No. 12-1380
IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

WILLIAM NEWLAND; PAUL NEWLAND; JAMES NEWLAND; CHRISTINE KETTERHAGEN; ANDREW NEWLAND; and HERCULES INDUSTRIES, INC., a Colorado Corporation,

Plaintiffs-Appellees,

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of the U.S. Department of Health and Human Services, *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Colorado
The Honorable Judge John L. Kane, Jr.
No. 1:12-cv-01123

BRIEF *AMICI CURIAE* OF BART STUPAK AND DEMOCRATS FOR LIFE OF AMERICA IN SUPPORT OF PLAINTIFFS/APPELLEES AND SUPPORTING AFFIRMANCE

Of Counsel Attorneys for Amici Curiae
Thomas C. Berg
University of St. Thomas School of Law*
MSL 400, 1000 LaSalle Ave.
Minneapolis, MN 55403
(651) 962-4918
tcberg@stthomas.edu

*Institutional affiliation for identification purposes only

Sandra Payne Hagood (admission pending)
7660 Fay Avenue, Suite H-526
La Jolla, CA 92037
(858) 245-5741
sandra@hagoodappellate.com

Counsel of Record
L. Martin Nussbaum
Michael Francisco
Rothgerber Johnson & Lyons LLP
90 S. Cascade Avenue, Suite 1100
Colorado Springs, CO 80903
(719)386-3000
mnussbaum@rothgerber.com
mfrancisco@rothgerber.com

STATEMENT OF AUTHORSHIP AND FUNDING

No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting this brief. No person other than *amici* or their counsel contributed money that was intended to fund preparing or submitting this brief.

CORPORATE DISCLOSURE STATEMENT

Democrats for Life of America (DFLA) has no parent corporation, and no publicly held corporation owns stock in DFLA.

STATEMENT OF CONSENT TO FILE

This brief is filed with the consent of all parties to the case.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

OTHER AUTHORITIES

IDENTITY AND INTEREST OF *AMICI CURIAE*

Former Congressman Bart Stupak (D-Michigan) served as an active member of the Congressional Pro-Life Caucus throughout his 18 year career (1993-2011), including his last six years as Co-Chair. The Pro-Life Caucus is composed of both Republican and Democratic Members of the U.S. House of Representatives. The principal tenet of Caucus Members is their belief that life begins at conception and that any man-made disturbance of the embryo is considered a form of abortion.

Democrats for Life of America (DFLA) is the preeminent national organization for pro-life Democrats. We believe that the protection of human life is the foundation of human rights, authentic freedom, and good government. These beliefs animate our opposition to abortion, euthanasia, capital punishment, embryonic stem cell research, poverty, genocide, and all other injustices that directly and indirectly threaten human life. As pro-life Democrats, we share the party's historic commitments to supporting women and children, strengthening families and communities, and striving to ensure the equality of opportunity, a reduction in poverty, and the existence of an effective social safety net that guarantees that all people have sufficient access to food, shelter, healthcare, and life's other basic necessities.

Both *amici* supported the Affordable Care Act (the ACA or the Act); Stupak was among the pro-life Democratic members of Congress who voted for it.

Throughout the process leading to the ACA's passage, *amici* offered means by which it could ensure comprehensive health-care coverage while respecting unborn life and the conscience of individuals and organizations opposed to abortion. The House approved a version of the bill with the Stupak-Pitts Amendment, which prohibited the use of federal funds "to pay for any abortion or to cover any part of the costs of any health plan that includes coverage of abortion." Roll No. 884, 155 Cong. Rec. H12962 (Nov. 7, 2009).

As the ACA passed in final form, Rep. Stupak helped negotiate an Executive Order by President Obama reinforcing that under the Act the Hyde Amendment's restriction on federal funding for abortions applied, and that "longstanding Federal laws to protect conscience . . . remain intact and new protections prohibit discrimination against health care facilities and health care providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions." Executive Order No. 13535, 75 Fed. Reg. 15599, Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act, 2010 WL 1169591 (Mar. 24, 2010). Likewise, Rep. Stupak's colloquy in the final House debate made clear that "current law [on abortion] should apply" under the ACA and that "the intent behind both the legislation and the Executive order is to maintain a ban on Federal funds being used for abortion services, as is provided in the Hyde amendment." 156 Cong. Rec. H1859, H1860 (Mar. 21,

2010) (statements of Reps. Stupak and Waxman). Thereafter, DFLA defended the Executive Order's validity and identified mechanisms for ensuring that the ACA and the Order would successfully restrict funding for abortion and impositions on conscience.

Amici therefore have a strong interest in ensuring that neither the ACA nor its implementation imposes on longstanding conscience rights of individuals and organizations. *Amici* strongly support the ACA's mandate to cover preventive services and its emphasis on health care for women. DFLA's members take varying positions on the mandate's inclusion of contraception among required preventive services. But all *amici* are committed to protecting the conscience rights of individuals and organizations—including those engaged in commerce—with objections to facilitating abortion.

