No. 10-2347

IN THE

United States Court of Appeals

FOR THE FOURTH CIRCUIT

LIBERTY UNIVERSITY, INCORPORATED, a Virginia Nonprofit Corporation; MICHELE G WADDELL; JOANNE V. MERRILL

Plaintiffs-Appellants

v.

TIMOTHY GEITHNER, Secretary of the Treasury of the United States, in his official capacity; KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services, in her official capacity; HILDA L. SOLIS, Secretary of the United States Department of Labor; ERIC H. HOLDER, JR., Attorney General of the United States, in his official capacity

Defendants-Appellees.

On Appeal from the U.S. District Court for the Western District of Virginia;
On Remand from the
Supreme Court of the United States, No. 11-438

BRIEF OF 281 MEMBERS OF LEGATUS, AND CATHOLIC MEDICAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

In accordance with Rule 26.1 of the Federal Rules of Appellate Procedure, *Amici* make the following disclosures:

281 Members of Legatus file in their individual capacity. With over 70 chapters across the United States, Legatus is an organization of Catholic business leaders. *Amici* Legatus members joining this brief are CEOs, Presidents, Managing Partners, Business Owners, and spouses who participate as separate members. Because they file in their individual capacity, they do not herein represent any publicly held corporation or entity.

Catholic Medical Association is a nonprofit organization organized under Section 501(c)(3) of the Internal Revenue Code. It is not a publically held corporation, it has no parent corporations, and no publicly held corporations hold 10 percent or more of their stock.

DATED: March 6, 2013

/s/ *Dorinda C. Bordlee*____

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Constitutional Provisions

Cases

Statutes

Regulations

Other Authorities

ella Labeling Information (Aug. 13, 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (last visited March 5, 2013) 28

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 March 5, 2013) 28

Evangelium Vitae, 73 (1995) 1

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 March 5, 2013)…….. . . . 26

Christopher 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 Mar. 5, 2013) 24

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

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 (2011) 27

HHS Mandate Information Central, The Becket Fund for Religious Liberty, http://www.becketfund.org/hhsinformationcentral/ (last visited Mar. 5, 2013) 18

Ernest Istook, *The Real Status Quo on Abortion and Federal Insurance*, The Heritage Foundation (November 11, 2009), *available at* http://blog.heritage.org/2009/11/11/the-real-status-quo-on-abortion-and-federal-insurance/ (last visited May 5, 2011) 10

Ralph P. Miech, *Immunopharmacology of Ulipristal as an Eme2rgency Contraceptive*, 3 INT'L J. WOMEN'S HEALTH 391–397 (2011) 29

STATEMENT OF IDENTITY, INTEREST, AND AUTHORITY TO FILE[1]

Amici curiae are Catholic business executives and medical professionals who each have a moral duty[2] to oppose the egregious violations of conscience and free exercise rights imposed by the abortion-related mandates of the Affordable Care Act.[3]

281 Members of Legatus, whose names are listed in the Appendix, file in their individual capacity. With over 70 chapters across the United States, Legatus is an organization of Catholic business leaders. *Amici* Legatus members joining this brief are CEOs, Presidents, Managing Partners, Business Owners, and spouses who participate as separate members. *Amici* Legatus members present a closer look at the surgical "Abortion Premium Mandate" that applies in *certain* Exchange

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[1] Pursuant to Cir. Rule 29, counsel certifies that all parties have consented to the filing of this brief, and further certifies that no counsel for any party authored this brief in whole or in part, nor made a monetary contribution intended to fund the preparation or submission of the brief.

[2] As practicing Catholics, *Amici* assent to the teaching of Blessed Pope John Paul II: "Abortion [is a] crime[] which no human law can claim to legitimize. There is no obligation in conscience to obey such laws; instead there is a grave and clear obligation to oppose them by conscientious objection." *Evangelium Vitae*, 73 (1995).

[3] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), *as amended by* the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010)(hereinafter "ACA").

plans; and, more importantly, *Amici* bring this Court's attention to the fact that the HHS Preventive Mandate applies to *all* group and *individual* health plans, thus making it impossible for *Amici* or Plaintiffs to find *any* health plan, whether from their employer or in the individual market, that does not include drugs and devices capable of terminating the life of a human being at the embryonic stage of development. Once bootstrapped into the individual mandate with its "minimum essential coverages requirement," *Amici* will be unable to comply with their consciences without undergoing the substantial burden of placing themselves in the ranks of the uninsured *and* paying the individual mandate tax of 26 U.S.C. § 5000A.

Catholic Medical Association ("CMA") seeks to assist the Court by presenting the pharmacology of certain abortifacient drugs included in the HHS Preventive Mandate. CMA is a nonprofit national organization founded in 1932 to assist Catholic physicians in upholding and witnessing to the principles of their faith in the science and the practice of medicine. Comprised of over 1,500 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 public health and rights of conscience issues, through its annual conferences and quarterly journal, *The Linacre Quarterly*. CMA supports Catholic hospitals in faithfully applying Catholic moral principles in health care delivery.

