/~trussell/ (last visited Oct. 2, 2012).

prescription of "emergency contraception," testified under oath that "there is a new unique human life before" implantation of an embryo.[10]

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.

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.[11] Although called "contraception," the FDA's labeling

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

[11] 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, 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. A new case, *Tummino v. Hamburg* (E.D.N.Y. 12-12-763), was filed by the Center for Reproductive Rights in 2012.

acknowledges that Plan B can prevent implantation of a human embryo.[12] 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).**[13]

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**.[14]

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

---

[12] 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).

[13] 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) (emph. added).

[14] 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) (emph. added).

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 mifepristone."[15] 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.[16]

Studies confirm that *ella* is harmful to a human embryo.[17] The FDA's own labeling notes that *ella* may "affect implantation,"[18] and contraindicates (or advises

---

[15] 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).

[16] *See* C. Gacek, *Conceiving Pregnancy, supra*.

[17] 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 Sept. 30, 2012).

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."[19] While the study theorizes that the dosage used in its trial "might be too low to inhibit implantation,"[20] it states affirmatively that "an additional postovulatory mechanism of action," *e.g.* impairing implantation, "cannot be excluded."

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

---

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

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

[20] 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 even ending implantation, was not determinable.

the low pregnancy rate for women taking *ella* four or five days after intercourse suggests that the drug *must* have an "abortifacient" quality.[21]

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

---

[21] *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).

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.[22] 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.[23] In his study on "emergency

---

[22] *See id*.

[23] *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 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."

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.**"[24] 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 MANDATE REQUIRING SPONSORSHIP OF HEALTH-INSURANCE PLANS THAT PAY FOR DRUGS AND DEVICES WITH KNOWN LIFE-ENDING MECHANISMS OF ACTION VIOLATES SINCERELY HELD RELIGIOUS BELIEFS AND FREEDOM OF CONSCIENCE.

As discussed above, employers are required under the Mandate to provide insurance coverage for "emergency contraception"—drugs and devices with life-ending mechanisms of action. If employers do not meet the criteria for the narrow religious employer exemption to the Mandate, and their private insurance plans are not "grandfathered," such employers must provide coverage or face heavy penalties.[25]

---

[24] *See* J. Trussell, *Emergency Contraception, supra* (emph. added).

[25] *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.

The Defendants' 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…,"[26] 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.[27] 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.[28] 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."[29] 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

---

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).

[26] 42 U.S.C. § 18023.

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

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

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

> powers of government extend to such acts only as are injurious to others.[30]

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.[31]

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*.[32] In 1973, Congress passed the first of the Church Amendments (named for its sponsor, Senator Frank Church).[33] 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.

---

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

[31] James Madison, *Memorial and Remonstrance Against Religious Assessments* ¶ 15.

[32] 410 U.S. 113 (1973).

[33] 42 U.S.C. 300a-7.

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 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.[34]

Further, the Mandate's application to the individual Plaintiffs violates the Religious Freedom Restoration Act (RFRA).[35] To abide by RFRA, the Mandate

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

[35] 42 U.S.C. §§ 2000bb *et seq*.

(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 Defendants fail to offer a "compelling" interest for the Mandate. Moreover, the Mandate and the proposals in the Advanced Notice of Proposed Rulemaking (ANPRM), addressed below, clearly are not the "least restrictive" means to accomplish the Defendants' stated interest of increasing "access" to contraception. Furthering that goal does not require forcing the Americans 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 employers such as Plaintiffs Catholic Social Services, Pius X, and Catholic Mutual 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 objections (or face heavy penalties).

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

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

In response to a dramatic outpouring of concerns regarding the Mandate, Defendant Secretary Sebelius acknowledged in January 2012 that there are "important concerns" about "religious liberty." Nonetheless, the Defendants did not change the Mandate[36] or broaden its exception; rather, they decided to "add an 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."**[37]

Secretary Sebelius stated that the "extension" for nonprofit groups with a religious-based objection to providing coverage for "contraception" was "the

---

[36] 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. Reg. 8725-01, 8729 (published Feb. 15, 2012) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147).

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

appropriate balance" for "respecting religious freedom."[38] However, putting an expiration date on the freedom of conscience is not a "balance;" it is a denial of rights guaranteed by the First Amendment.[39]

Further, employers like Plaintiffs Catholic Social Services, Pius X, or Catholic Mutual 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). Regardless, the end result

---

[38] 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* American Civil Liberties Union (ACLU) Reproductive Freedom Project, *Religious Refusals and Reproductive Rights* (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."

[39] 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).

will be the same for these Plaintiffs 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* Defendants will be allowed to satisfy the Mandate, and therefore will not protect freedom of conscience.

The Defendants 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, 2012."[40] However, the Defendants' Advance Notice of Proposed Rulemaking (ANPRM) fails to promise timely or sufficient conscience protection.

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….[41]

---

[40] 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).

[41] *Id.* at 16503.

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.[42]

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 contraceptive services... without charge to the organization, group health plan, or plan participants or beneficiaries."[43]

In other words, the "accommodation" still requires that employers 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.[44]

---

[42] *Id.*

[43] *Id.* at 16505-06.

[44] *Id.* at 16505.

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, in the form of higher premiums, is clearly suspect.[45]

In sum, the ANPRM offers no protection from complicity in providing insurance coverage for or access to life-ending drugs and devices. It is merely another attempt by Defendants to obfuscate the true nature of the Mandate—it is an unprecedented requirement on religious employers to choose between violating their sincerely held religious beliefs (by providing insurance coverage for life-ending drugs and devices) or facing stiff government penalties.

[45] *See* discussion in 77 Fed. Reg. 1605-16507.

CONCLUSION

The decision of the lower court should be reversed.

Respectfully submitted,

/s/ Mailee R. Smith
Mailee R. Smith
Counsel of Record for Amici Curiae
Americans United for Life
655 15th St. NW, Suite 410
Washington, D.C. 20005
Telephone: 202-289-1478
Facsimile: 202-289-1473

Dated: November 13, 2012

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because:

   _X_ this brief contains **4,964** words excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because:

   _X_ this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in Times New Roman font, size 14.

/s/ Mailee R. Smith
Counsel of Record for *Amici Curiae*

Dated: November 13, 2012

CERTIFICATE OF VIRUS SCAN

I hereby certify that this brief has been scanned for viruses, and it is virus-free.

/s/ Mailee R. Smith
Counsel of Record for *Amici Curiae*

Dated: November 13, 2012

CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2012, I electronically filed the foregoing *Amicus Curiae* Brief with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit through the CM/ECF system, by emailing a true and correct copy of said brief to the case manager per her instructions. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system as well as by email.

/s/ Mailee R. Smith
Counsel of Record for *Amici Curiae*