SUMMARY OF ARGUMENT

The preliminary injunction in favor of plaintiffs should be affirmed, at least as to their challenges to medicines that they believe may act to terminate an embryo after fertilization.[1]

[1] This brief does not take a position on whether the preliminary injunction should be affirmed as to contraceptive methods that plaintiffs do not claim may act to terminate an embryo. However, we do believe, as to those methods, that the application of the mandate substantially burdens religious freedom and must satisfy the "compelling governmental interest" test of RFRA.

I. Multiple federal and state laws show that our nation's tradition of protecting conscience, including religious conscience, is at its strongest and broadest for individuals and organizations that object to facilitating abortions. Plaintiffs' complaint alleges that the mandate, as applied to emergency contraceptives that may cause abortions, violates several such provisions, including in the Affordable Care Act itself. But the widespread pattern of conscience protection for objectors to abortion also supports plaintiffs' claim under the Religious Freedom Restoration Act ("RFRA"), which served as the basis for the preliminary injunction. Three conclusions can be drawn from this pattern of conscience protection. First, although health-care conscience laws cover religious and moral objections to several procedures, objections to abortion carry especially strong weight in American law. They fall within our tradition of protecting objectors from participating in actions, including assisted suicide, abortion, capital punishment, and war, that the objectors believe unjustly take human life. Second, the right not to facilitate or support abortions protects a wide range of objectors, regularly extending to individuals engaged in for-profit commerce and to for-profit businesses. Finally, our tradition protects objectors to abortion far beyond the case of direct involvement in the performance of the abortion.

Plaintiffs' objection to covering emergency contraception falls within the tradition of broadly protecting conscientious objections to facilitating abortions.

Although the government claims that terminating an embryo before it implants in the uterus is not an abortion, the relevant matter for the claim of conscience under RFRA is *plaintiffs' belief* that a distinct human life begins at fertilization: it is no salve to their conscience to be told that the government defines abortion differently. There is a colorable reason to believe that emergency contraceptives may act to terminate embryos. And even applying the government's definition, there is evidence that Ella may terminate embryos after implantation.

II. The longstanding, pervasive tradition of broadly accommodating conscientious objections to facilitating abortions has two implications for this case. First, it supports plaintiffs' argument that the contraception mandate "substantially burdens" their religious exercise, triggering the government's duty under RFRA to demonstrate that this burden serves a "compelling governmental interest" and does so by the "least restrictive means." 42 U.S.C. § 2000bb-1(a), (b). The mandate requires plaintiffs to provide insurance coverage for procedures they believe are grave moral evils. The government's attempts to deny this burden must be rejected. The government says that for-profit corporations and their owner-operators cannot engage in religious exercise; it also says that an employer suffers only an insubstantial, "attenuated" burden from being forced to cover methods and procedures that employees choose for themselves whether or not to use. Both arguments are irreconcilable with our tradition of protecting health-care-related

conscience in the commercial sphere—in particular the strong tradition, under federal and state laws, of protecting objections to abortion. Protections for objections to facilitating abortion extend to multiple categories of for-profit entities and individuals engaged in commerce, and to many kinds of indirect facilitation, including mandatory coverage of abortion in insurance plans. When impositions are repeatedly prohibited under various conscience provisions, they cannot be dismissed as "insubstantial" burdens under RFRA.

At the very least, this Court should find that the mandate substantially burdens plaintiffs to the extent that it requires them to cover methods they colorably believe may act to terminate an embryo after fertilization. Again, it cannot be that impositions repeatedly prohibited under abortion-conscience provisions are only "insubstantial" burdens under RFRA.

Second, with respect to methods that plaintiffs claim here are abortifacients, plaintiffs are likely to succeed on the merits of their RFRA claim, because the government has not articulated arguments that would demonstrate a compelling interest in requiring coverage of such methods. The strong tradition of exempting objections to abortion—among other factors—undercuts the government's claim that it has a compelling interest in requiring coverage of possible abortifacients.

ARGUMENT

I. THIS CASE IMPLICATES THE NATION'S STRONG TRADITION OF BROADLY ACCOMMODATING OBJECTIONS TO FACILITATING ABORTION, INCLUDING OBJECTIONS BY ORGANIZATIONS AND INDIVIDUALS IN FOR-PROFIT SETTINGS.

A. Numerous Laws, Including the Affordable Care Act Itself, Reflect the Nation's Strong Tradition of Accommodating Conscientious Objections to Facilitating Abortions.

Our nation's tradition of protecting conscience is strongest, and broadest, for those who object to supporting abortions. Many federal and state laws protect such objections; provisions in three federal laws apply directly to this case, serving as grounds for relief in plaintiffs' complaint. See Compl. ¶¶ 166-168. The Hyde-Weldon Amendment, included each year since 2005 in continuing appropriations acts, prohibits federal funds for the HHS and Labor departments from being "made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, *provide coverage of*, or refer for abortions." Consolidated Appropriations Act, 2012, § 507(d)(1), Pub. L. No. 112-74, 125 Stat. 786 (112th Cong. 1st Sess. Dec. 23, 2011) (emphasis added). The protected entities include "health insurance plan[s]," as well as other commercial entities, including "a hospital, a provider-sponsored organization, [or] a health maintenance organization." *Id.* § 507(d)(2).

Thus, plaintiffs' refusal to provide coverage for abortifacients in Hercules's health plan is directly protected by the Amendment.