SUMMARY OF THE ARGUMENT

Like a Russian nesting doll, the individual mandate provision of 26 U.S.C. § 5000A has nestled within it two abortion-related mandates: one mandate relates to surgical abortion premiums that are inescapable in *certain* Exchange health plans; and the other relates to abortifacient drugs and devices imposed as essential "preventive" benefits in *all* health plans, both group *and individual*, each without an exemption for individuals with religious objections.

This amicus brief more fully addresses the individual mandate tax as impacted and triggered by the inner workings of these two internal mandates. Each mandate is being implemented under the guidance of two sets of federal regulations that were finalized by the Department of Health and Human Services (HHS) after this Court's prior consideration of the pending matter, and even after final briefing was submitted to the U.S. Supreme Court by the parties in the case of *United States Dep't. of Health and Human Services v. State of Florida*, decided *sub nom. NFIB v. Sebelius*, 132 S.Ct. 2566 (2012) (No. 11-398).

The "Abortion Premium Mandate" regulations issued on March 27, 2012 implement Section 1303 of the ACA.[4] These regulations would burden the free exercise rights of *Amici* and millions of pro-life Americans who find themselves in

[4] *Segregation of funds for abortion services*, 45 C.F.R. § 156.280, 77 Fed. Reg 18472 (March 27, 2012)(implementing ACA, Section 1303 as codified at 42 U.S.C. § 18023)(hereinafter "Abortion Premium Mandate").

Exchange plans that cover elective abortion after January 1, 2014. Pro-life individuals may find themselves in such a plan because it was the choice of their employer, or because they were entrapped via the "secrecy clause" that effectively instructs issuers to conceal abortion coverage and abortion premiums when advertising in the Exchanges. 45 CFR § 156.280(f). With no ability to decline the abortion coverage, each enrollee is mandated to make "a separate payment" *from their own personal funds or payroll deduction* directly into an allocation account to be "used exclusively to pay for" other people's elective surgical abortion. 45 CFR § 156.280(e). This abortion premium mandate applies "without regard to the enrollee's age, sex, or family status," and with no exemption for enrollees who consider the practice and direct funding of surgical abortion to be a grave moral evil.

While the the "Abortion Premium Mandate" applies only to enrollees in *certain* Exchange plans, the equally immoral abortifacient drugs imposed as a "minimum essential coverage" by the "HHS Preventive Mandate" regulations[5] apply to *all* health plans, both group *and individual*, including plans that do not cover elective abortion.

[5] *Certain Preventive Services under the Affordable Care Act*, 77 Fed. Reg. 8725 (February 15, 2012)(hereinafter "HHS Preventive Mandate"). This mandate applies not only to plans purchased in the subsidized Exchanges, but also to all group and individual plans by virtue of the mandate being on all "issuers." *Id.*

In Section I (B), *Amici* bring this Court's attention to the lesser known, but determinative provision showing that the coercive HHS Preventive Mandate is applicable not only to group health plans (via the employer mandate), but also to every *individual* health plan purchased pursuant to the individual mandate. *See* 77 Fed. Reg. 8725 ("requires that non-grandfathered group health plans and health insurance issuers offering group **or individual health insurance coverage** provide benefits for certain preventive health services without imposition of cost sharing . . . .that include . . . . '[a]ll FDA approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity. . . .'")(emphasis added).

The HHS Preventive Mandate thus twists the individual mandate tax into a weapon that inflicts a crisis of conscience not only on *Amici* and Plaintiffs, but on every American who objects to collaborating in the payment and no-cost provision of abortifacient drugs (even to their minor dependents who have reached "reproductive capacity").

Section II demonstrates that *Amici's* religious objections to the abortifacient capabilities of the mandated "emergency contraceptives" are reinforced by science. This Section sets forth the uncontroverted evidence that the life of a unique human individual begins at fertilization, not implantation. It then presents a brief survey on the pharmacology of two of the many abortifacient drugs included in the HHS

Preventive Mandate, Plan B and *ella*, which are capable of terminating the life of a human being at the embryonic stage of development by either preventing implanation, or by causing an already implanted human embryo to lose sustenenance from the uterine lining.

The bottom line in light of the law and the science is that it will be impossible for *Amici* and Plaintiffs to avoid the individual mandate tax of § 5000A. The internal mandates operate such that all qualified health plans, both group and individual, will cover either surgical abortion or abortifacient drugs, or both, with no exception for individuals like *Amici* whose religious beliefs prohibit their collaboration with either of these grave moral evils.

The Affordable Care Act thus coerces *Amici* and the individual Plaintiffs to either violate their conscience with the purchase of morally unacceptable qualified health plans, or place themselves in the ranks of the uninsured. Because the conscience protecting option of dropping all coverage subjects *Amici* and the individual Plaintiffs to the individual mandate tax imposed via 26 U.S.C. § 5000A, it is – in effect – an unconstitutional tax on pro-life conscience.[6]

[6] Legatus members undertake a mission "to study, live and spread the Catholic faith in their business, professional and personal lives." While this brief addresses objections to abortion and abortifacient drugs, *Amici* note that the inclusion of surgical sterilization and contraceptive drugs and devices are also in conflict with Catholic teaching. *See Catechism of the Catholic Church*, ¶¶ 2366-2372.

ARGUMENT

I. The Individual Mandate's Shared Responsibility Payment, 26 U.S.C. § 5000A, Operates as An Unconstitutional Tax on Pro-Life Conscience

In light of the Supreme Court's remand in this case, this Court has requested new briefing on, *inter alia,* the question of "whether and how any developments since the previous briefing in this case may affect the constitutionality of the individual mandate, 26 U.S.C. § 5000A, and the employer mandate under the Free Exercise, Establishment, and Equal Protection Clauses." Supp. Briefing Order (Jan. 17, 2013).

This Section sets forth the mechanics of two abortion-related mandates within the individual mandate's "[r]equirement to maintain minium essential coverage," 26 U.S.C. § 5000A(a). The lack of applicable conscience exemptions in each render the shared responsibility "tax" an unconstitutional violation of free exercise rights.[7]

A sharply divided decision of the U.S. Supreme Court determined last summer that "Congress had the power to impose the exaction in § 5000A under the taxing power," *NFIB v. Sebelius*, 132 S.Ct. at 2598. However, subsequently

[7] *Amici* adopt Plaintiffs' Free Exercise and Religious Freedom and Restoration Act (RFRA) analysis, as set forth in their supplemental brief, and respectfully submit this brief to provide this Court with a closer look at the underlying mandate provisions and the applicable science that reinforces Plaintiffs' religious objections.

finalized mandates that trigger imposition of that tax must still comport with the religious liberty protections of the First Amendment. U.S. CONST. AMEND. I, § 1. As Justice Ginsburg cautioned in *NFIB v. Sebelius*, "[a] mandate to purchase a particular product would be unconstitutional if, for example, the edict impermissibly. . .interfered with the free exercise of religion." 132 S.Ct. at 2624 (Ginsburg, J., concurring in part).

Section I (A) sets forth the inner workings of the Abortion Premium Mandate imposed on pro-life enrollees who find themselves trapped (via their employer plan or perhaps unwittingly due to its "secrecy clause") in subsidized Exchange plans that cover elective abortion, [8] pursuant to Section 1303 of the Affordable Care Act and the implementing federal regulations finalized on March 27, 2012.

Section I (B) emphasizes that the HHS Preventive Services Mandate, as finalized on February 15, 2012, is imposed not only on employer group plans, but also on all *individual* health plans, with no exception for individual religious

[8] The phrase "elective abortion" is used in this brief to refer to abortions that have long been ineligible for federal funding in major health programs under the Hyde Amendment – specifically, all abortions except for cases of rape, incest or danger to the life of the mother. *See, e.g.,* USCCB, Backgrounder: The New Federal Regulation on Coerced Abortion Payments, 2, fn. 3 (April 11, 2012), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Backgrounder-The-New-Federal Regulation-on-Coerced-Abortion-Payments.pdf (last visited March 5, 2013).

objectors to decline coverage for drugs capable of terminating the life of a human being at the embryonic stage of development.

If the individual mandate survives this challenge and goes into effect on January 1, 2014, Plaintiffs Waddell and Merrill and other individuals in the subsidized Exchanges who, like *Amici* Legatus members, respect the sanctity of human life from the moment of conception, will be faced with a Hobson's choice: Either (1) comply with the individual mandate and purchase a federally qualified health plan that profoundly violates their religious beliefs, or (2) act in accord with their religious beliefs by placing themselves in the ranks of the uninsured since they will be unable to find any insurance not subject to the HHS Preventive Mandate, either group or individual. In addition to the burden of being uninsured, Option 2 violates free exercise rights because it subjects the individual plaintiffs to the "tax" penalty of § 5000A.[9]

[9] Option 2 also subjects Plaintiff Liberty University as an employer to the devastating penalties of the ACA's employer mandate, as set forth in Plaintiffs' supplemental brief.

A. The ACA Accounting Scheme Designed to Avoid Federal Funding of Abortion Imposes an Unconstitutional "Abortion Premium Mandate" That Compels Religious Objectors in Certain Plans To Pay a Designated Elective Abortion Premium From Their Own Pocket.

This section attempts to clear the fog surrounding the inner workings and unconstitutional impact of the Abortion Premium Mandate that originated in Section 1303 of the Affordable Care Act, as codified at 42 U.S.C. § 18023, and then subsequently implemented in regulations governing Exchanges that were finalized on March 27, 2012, *Segregation of funds for abortion services, supra* note 4 (Collectively referred to as "Section 1303" or the "Abortion Premium Mandate").