Second, the Affordable Care Act itself protects qualified health plans from being forced to cover abortion. The Act states that "nothing in this title [which includes the section concerning "preventive services"] shall be construed to require a qualified health plan to provide coverage of [abortion] services . . . as part of its essential health benefits for any plan year." 42 U.S.C. § 18023(b)(1)(A)(i). This provision protects plaintiffs' refusal to cover abortifacients in their health plan. The Act has other abortion-conscience protections: It restates the Hyde-Weldon principle that "[n]o individual health care provider or health care facility," including commercial entities, may be discriminated against because of a religiously or morally based refusal "to provide, pay for, provide coverage of, or refer for abortions." 42 U.S.C. § 18023(b)(4). And it expressly states that "[n]othing in [t]he Act shall be construed to have any effect" on federal laws concerning "conscience protection; willingness or refusal to provide abortion; and "discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." 42 U.S.C. § 18023(c)(2)(A).

President Obama summarized these provisions in his March 2010 Executive Order, which some of these *amici* helped negotiate:

> Under the [ACA], longstanding Federal laws to protect conscience (such as the Church Amendment and the Weldon Amendment) remain intact and new protections prohibit discrimination against health care facilities and health care providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.

Executive Order No. 13535, 75 Fed. Reg. 75 Fed. Reg. 15599, 2010 WL 1169591 (Mar. 24, 2010) (citations omitted).

We agree with the complaint's allegations that the mandate violates the ACA, 42 U.S.C. § 18023(b)(1)(A)(i), and the Hyde-Weldon Amendment by requiring plaintiffs to cover drugs that may cause abortions. But these provisions are also highly relevant to the issues before this Court concerning the Religious Freedom Restoration Act (RFRA) and the First Amendment. The ACA and Hyde-Weldon provisions offer just two examples of the nation's tradition of broad protection for objections to facilitating abortion. As we discuss *infra*, this Court should take that tradition into account in interpreting RFRA.

Protections for objectors to abortion pre-date *Roe v. Wade*, 410 U.S. 113 (1973): states that liberalized their abortion laws before *Roe* "included explicit conscience protections for individuals and institutions in the [liberalization] statutes" or in separate laws. Mark L. Rienzi, *The Constitutional Right Not to Participate in Abortions:* Roe, Casey, *and the Fourteenth Amendment Rights of Healthcare Providers*, 87 Notre Dame L. Rev. 1, 30-31 & n.142 (2011). In announcing constitutional abortion rights in *Roe* and *Doe v. Bolton*, 410 U.S. 179

(1973), the Supreme Court simultaneously endorsed conscience protections. *Doe*, for example, noted that the Georgia statute in question had provisions "to afford appropriate protection to the individual and to the denominational hospital": for example, "the hospital is free not to admit a patient for an abortion. It is even free not to have an abortion committee." 410 U.S. at 197-98.

Soon after *Roe*, Congress passed the Church Amendment of 1973, which protects federally funded entities and their personnel from having to perform or provide facilities for abortions or sterilization against their "religious beliefs or moral convictions." Health Programs Extension Act of 1973, § 401, Pub. L. No. 93-45, 87 Stat. 91, 95 (1973), codified at 42 U.S.C. § 300a-7 (also pleaded in plaintiffs' complaint at ¶168). The Church Amendment also protects individual health-care personnel against discrimination by their employers for such refusals. *Id.* Similar conscience clauses have been enacted in other federal laws and, as of 2007, in 47 states. James T. Sonne, *Firing Thoreau: Conscience and At-Will Employment*, 9 U. Pa. J. Lab. & Emp. L. 235, 269-71 (2007). Quite a few of those states have covered objections concerning other procedures besides abortion. See *id.* at 271 (14 states protect health-care provider conscience concerning contraception, 18 concerning sterilization, and 3 concerning all health procedures). But every one of the 47 states protects provider conscience concerning abortion,

and the abortion provisions "are remarkable" in, among other things, "the range of persons covered." *Id.*

Federal law also protects, for example, federally funded entities from any sex-discrimination challenge for refusing "to provide or pay for any service, including the use of facilities, related to an abortion." 20 U.S.C. § 1688. It protects "any health care entity," including an individual, from discrimination by federal or state governments for refusing to provide training, to undergo training, or even to refer someone for training, in performing abortions. 42 U.S.C. § 238n(a), 238n(c)(2). It prohibits the use of legal aid funds to assist any proceeding or litigation that seeks "to compel any individual or institution" to perform, assist with, or provide facilities for an abortion in violation of religious or moral convictions. 42 U.S.C. § 2996f(b)(8). And it protects various health plans and providers from having to cover counseling or referral concerning a service if they object to the provision of such service on moral, ethical, or religious grounds. 42 U.S.C. § 1396u-2(b)(3)(B); 42 U.S.C. § 1395w-22(j)(3)(B); 48 C.F.R. § 1609.7001(c)(7).

Several conclusions follow from this array of federal and state conscience protections. First, although protections for objections to a number of health-care procedures (including contraception) are well established in American law, conscientious objections to abortion carry especially strong weight. See Rienzi, 87

Notre Dame L. Rev. at 35 ("The unique history of abortion-related conscience protections shows a collective judgment, arguably over the entire history of the nation, that healthcare providers should not be forced by the government to participate in abortions against their will."). These provisions reflect a more general principle: the seriousness of the burden on conscience when the objector is forced to take a life. The "right to refuse to take a human life over a sincere religious or moral objection" has "been consistently protected for health care practitioners in the context of abortion, abortifacient drugs, assisted suicide, and capital punishment," as well as for "conscientious objectors to military service." *Stormans v. Selecky*, 844 F. Supp. 1172, 1183 (W.D. Wash. 2012); see Mark L. Rienzi, *The Constitutional Right Not to Kill*, 62 Emory L.J. 121, 147-48 (2012) ("government efforts to ensure that unwilling individuals are not forced to engage in what they believe to be killings" have been "systematic and all encompassing").

Second, the right not to facilitate or support abortions regularly extends to individuals engaged in for-profit commerce, and to for-profit businesses. Both the Affordable Care Act and the Hyde-Weldon Amendment protect not only health insurance plans—directly covering this case—but other commercial entities such as hospitals, HMOs, and provider-sponsored organizations. See *supra* pp. 7-9. All of the relevant provisions, from the Church Amendment through state conscience

clauses to Hyde-Weldon and the ACA, protect individuals engaged in commerce—health-care personnel of various kinds—from having to participate in abortions.

Finally, our tradition protects objectors to abortion far beyond the case of direct involvement in the performance of the abortion. Health-insurance plans are exempt, under the Hyde-Weldon Amendment and the ACA, from having to facilitate abortions through the provision of coverage. Entities and individuals are protected not only from having to participate in the abortion, but from having to refer anyone for an abortion, or for abortion training, or from having to assist in other ways. See statutes cited *supra* p. 11; Rienzi, 87 Notre Dame L. Rev. at 34 ("[t]hese protections extended not only to direct personal performance of an abortion, but more broadly to providers who have an objection to being forced to 'participate,' 'refer,' 'assist,'" or facilitate in other ways concerning abortion).

The broad range of objectors and actions that these protections cover indicate society's recognition of the seriousness of the burden on the objector who believes abortion takes a life. The protections indicate powerfully that—for purpose of RFRA and the Free Exercise Clause—mandating coverage of abortions imposes a "substantial burden," even on for-profit entities, and does not serve a "compelling governmental interest." See *infra* part II.

B. Plaintiffs' Objection to Covering Emergency Contraceptives Falls Within the Tradition of Especially Strong Protections for Abortion Objections, Because Those Medicines May Colorably Be Thought to Terminate a Newly Fertilized Embryo.

This case implicates the tradition of protecting conscientious objections to abortion, insofar as plaintiffs object to certain "emergency contraceptives" because they may act to terminate a newly fertilized embryo. This is true for plaintiffs' claim under the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.* ("RFRA"), which was the basis for preliminary injunction entered by the district court. Plaintiffs—Hercules Industries and the Newlands, the controlling shareholders and operators of the business— claim that the HHS mandate imposes a "substantial burden" on their religious exercise, 42 U.S.C. § 2000bb-1(a), because the requirement to include "abortifacient drugs, contraception, or sterilization through health insurance coverage they offer at Hercules" forces them to violate their faith. Compl. ¶¶2-3. Plaintiffs unquestionably rest on their "sincerely held religious beliefs as formed by the moral teachings of the Catholic Church" (*id.* ¶2) and therefore view the intentional termination of an embryo, at any time after fertilization, as an impermissible abortion, taking the life of a distinct human person. See *id.* ¶¶48-50 (alleging that "emergency contraceptive" drugs can cause "the demise of an already-conceived but not-yet implanted human embryo" or even one that "has implanted in the uterus"); see *Catechism of the Catholic Church* ¶¶2271, 2270 (describing procured abortion as "a moral evil . . .

gravely contrary to moral law" because "[h]uman life must be respected and protected absolutely from the moment of conception").

The strong tradition of protecting conscience concerning abortion applies here notwithstanding the government's assertion that the emergency contraceptives to which plaintiffs object "are not abortifacients within the meaning of federal law because they have no effect if a woman is pregnant." Govt. Brief at 4-5 n.3; see Govt. Motion to Dismiss at 52-55. The government's assertion is both irrelevant to a claim under RFRA and wrong on its merits.

1. The fundamental issue in a case involving RFRA or the Free Exercise Clause is the *objector's belief*. The government imposes a substantial burden on religious exercise under RFRA when it (among other things) "requires participation in an activity prohibited by a sincerely held religious belief." *Abdulhaseeb v. Calbone*, 600 F.3d 1301, 1315 (10th Cir. 2010) (interpreting identical standard in the Religious Land Use and Institutionalized Persons Act, 42 U.S.C. § 2000cc *et seq.*). The Newlands, like millions of other Americans, believe that the life of a distinct human person begins at fertilization and that the grave wrong of abortion includes intentionally preventing the embryo's implantation. The government, of course, cannot question the validity of that moral view. See *Thomas v. Review Board*, 450 U.S. 707, 714 (1981) (under Free Exercise Clause, whether a law conflicts with a claimant's religious belief "is not to turn upon a

judicial perception of the particular belief or practice in question"); accord *Abdulhaseeb*, 600 F.3d at 1314 n.6. Since these objectors believe that a distinct life begins at conception, it is no salve to their conscience to be told that the government defines abortion differently. Whatever the government's definition, objectors like plaintiffs are suffering the particularly serious burden of being forced to facilitate acts that they believe take a life. The nation's tradition of broadly protecting abortion objections should extend to them, and to their claims under RFRA.