The accounting scheme laid out in the provisions of Section 1303 was devised to overcome the political hurdle of "taxpayer subsidized abortion." This became necessary because the ACA allowed health plans to provide elective abortion coverage within the government subsidized Exchanges, contrary to former federal policy.[10]

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[10] The ACA breaks with the consistent federal policy since 1996 of prohibiting coverage for elective abortion in subsidized plans offered through the Federal Employees Health Benefits Plan, military insurance through TRICARE, or Indian Health Services. Ernest Istook, *The Real Status Quo on Abortion and Federal Insurance*, The Heritage Foundation (November 11, 2009), *available at* http://blog.heritage.org/2009/11/11/the-real-status-quo-on-abortion-and-federal-insurance/ (last visited Feb. 21, 2013).

Section 1303 became known as the "Nelson Compromise" because it arose out of an attempt by Senator Ben Nelson, a pro-life Democrat, to find language that would "make it clear that [the healthcare bill] does not fund abortion with

1. How the Abortion Premium Mandate Operates.

Section 1303, as challenged by Plaintiffs, was described by the district court below:

> In plans that do provide non-excepted [elective] abortion[11] coverage, a separate payment for non-excepted [elective] abortion services must be made by the policyholder to the insurer, and the insurer must deposit those payments in a separate allocation account that consists solely of those payments; the insurer must use only the amounts in that account to pay for non-excepted [elective] abortion services. ACA, § 1303(b)(2)(B), (C). Insurers are prohibited from using funds attributable to premium tax credits or [federal] cost-sharing reductions … to pay for non-excepted [elective] abortion services. ACA § 1303(b)(2)(A).

Liberty University v. Geithner, 753 F. Supp. 2d 611, 643 (W.D. Va. 2010).

In denying Liberty University's free exercise claims, the district court seemed to focus on the *policy* issue of "taxpayer funded abortion," rather than on the *constitutional* issue of how the Act mandates elective abortion premiums from enrollee's private dollars. The district court properly noted that Section 1303 does indeed avoid (at least superficially) the direct *taxpayer* subsidy of elective abortions in subsidized plans purchased in the Exchange. However, the court's

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government money." *Abortion Haggling Looms Over Health Care Debate in Senate* (Nov. 10, 2009), available at http://www.foxnews.com/politics/2009/11/10/abortion-haggling-looms-health-care-debate-senate/ (last visited March 5, 2013).

[11] The court used the ACA phrase "non-excepted" to describe elective abortions (all abortions other than those in cases of rape, incest or life of the mother). ACA, §1303(b)(1)(B).

decision failed to note that it does so by mandating a *personal* payment into an elective abortion fund in violation of free exercise rights.

With the finalization of the implementing regulations that mirror Section 1303, each enrollee in Exchange plans that happen to include abortion coverage is mandated to make "a separate payment" *from their own personal funds or payroll deduction* directly into an allocation account to be "used exclusively to pay for" other people's elective surgical abortion. 45 CFR § 156.280(e) (implementing ACA, Section 1303(b)(2)(B) as codified at 42 U.S.C. § 18023). This abortion premium mandate applies "without regard to the enrollee's age, sex, or family status," 45 CFR § 156.280(e)(2)(i), and with no exemption for enrollees who consider the practice and direct funding of surgical abortion to be a grave moral evil. *See* note 14, *infra.*

While the district court's decision missed the import of mandated surgical abortion premiums in certain Exchange plans, it also could not have foreseen the finalization of the HHS "preventive services" regulations, which mandate abortifacient drugs and devices in every single group and individual plan, as set forth in Section I (B).

2. How the "Secrecy Clause" Creates Religious Liberty Landmines

If the individual mandate provision goes into effect on January 1, 2014, pro-life Americans such as *Amici* and the individual Plaintiffs may find themselves subject to the Abortion Premium Mandate because (1) the abortion inclusive plan was the choice of their small employer who purchased a subsidized group plan in the Exchange,[12] or (2) if they become entrapped via the "secrecy clause" that effectively instructs issuers to conceal abortion coverage and abortion premiums when advertising in the Exchanges (and even to conceal the break out of the separate abortion premium in the summary of benefits provided at enrollment). 45 CFR § 156.280(f). [13]

Given the profound religious freedom issues that arise from the ACA's inclusion of plans that cover elective surgical abortion, the burden should be on the government to clearly warn consumers who respect the sanctity of human life to avoid certain Exchange plans that will subject them to the Abortion Premium Mandate. But, quite to the contrary, the ACA and its implementing regulations

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[12] Small Business Health Care Tax Credit for Small Employers, Internal Revenue Service (Sept. 26, 2012), *available at* http://www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-for-Small-Employers (last visited March 5, 2013).