Plaintiffs' beliefs also include a factual component: that emergency contraceptives pose a risk of terminating a new embryo (a risk in turn sufficiently great that they may not facilitate such medicines' use). This judgment too must receive deference from a court. Objectors such as plaintiffs weigh the risk in the light of the seriousness with which they view the intentional termination of embryonic life; proper deference to this weighing means the court should give objectors great leeway on evaluating the extent of the risk. When it is colorable to believe that a drug or method may operate before implantation, the objector's claim should fall within our tradition of particularly broad protection for objections to abortion.

2. Objectors have a colorable basis for fearing that emergency contraception may cause termination of embryos. The labeling information on both Ella

(ulipristal acetate) and Plan B (levonorgestrel) states that although the primary mechanism for preventing pregnancy is inhibition or delay of ovulation, "[a]lterations to the endometrium that may affect implantation may also contribute to efficacy." *Ella* Full Prescribing Information, 12.1 (Aug. 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (last visited June 18, 2012). See also Plan B One-Step Prescribing Information, 12.1 (rev. July 2009), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf (stating that Plan B believed to act principally by preventing ovulation or fertilization; "[i]n addition, it may inhibit implantation (by altering the endometrium).").[2] Making the endometrium, the uterine lining, unreceptive to implantation is one way to cause the abortion of a new embryo. Based on these statements, an organization or individual convinced that a distinct human life begins at fertilization has a reasonable basis for objecting to being forced to cover potential abortifacients. On a matter as grave as the risk of terminating life, the objector is entitled to take seriously the government's statement that the risk exists.

[2] Secretary Sebelius herself has admitted that FDA-approved emergency contraceptives are "a category [of drugs] that prevent fertilization and implantation." Kelly Wallace, *Health and Human Services Secretary Kathleen Sebelius Tells iVillage "Historic" New Guidelines Cover Contraception, Not Abortion* (Aug. 2, 2011), http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception-not-abortion/4-a-369771.

With respect to Ella (ulipristal) in particular, objectors clearly have ample reason to conclude that the medication may terminate an embryo. Ulipristal is a selective progesterone receptor modulator (SPRM); as such it is structurally similar and "has similar biological effects to mifepristone, the antiprogestin used in medical abortion."[3] Although Ella involves lower doses of mifepristone than does RU-486, the so-called abortion pill, the record of the FDA's approval for Ella contains multiple statements that when administered after ovulation, the drug affects the endometrium in a way that could prevent implantation of a fertilized embryo. For example, the background document for the FDA advisory committee on Ella states that "[a]dministration of ulipristal in the luteal phase [of the menstrual cycle] also alters the endometrium. Based on the findings of the pharmacodynamic studies, ulipristal appears to exert an anti-progesterone contraceptive effect on both the ovary and endometrium, depending on the dose and time of drug administration during the menstrual cycle."[4] As one member of

---

[3] G. Bernagiano & H. von Hertzen, "Towards more effective emergency contraception?," 375 *The Lancet* 527-28 (Feb. 13, 2010), at 527.

[4] See Background Document for meeting of Advisory Committee for Reproductive Health Drugs, FDA Advisory Committee Materials, NDA 22-474 (Ella) (June 17, 2010), at 11-12, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM215425.pdf (hereinafter "FDA Background Document"). See also Transcript of Proceedings, Advisory Committee on Reproductive Health Drugs (June 17, 2010), at 121 (Dr. Ronald Orleans, FDA Medical Officer) ("Another possible mode of action is delaying the normal endometrial maturation which occurs in the luteal phase of the

the FDA's advisory committee stated: "I'll even concede that the primary mechanism of action might be delayed ovulation, but not in this group that's five days out from unprotected intercourse. . . . I can't imagine how we can put all of these numbers together to say that delayed ovulation explains this continued efficacy [at five days after intercourse]."[5]

There is also evidence that Ella may have effects post-implantation, a time period that satisfies even the government's asserted definition for abortion of a pregnancy. The FDA's own materials cite studies in pregnant rats and rabbits in which ulipristal "at drug exposures comparable to human exposure based on surface area (mg/m2)" were lethal to embryos.[6] Similarly, the European Medicines Agency (EMEA), the EU equivalent of the FDA, found embryotoxic effects in rats, rabbits, guinea pigs, and macaques (similar to monkeys). See European Medicines Agency, " CHMP Assessment Report for EllaOne," (Doc.Ref.: EMEA/261787/2009), at 16, 10 (finding that *ella* "is embryotoxic at low doses, when given to rats and rabbits" and "[was] approximately equipotent at the dose levels of 10 and 30 mg/day in terminating pregnancies in guinea-pigs"), available

---

cycle. This delay of maturation could possibly prevent implantation."), available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf (hereinafter "Advisory Committee Proceedings").

[5] Advisory Committee Proceedings, *supra* note 4, at 160, 164 (Dr. Scott Emerson).

[6] FDA Background Document, *supra* note 4, at 10.

at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf. These studies may not have conclusively determined the drug's effect on fetal development after implantation,[7] but they unquestionably raise significant concerns for the objector who believes that the genetically distinct human life that begins at fertilization must be protected.

With respect to Plan B, while some scientific studies have concluded that it does no more than prevent conception,[8] other studies, as well as the government's own labeling and statements, indicate that it may act after fertilization. For example, a summary of various effectiveness studies for levonorgestrel concludes that there are significant discrepancies between the effectiveness reported and the effectiveness that can be attributed to the drug's disturbance of ovulation. The authors conclude that "[e]ither the actual clinical effectiveness is far lower than has been estimated in the literature to date" or "that mechanisms of action other than disturbance of ovulation contribute to the reduction of clinical pregnancy,

---

[7] *Id.* at 10-11.

[8] See, e.g., Sandra E. Reznik, "Plan B": How It Works, Health Progress (Jan.-Feb. 2010), at 59, available at www.chausa.org/workarea/DownloadAsset.aspx?id=6159. These arguments concerning the mechanism of action of levonorgestrel do not apply to ulipristal, which "is a new chemical entity, has a different mechanism of action, and a more limited safety profile." Advisory Committee Proceedings, *supra* note 4, at 222-23 (statement of Dr. Carol Ben-Maimon).

including mechanisms acting after fertilization."[9] Given such uncertainties, together with the medication's labeling and the government's other statements, objectors have a colorable basis for believing that that Plan B may affect implantation.

In short, the colorable fears that plaintiffs have that Ella and Plan B may terminate a new embryo are sufficient to bring this case within the tradition of making especially broad accommodation for conscientious objections to facilitating abortions.

II. PLAINTIFFS HAVE A SUFFICIENT LIKELIHOOD OF SUCCESS ON THE MERITS OF THEIR RELIGIOUS FREEDOM RESTORATION ACT (RFRA) CLAIM, AT LEAST AS TO THEIR CHALLENGES TO MEDICINES THAT MAY ACT TO TERMINATE A NEW EMBRYO.

The Religious Freedom Restoration Act ("RFRA") provides that the federal government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability," unless the government demonstrates that imposing that burden "(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(a), (b).

[9] Rafael T. Mikolajczyk and Joseph B. Stanford, *Levonorgestrel: emergency contraception: a joint analysis of effectiveness and mechanism of action*, 88 Fertility and Sterility 565, 569, 570 (Sept. 2007).

These widespread exemptions we have listed are highly probative for plaintiffs' claims under RFRA and the First Amendment. They provide strong indication, under our traditions, that mandating coverage of abortions imposes a "substantial burden" on an objector, including a for-profit closely-held business and its individual owners. And the fact that the protections are so numerous indicates that there is not a compelling interest, generally, in forcing objectors to facilitate abortions.

A. The Mandate Imposes a Substantial Burden on Plaintiffs' Religious Exercise.

We agree with plaintiffs that they are engaged in "religious exercise" by seeking to run their closely-held business according to Catholic principles. Compl. ¶115. We also agree that the government substantially burdens plaintiffs' religious exercise when it requires them to support procedures, including contraception, abortifacients, and sterilization, that they regard as sinful by including them in their insurance plan and paying premiums to cover them. *Id.* ¶114. Accordingly, plaintiffs' claims trigger RFRA, and the government must show a compelling interest in imposing these burdens on them.

1. The government's attempts to deny the burden on religious exercise conflict with the pattern of accommodating conscientious objections to facilitating abortion in multiple contexts.

The government argues that the burden on plaintiffs does not trigger RFRA. See Govt. Brief at 14 ("RFRA is not implicated here because the contraceptive-coverage requirement does not impose a substantial burden on any exercise of religion by Hercules Industries or the Newlands.") The government's argument is unacceptable, for variety of reasons. We focus on the right of conscientious objection against abortion and the logical effect that the government's arguments would have on that right. The government's narrow conception of "substantial burden" is irreconcilable with the nation's particularly strong tradition of protecting objections to abortion.

The government first claims that the plaintiffs are not engaged in "any exercise of religion," because Hercules is a for-profit corporation and the Newlands as individuals are separate from the corporation. Govt. Br. at 14-20. We agree with plaintiffs' responses: RFRA's protections are not limited to "religious organizations" (Pls.' Br. at 16-19), and that both individuals and the corporations they form can exercise religion in the for-profit corporate setting.

The government's highly restrictive approach is wrong for another reason. It would mean that, so far as RFRA was concerned, an employer could be forced to cover the cost of procedures that unquestionably cause an abortion. This is

irreconcilable with the strong pattern of accommodations in federal and state law for those objecting to participating in abortions—including the objections of commercial entities such as businesses and health insurers. See *supra* pp. 7-9, 12. Over and over again, federal and state laws have recognized that individuals and entities engaging in commerce exercise their religious conscience in objecting to facilitating abortions and other procedures and should be protected. It would make no sense to say that an interest recognized so consistently does not involve the "exercise of religion" under RFRA. On the contrary, as one state court has recognized, what health-care conscience laws do, "by offering protections to those who seek not to act in the health-care setting due to religious convictions," is precisely to "bolste[r]" "'a person's exercise of religion.'" *Morr-Fitz, Inc. v. Quinn*, 976 N.E.2d 1160, 1171 (Ill. App. 4th Dist. 2012) (using state health-care conscience act to protect corporate owners of pharmacies, as well as individual pharmacists, from state rules requiring them to provide emergency contraception), appeal dismissed, --- N.E.2d ---- (Ill. Jan 30, 2013) (Table, No. 115122). The court treated the purposes of Illinois's conscience act and its state version of RFRA as harmonious. This Court should do the same for the federal RFRA.