[13] For a two-page review of the regulations' abortion mandate and secrecy clause, *see* USCCB, Backgrounder: The New Federal Regulation on Coerced Abortion Payments (April 11, 2012), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Backgrounder-The-New-Federal Regulation-on-Coerced-Abortion-Payments.pdf. (last visited Mar. 5, 2013).

effectively instruct the issuers to *conceal* elective abortion coverage and the separate abortion premium. The provision in section (f)(1) of 45 CFR § 156.280 provides that notice about a plan's inclusion of elective abortion coverage be disclosed *not* in Exchange advertising, but rather "*only*. . . at the time of enrollment." Further, section (f)(2) prohibits issuers from disclosing the separate elective abortion premium in Exchange advertisements, and even in the summary of benefits provided at enrollment. Rather, it requires that the issuer must provide notice "only with respect to *the total amount of the combined payments*" of regular premiums and the abortion premium. The "secrecy clause" reads as follows:

> (f) *Rules relating to notice*.
>
> (1) *Notice*. A QHP [qualified health plan] that provides for coverage of services in paragraph (d)(1) of this section [elective abortion] , must provide a notice to enrollees, **only** as part of the summary of benefits and coverage explanation, **at the time of enrollment**, of such coverage.
>
> (2) *Rules relating to payments*. The notice described in subparagraph (f)(1) of this section, any advertising used by the QHP issuer with respect to the QHP, any information provided by the Exchange, and any other information specified by HHS must provide information **only with respect to the total amount of the combined payments** for services described in paragraph (d)(1) of this section [elective abortion] and other services covered by the QHP.

45 C.F.R. § 156.280(f), 77 Fed. Reg 18472-73 (emphasis added).

3. How the Mandates Are Not Laws of General Applicability.

The severe religious liberty burdens imposed by the Abortion Premium Mandate subject it to strict scrutiny because neither Section 1303 nor the individual mandate within which it is nestled is generally applicable.

First, as noted in Plaintiffs' supplemental brief, the lack of general applicability of the overarching individual mandate provision, § 5000A, is evidenced by its plethora of waivers and exemptions, in addition to a very limited religious exemption.[14] Furthermore, the Abortion Premium Mandate regulations are not generally applicable because they apply only to enrollees in subsidized Exchange plans that cover elective abortion.[15] It does not apply to enrollees who purchase individual or group plans that include abortion coverage outside the

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[14] The only religious exemption found in the entire ACA is in Section 1501, which exempts groups such as the Amish who have religious objections to insurance as a whole. Section 1501 of the Act provides that the individual mandate does not apply to members of a "recognized religious sect or division" with "established tenets or teachings" that bar the "acceptance of benefits of any private or public insurance". By favoring the religious liberty of the Amish only, combined with the waivers and exemptions that release millions of people from the requirements of the individual mandate, it can hardly be said to be a law of general applicability. *See, e.g., Employment Division v. Smith*, 494 U.S. 872 (1990).

[15] The *Segregation of funds for abortion services* regulations, 45 C.F.R. 156.280, comprise a small section within the over 600 pages of regulations entitled, "Establishment of Exchanges and Qualified Health Plan" 45 C.F.R. Parts 155, 156, 157 (March 27, 2012).

Exchanges,[16] nor to enrollees who purchase from Exchanges that are prohibited from offering plans with elective abortion pursuant to state opt-out laws.[17]

4. How the Mandates Fail Strict Scrutiny.

This lack of general applicability requires the strict scrutiny analysis presented in Plaintiffs' supplemental brief, a standard that the mandates cannot meet. Our nation's history and tradition is grounded in the first freedom of religious exercise and respect for the rights of conscience, such that the Supreme Court has decades ago determined that the federal government has no compelling interest that would justify tax-payer subsidized elective abortion, much less a government mandate coercing private citizens to *personally* subsidize of elective

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[16] Abortion Premium Mandate regulations apply only to enrollees in subsidized abortion covering Exchange plans, but not to enrollees in non-subsidized abortion covering plans. Thus, individuals who don't qualify for the Exchange subsidies would be able to choose any plan outside the Exchanges that best fits their health needs or preferred doctor network. Even if the issuer of that preferable plan had chosen to include elective abortion coverage, the ACA would not prohibit enrollees from opting to decline abortion coverage and related premiums altogether.

[17] Under 42 U.S.C. § 8023(a)(1), a "State may elect to prohibit abortion coverage in qualified health plans offered through an Exchange in such State." As of October 2012, seventeen states had enacted "abortion opt-out" laws: **Alabama, Arizona, Florida, Idaho, Indiana, Kansas (in litigation), Louisiana, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Oklahoma, Tennessee, Utah, Virginia, and Wisconsin**.

See National Conference of State Legislatures, *Health Reform and Abortion Coverage in the Insurance Exchanges* (Nov. 2011), *available at* http://www.ncsl.org/default.aspx?tabid=21099 (last visited March 5, 2013).

abortion. *See Harris v. McRae,* 448 U.S. 297 (1980)(upholding the Hyde Amendment policy of protecting the conscience rights of taxpayers who object to tax subsidized elective abortion.)

B. Enrollees Who Select Plans not Subject to the Abortion Premium Mandate Are Nonetheless Subject to the HHS "Preventive Services" Mandate, Without the Ability to Decline Coverage for Drugs and Devices Capable of Terminating the Life of a Human Being at the Embryonic Stage of Development.

The surgical-abortion free plan required by ACA, § 1334(a)(6) does not provide relief from the burden of Section 1303 because the HHS Preventive Mandate discussed below puts abortion-inducing drugs into every single qualified health plan, both group and individual. In short, there is no escape for *Amici* or any individual or employer who respects the sanctity of life, because the ACA and its mandates coercively impose surgical abortion premiums or abortifacient drugs, or both, without a religious exemption that would apply to *Amici*.[18]

This subsection brings this Court's attention to the determinative, but lesser known, provision showing that the HHS Preventive Mandate applies not only to all

[18] The HHS Preventive Mandate contains absolutely no "accommodation" for individuals who object to the mandated drugs and devices. Further, *Amici* are also not eligible for the limited religious exemptions provided for in the individual mandate set forth in ACA Section 1501 (codified at I.R.C. 5000A).

employer group plans (resulting in nearly 50 legal challenges across the nation),[19] but also to all ***individual*** health insurance plans:

> non-grandfathered group health plans and **health insurance issuers offering** group **or individual health insurance coverage** [shall] provide benefits for certain preventive health services without imposition of cost sharing . . . .that include . . . . '[a]ll FDA approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity. . . .

77 Fed. Reg. 8725(emphasis added)(implementing 42 U.S.C. § 300gg-13(a)).[20]

As discussed in more detail below, FDA-approved "contraceptives" include drugs that are capable of terminating the life of a human being at the embryonic stage of development. The mandatory inclusion of these immoral drugs and devices as an essential "preventive" benefit requires no-cost (and thus incentivized) access not only to adult enrollees, but also to their dependent minor daughters.[21] The HHS Preventive Mandate thus twists the individual mandate tax into a weapon that inflicts a crisis of conscience on *Amici* and their moral rights

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[19] *See HHS Mandate Information Central*, The Becket Fund for Religious Liberty, http://www.becketfund.org/hhsinformationcentral/ (last visited March 5, 2013).

[20] The HHS Preventive Mandate as applied to employers by virtue of the employer mandate is discussed in Plaintiffs' supplemental brief.

[21] Because sterilization, contraception, and abortifacient drugs must be provided "without cost-sharing" for enrollees *and dependents* who are 'women with reproductive capacity," 77 Fed. Reg 8725 (quoting HRSA Guidelines)), the HHS Preventive Mandates provides free access even to *Amici*'s minor daughters, thus undermining the Catholic moral duty of a parent to guide their children concerning the right ordering of human sexuality. *See supra* note 6.

and responsibilities toward their children, and also on every American who objects based on their respect for the sanctity of human life from the moment of conception.

II. Scientific Evidence Reinforces the Religious Objections of *Amici* and Plaintiffs to the Abortifacient Capability of the "Emergency Contraceptives" Required by the HHS Preventive Mandate.

As Catholics, *Amici* believe that all human beings have inherent moral value. Science aids them in determining what beings are human, and therefore worthy of protection. The science of human embryology establishes that an individual human being comes into existence at the moment of sperm-egg fusion. Thus, any action, whether chemical or mechanical that harms a human being from the one-celled stage onward is a grave moral evil.

Thus, Amici ascribe the same inherent moral value to pre-implantation human beings (whose lives may be ended by abortifacient drugs) as they do to human beings at later stages of fetal development (who lives might be ended by surgical or drug-induced abortion).

Supreme Court jurisprudence is replete with the understanding that "there are common and respectable reasons for opposing abortion," *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993), because it carries "profound moral and spiritual implications." *Planned Parenthood v. Casey*, 505 U.S. 833, 850 (1992). In fact, the Supreme Court has acknowledged that "[m]illions of

Americans **believe that life begins at conception** and consequently that an abortion is akin to causing the death of an innocent child." *Stenberg v. Carhart*, 530 U.S. 914, 920 (2000)(emphasis added).

This Section presents the reasonable and scientifically supportable basis of the *Amici*'s religious objections to purchasing health plans that must include drugs that have the capacity of terminating human life either before or after implantation. While the HHS Preventive Mandate covers many abortifacient drugs and devices, this brief presents information on only two: namely, the so-called "emergency contraceptive" drugs known as Plan B and *ella*.

The first subsection presents a concise survey of the relevant human embryology establishing that the biological life of the human embryo begins at fertilization, not implantation. This is followed by the second subsection's review of the medical literature, FDA directives, and FDA-approved labeling establishing the mechanisms of action that make Plan B and *ella* capable of ending the life of a human being at the embryonic stage of life, whether before or after uterine implantation.[22]

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[22] In addition to scientists and developmental biologists, other prominent scholars have recognized that a human embryo is indeed a *human being*:

> The embryo is a being; that is to say, it is an integral whole with actual existence. The being is human; it will not articulate itself into some other kind of animal. Any *being* that is *human* is a human being. If it is objected that, at five days or fifteen days,

A. Modern Embryology establishes that the life of a new human individual begins at fertilization, and that implantation is simply a later but necessary stage to continue human pregnancy.

To clearly understand the basis of the *Amici*'s conscientious objection to being morally complicit with the objectionable drugs in any way, it is necessary to distinguish "fertilization" (which marks the beginning of an individual human life) from "implantation" (which is often considered to mark the beginning of a woman's state of pregnancy).