Next, the government argues that any exercise of religion by plaintiffs is not "substantially burdened" because they are not being forced to do anything directly

sinful themselves. The government argues that plaintiff suffer only an "indirect and attenuated" burden when their claim is

> that funds, which plaintiffs will contribute to a group health plan, might, after a series of independent decisions by health care providers and patients covered by [the corporate] plan, subsidize *someone else's* participation in an activity that is condemned by plaintiff[s'] religion.

Govt. Brief at 23 (quoting, *inter alia*, *Hobby Lobby Stores, Inc. v. Sebelius*, No. 12-6294 (10th Cir.), 12/20/12 Order, at 7) (emphasis in original) (order of 2 judges denying injunction pending appeal)). As plaintiffs point out, this ignores that they believe it is wrong for them to facilitate the wrongs of others. Pls.' Br. at 33-34 & n.19. Again, the government's argument conflicts with *Thomas v. Review Board*, where the claimant quit his job because, based on his religious beliefs, he was unwilling to work in a factory that produced tank turrets. The state denied him unemployment benefits and argued that his objection was unfounded because he had been willing to work in a different factory that produced materials that might be used for tanks. The Supreme Court held that in determining whether Thomas's religious beliefs were burdened, it could not second-guess his judgment about what connection to armament production was unacceptably close for him: "Thomas drew a line, and it is not for us to say that the line he drew was an unreasonable one." *Thomas*, 450 U.S. at 715. Plaintiffs are entitled, just as much as Mr. Thomas was, to make judgments about when their connection becomes too close to conduct they believe is immoral.

The government's argument would mean that there is no burden on *any* employer that is forced to provide insurance coverage of behavior to which it objects: there would be no burden even on a religious organization, even on a Catholic diocese. As plaintiffs note, HHS's own exemption and accommodation for religious organizations shows that it recognizes that an organization is significantly burdened by having to provide its employees insurance coverage to fund procedures it regards as sinful. Pls.' Br. at 30-32.

The government's position here is also irreconcilable with the long tradition of protecting conscientious objectors from more than just direct personal involvement in the abortion. In multiple ways and contexts, federal and state laws protect those who refuse to help others get or perform abortions. Objectors are freed from having to refer someone to an abortion provider, from having to provide facilities, and from having to conduct training sessions or refer someone for training sessions—even though in all those cases it could be said that the objector was merely facilitating someone else's voluntary participation. See *supra* p. 13. And most relevantly, both the ACA and the Hyde-Weldon Amendment specifically protect health plans (and by extension, employers purchasing them) from having to cover abortions. Burdens that over and over again trigger protections in federal and state laws cannot be dismissed "insubstantial" under RFRA.

2. At the very least, plaintiffs are substantially burdened by the requirement that they cover contraceptives that may act as abortifacients.

At the very least, this Court should find a "substantial burden" on plaintiffs to the extent that the mandate requires them to cover methods they claim are abortifacients. To find no burden here would mean that government could force a small or closely held business to fund any abortion whatsoever, with no barrier from RFRA. Again, that would be irreconcilable with the nation's tradition of broad conscience protection for objectors to abortion, including individuals and entities in the for-profit sphere.

B. The Government Has Not Shown That Requiring Employers to Cover Emergency Contraceptives Serves a Compelling Interest, Or That It Is the Least Restrictive Means.

Once the plaintiff demonstrates a substantial burden, the government has the burden to demonstrate that application of the burden to the plaintiff furthers a compelling governmental interest and is the least restrictive means of furthering that interest. 42 U.S.C. § 2000bb-1(b). "[D]emonstrates" means that the government must "mee[t] the burdens of going forward with the evidence and of persuasion." 42 U.S.C. § 2000bb-2(3).

The government has not met either of those burdens at this stage of the litigation with respect to emergency contraceptives, because it has offered no specific evidence concerning them at all. It has merely lumped together possible

abortifacients with contraceptives in its argument that requiring objecting employers to cover them is necessary to promoting women's health and equity. That cannot suffice to overcome claims of conscience concerning abortifacients, for a combination of reasons, some relating particularly to abortifacients, others applying more broadly.

By the Secretary's own admission, contraception is widely available in "community health centers, public clinics, and hospitals with income-based support," http://www.hhs.gov/news/press/2012pres/01/20120120a.html, and there is no demonstration that emergency contraception is different. Emergency contraceptives are also subject to the large coverage gaps that the ACA leaves for contraceptives in general: the exemption of small business (under 50 full-time employees) from the underlying requirement to provide health insurance, and the grandfathering of thousands of plans covering millions of employee. Pls.' Br. at 36-40.