1. Fertilization

As stated in one of the most definitive texts used in United States medical schools on the subject of clinical embryology:

> **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**.[23]

> the embryo does not look like a human being, it must be pointed out that this is precisely what a human being looks like – and what each of us looked like – at five or fifteen days of development. Clarity of language is essential to clarity of thought.

Ramsey Colloquium, *The Inhuman Use of Human Beings: A Statement on Embryo Research*, 49 FIRST THINGS 17, 18 (1995), *available at* http://www.firstthings.com/article/2008/08/001-the-inhuman-use-of-human-beings-23 (last visited Nov. 18, 2012).

[23] Keith L. Moore and T.V.N. Persuad, THE DEVELOPING HUMAN: CLINICALLY ORIENTED EMBRYOLOGY 16 (7th ed. 2003)(emphasis added); *see also*, Maureen L. Condic, Ph.D., *When Does Human Life Begin? A Scientific Perspective* ix (October 2008), *available at* http://www.bdfund.org/whitepapers (last checked November 8, 2012). ("Based on universally accepted scientific criteria," every human begins his

The established medical fact that "a unique individual" begins his or her life "at fertilization" is the factual predicate of the *Amici* and Plaintiffs' religious objection to plans including drugs and devices that have the capacity to halt the natural processes involved in the ongoing nourishment and development of the newly formed human embryo.

It is notable that just this past year, a federal district court expressly relied on an expert declaration to find that a required informed consent for abortion statement was based on embryology, and not "ideology":

> Plaintiffs argue that classifying the fertilized egg and subsequent organism as a "human physical life" is an ideological statement that goes to the heart of the abortion debate and is thus impermissible compelled speech. The Commissioner disagrees, framing the statement as a biological truth conveying the fact that post-fertilization, the existing living organism is indeed a "human physical life." The Commissioner has some support for its position. Specifically, Maureen L. Condic, Ph.D, a Professor of Neurobiology and Anatomy at the University Of Utah School Of Medicine whose primary research focus has been the development and regeneration of the nervous system, testified as follows:
>
> > The unique behavior and molecular composition of embryos, from their initiation at sperm-egg fusion onward, can be readily observed and manipulated in the laboratory using the scientific method. Thus, the conclusion that a human zygote is a human being (i.e. a human organism) is **not a matter of religious belief, societal convention or**

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or her life "as a new cell, the human zygote, which comes into existence at the moment of sperm-egg fusion, an event that occurs in less than a second").

emotional reaction. It is a matter of observable, objective, scientific fact.[24]

2. Implantation

The human embryo begins the self-directed process of attaching to the uterine lining approximately five to six days after the new human being has come into existence.[25] Uterine implantation is necessary for the human embryo's continued development because it provides nourishment from surrounding maternal tissues. Thus, if a human embryo is unable to attach to the uterus due to the mechanism of the objectionable drugs, the human embryo, now one week old, will not have the environment to continue its nourishment and growth.[26]

B. Plan B and *ella* have the capacity to end the life of a human being at the embryonic stage of development in the event fertilization has occurred.

Embryology establishes that the life of a unique human being begins at fertilization, not implantation. Therefore, Plaintiffs and Amici properly conclude

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[24] *Planned Parenthood of Ind. v. Comm'r*, 794 F. Supp.2d 892, 916–17 (S.D. Ind. 2011) (emphasis added).

[25] *See,* Moore and Persaud, *supra* note 23, at 37.

[26] Just as a newly born human infant left alone in an environment without human milk or formula is no less human, neither is a human embryo any less human when a drug interferes with the embryo's nourishment that can only be received in the environment of uterine implantation.

that drugs and devices with post-fertilization mechanisms of action are life-ending, i.e., abortifacient. Although these drugs or devices have the capacity to end a developing, distinct human being's life either before or after uterine implantation, they are labeled by the FDA as "contraception" (a term that connotes simply preventing fertilization or conception) because the FDA's relevant criterion is whether they can work by preventing "pregnancy," which they define as beginning at "implantation," not fertilization.[27]

Moreover, as will be discussed below, with the approval of the drug *ella* in 2010, the FDA definition of "contraception" now encompasses a drug or device that can end the life of a human embryo even *after* implantation.

In his 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. . . ."[28] In other words, Dr. Trussell, although an

[27] For an overview of how the definition of pregnancy has changed, *see* Christopher 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).

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

advocate of "emergency contraception,"[29] 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.[30]

Moreover, a new drug classified by the FDA as "emergency contraception"—Ulipristal Acetate (*ella*)—meets even the Secretary's definition of an abortion-inducing drug because it can cause the death of a human embryo *after* implantation (similar to the well known abortion drug RU-486). The mechanisms of action of each common type of "emergency contraception" are discussed in more detail below.

1. Plan B can end the life of a human embryo by preventing implantation.

In 1999, the FDA first approved the distribution of "emergency

[29] See Profile of Dr. James Trussell, *available at* https://www.princeton.edu/~trussell/ (last visited March 5, 2012).