In addition, there are particular reasons to doubt that the government's interest is compelling with respect to potential abortifacients. First, the nation's tradition of broadly accommodating conscientious objections to facilitating abortion makes it extremely unlikely that the government can show a compelling interest in overriding employers' conscience concerning embryo-terminating drugs. On abortion the government accommodates the conscientious scruples of

for-profit employers, health-insurance plans, health-care facilities, and individual salaried providers. The government cannot overcome the strong claim of conscience here concerning potential abortifacients by the mere declaration that all FDA-approved contraceptives should be covered or that terminating an embryo is not an abortion before implantation.

Second, the government has justified the mandate throughout based on arguments that the costs of contraceptive methods may deter a significant number of women from using them. See, e.g., Final Rules, 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, 8728 (Feb. 15, 2012). But even if that argument were valid, there is no specific showing it should also apply to emergency contraceptives. While the proper use of routine contraception should be frequent and regular over months, medicines like Ella and Plan B are appropriate for only a limited range of situations—shortly "after unprotected intercourse or a known or suspected contraceptive failure"—and neither is "intended for routine use as a contraceptive."[10] The costs of regularly ingested contraceptives mount over months; according to one chart, they reach up to $960 a

[10] FDA, Ella Prescribing Information, ## 2, 1, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf; FDA, Plan B One-Step Prescribing Information, ## 2, 1, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf.

year for uninsured women taking certain pills.[11] Ella and Plan B cost roughly $35 to $55 per dose.[12] Thus, it would take multiple uses of Ella or Plan B in a year (up to 20) to equal the yearly cost of routine contraception—a pattern contradicting the direction that neither Ella nor Plan B is "intended for routine use as a contraceptive." In that light, the government cannot simply equate the expenses for emergency and regular contraception without demonstrating the compelling need to require objecting employers to cover the former. Since there is no such showing at this point, the preliminary injunction must be upheld as to these medicines.

[11] Center for American Progress, The High Costs of Birth Control: It's Not Affordable As You Think (Feb. 15, 2012), available at http://www.americanprogress.org/issues/women/news/2012/02/15/11054/the-high-costs-of-birth-control/.

[12] See, e.g., Andrea Kim and Mary Barna Bridgman, *Ulipristal Acetate (ella): A Selective Progesterone Receptor Modulator For Emergency Contraception,* 36 Pharmacy & Therapeutics 325, and Table 1 (June 2011), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3138379.

CONCLUSION

The preliminary injunction should be affirmed, at least for plaintiffs' objections to the methods they believe may act as abortifacients.

Respectfully submitted.

Thomas C. Berg
University of St. Thomas School of Law*
MSL 400, 1000 LaSalle Ave.
Minneapolis, MN 55403
(651) 962-4918
tcberg@stthomas.edu

*Institutional affiliation for identification purposes only

L. Martin Nussbaum
Michael Francisco
Rothgerber Johnson & Lyons LLP
90 S. Cascade Avenue, Suite 1100
Colorado Springs, CO 80903
(719)386-3000
mnussbaum@rothgerber.com
mfrancisco@rothgerber.com

Sandra Payne Hagood (admission pending)
7660 Fay Avenue, Suite H-526
La Jolla, CA 92037
(858) 245-5741
sandra@hagoodappellate.com

Attorneys for Amici Curiae

Certificate of Compliance with Word Count

As required by Federal Rule of Appellate Procedure 32(a)(7)(C), I certify that this brief is proportionally spaced and contains 6,601 words. I relied on my world processor to obtain the word count (Microsoft Word 2010). I certify that the information on this form is true and correct to the best of my knowledge and belief formed after a reasonable inquiry.

/s/ *L. Martin Nussbaum*
L. Martin Nussbaum

Certificate of Compliance with Digital Submissions

As required by this Court's Order regarding the Electronic Submission of Documents, filed August 10, 2007, the undersigned counsel certifies that (1) no privacy redactions were needed and every document submitted in digital fom or scanned PDF format is an exact copy of the written document filed with the Clerk, and (2) the digital submissions have been scanned for viruses with the most recent version of a commercial virus scanning program, CheckPoint Endpoint Security, Version E80.30 (8.1.302), last updated 1 March 2013, and according to this program, are free of viruses.

/s/ *L. Martin Nussbaum*
L. Martin Nussbaum

CERTIFICATE OF SERVICE

I hereby certify that on March 1, 2013, I electronically filed the foregoing *AMICUS CURIAE* BRIEF IN SUPPORT OF PLAINTIFFS/APPELLEES FOR AFFIRMANCE with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

I further certify that some of the participants in the case are not CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid, to the following non-CM/ECF participants:

Steven H. Aden
Alliance Defending Freedom
801 G Street NW, Suite 509
Washington, D.C. 20001

Michelle Bennett
U.S. Department of Justice-DC-Federal Programs
20 Massachusetts Ave. NW
Washington, D.C. 20008

Ayesha N. Kahn
Americans United for Separation of Church and State
1301 K Street NW
Suite 850, East Tower
Washington, D.C. 20005

Frank Manion
Geoffrey R. Surtees
American Center for Law and Justice
6375 New Hope Road
New Hope, KY 40052

s/ *L. Martin Nussbaum*
L. Martin Nussbaum
Counsel of Record for Amici Curiae