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

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.[31] Although called "contraception," the FDA's labeling acknowledges that Plan B can prevent implantation of a human embryo.[32] 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).**[33]

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**

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[31] 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 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.

[32] Plan B Approved Labeling, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021045s015lbl.pdf (last visited March 5, 2013).

[33] 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 March 5, 2013) (emphasis added).

may inhibit implantation."[34]

2. *Ella* can end the life of a human embryo by preventing implantation or by causing an implanted human embryo to lose sustenance from the uterine lining.

In 2010, the FDA approved the drug Ulipristal Acetate (*ella*) as another "emergency contraceptive." Importantly, *ella* is not a variant 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."[35] 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 prohibit a human embryo from implanting in the uterus, or it can abort a human embryo that has already implanted in the uterine lining. Therefore, *ella* has the capacity to abort a pregnancy even under a definition that limits

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[34] 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 March 5, 2013) (emphasis added).

[35] 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, 115–19 (2011).

abortion to the time after the embryo implants in the uterus.[36]

Studies confirm that *ella* is toxic to a human embryo.[37] The FDA's own labeling notes that *ella* may "affect implantation,"[38] and advises against the 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."[39] While the study theorizes that the dosage used in its trial "might be too low to inhibit implantation,"[40] it states affirmatively "an additional postovulatory mechanism of

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[36] *See* Gacek, *Conceiving Pregnancy*, *supra* note 27.

[37] 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 March 5, 2013).

[38] *ella* Labeling Information (Aug. 13, 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (last visited March 5, 2013).

[39] Glasier et al, *Ulipristal acetate versus levongestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis*, 375 THE LANCET 555, 555–62 (2010).

[40] *Id*. 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." *Id.* 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. *Id.* *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). *See id.* The only criterion for *ella*

action," e.g. impairing implantation, "cannot be excluded."[41]

And according to a commentary by a professor of molecular pharmacology in the *International Journal of Women's Health*, "[w]hen unprotected intercourse and the administration of ulipristal occur at or within 24 hours of ovulation, then ulipristal has an abortifacient action."[42]

In fact, *ella*'s deadliness is confirmed by its high rate of "effectiveness." Notably, at the FDA advisory panel meeting for *ella*, panelist Dr. Scott Emerson, a professor of biostatistics at the University of Washington, 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.[43]

In short, the FDA-approved "contraceptive" *ella* is capable of ending an established pregnancy.

"working" was that a woman was not pregnant in the end. *See id.* Whether that was achieved through blocking implantation, or even ending implantation, was not determinable. *See id.*

[41] *Id.*

[42] Ralph P. Miech, *Immunopharmacology of Ulipristal as an Eme2rgency Contraceptive*, 3 INT'L J. WOMEN'S HEALTH 391–397 (2011).

[43] *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 March 5, 2013).

CONCLUSION

The individual mandate of 26 U.S.C. § 5000A and its internal mandates coercively impose an ideology that normalizes elective abortion and abortifacient drugs as "healthcare." *Amici* join Plaintiffs in the belief that the killing of vulnerable human beings at the beginning of their lives is far from healthcare; rather, it is a crime against the dignity of the human person and a grave moral evil.

Multiple mandates compel Plaintiffs and *Amici* to purchase health plans that inescapably include abortion and/or abortifacient drugs, with the only conscience-protecting option being to drop all health insurance *and* pay a tax for practicing their religious beliefs. The government has no legitimate power to compel such a choice. The First Amendment and RFRA do not sanction a tax on pro-life conscience.

Amici urge reversal.

Respectfully submitted this 6th day of March, 2013,

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1. This brief has been prepared using 14 point, proportionately spaced Times New Roman typeface in Microsoft Word: Mac 2011.

2. Exclusive of the corporate disclosure statement; table of contents; table of citations; and the certificate of service, the brief contains 6,916 words.

I understand that a material misrepresentation can result in the Court's striking the brief and imposing sanctions.

Dated: March 6, 2013

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I certify that on March 6, 2013, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all registered participants in the case will receive service by the CM/ECF system.

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Mary Ferguson
Great Falls, VA

Brian Fimian
Falls Church, VA

Keith Fimian
Oakton, VA

John Guevremont
Washington, VA

Rebecca Irving
Bristow, VA

Kathleen Kampa
Oak Hill, VA

Suzy Kelly
Chesapeake, VA

Stephen Moriarty
Great Falls, VA

Timothy O'Donnell
Front Royal, VA

Frank O'Reilly
Front Royal, VA

Nancy Tanner
Great Falls, VA

Mark Weber
Oakton, VA

Paul Wise
Oak Hill, VA

Washington

Ann Kelly
Seattle, WA

JTS Mullally
Seattle, WA

Jeff Thiede
Vancouver, WA

Frederic Weiss
Seattle, WA

Wisconsin

Robert Gunderson
Franklin, WI

Paul Hundt
Elm Grove, WI