

Nos. 12-35221 & 12-35223

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

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STORMANS, INC., *doing business as Ralph's Thriftway, et al.*,  
Plaintiffs-Appellees,

v.

MARY SELECKY, Secretary of the  
WASHINGTON DEPARTMENT OF HEALTH, *et al.*,  
Defendants-Appellants,

*and*

JUDITH BILLINGS, *et al.*,  
Intervenors-Appellants.

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**On Appeal from the United States District Court for the  
Western District of Washington at Tacoma  
Case No. 07-CV-05374-RBL (Honorable Ronald B. Leighton)**

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**Brief *Amici Curiae* of Christian Medical Association,  
American Association of ProLife Obstetricians & Gynecologists,  
Catholic Medical Association,  
Association of American Physicians & Surgeons, and  
Christian Pharmacists Fellowship International**

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Kimberlee Wood Colby  
Center for Law & Religious Freedom  
CHRISTIAN LEGAL SOCIETY  
8001 Braddock Road, Suite 302  
Springfield, VA 22151  
Tel: (703) 894-1087  
Fax: (855) 257-9801

Nikolas T. Nikas  
Dorinda C. Bordlee  
*Counsel of Record*  
BIOETHICS DEFENSE FUND  
6811 E. Voltaire Avenue  
Tel: (480) 483-3597  
Fax: (480) 483-3658

*Counsel for Amici Curiae*

## **CORPORATE DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1, *Amici Curiae* Christian Medical Association, American Association of ProLife Obstetricians & Gynecologists, Catholic Medical Association, Association of American Physicians & Surgeons, and Christian Pharmacists Fellowship International are nongovernmental corporate entities, but they have no parent corporations and no publicly held corporations hold 10 percent or more of their stock.

/s/ Dorinda C. Bordlee  
Counsel for *Amici Curiae*

Dated: November 20, 2012

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## **IDENTITY AND INTEREST OF *AMICI CURIAE*<sup>1</sup>**

*Amici curiae* are five national organizations whose members include physicians, pharmacists and other healthcare professionals who have a profound interest in defending healthcare rights of conscience consistent with the Free Exercise Clause of the First Amendment. *Amici* include the following medical associations:

**Christian Medical Association** is a nonprofit national organization of Christian physicians and allied healthcare professionals with over 16,000 members. In addition to its physician members, it also has associate members from a number of allied health professions, including nurses and physician assistants. CMA provides up-to-date information on the legislative, ethical, and medical aspects of defending conscience in health care for its members and other healthcare professionals, as well as for patients, institutions, and students in training. CMA is opposed to the practice of abortion as contrary to Scripture, a respect for the sanctity of human life, and traditional, historical and Judeo-Christian medical ethics.

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<sup>1</sup> Pursuant to this Court's Rule 37.3(a), all parties have submitted to the Clerk blanket consents to the filing of all *amicus* briefs. Pursuant to this Court's Rule 37.6, *Amici* state that no counsel for any party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of the brief.

**American Association of Pro-Life Obstetricians and Gynecologists** (“AAPLOG”) is a non-profit professional medical organization consisting of over 2,000 obstetrician-gynecologist members and associates. The American College of Obstetricians and Gynecologists (ACOG) recognizes AAPLOG as one of its largest special interest groups. The purpose of AAPLOG is to reaffirm the unique value and dignity of individual human life in all stages of growth and development from fertilization onward. AAPLOG views the physician’s role as a caregiver, responsible, as far as possible, for the well-being of both the mother and her unborn child.

**Catholic Medical Association** is a nonprofit national organization founded in 1932 to assist Catholic physicians in upholding the principles of their faith in the science and the practice of medicine and in witnessing to these principles within the medical profession, the Church, and society at large. Comprised of over 2,000 members covering over 75 medical specialties, CMA helps to educate the medical profession and society at large about issues in medical ethics, including health care rights of conscience, through its annual conferences and quarterly journal, *The Linacre Quarterly*. CMA supports Catholic hospitals in faithfully applying Catholic moral principles in health care delivery and helps Catholic physicians to collaborate and support one another in their common goal of providing conscientious health care that respects the dignity of the human person.

**Association of American Physicians and Surgeons** is a non-partisan professional association of physicians in all types of practices and specialties across the country. Since 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship and the practice of private medicine. The motto of AAPS is *omnia pro aegroto*, meaning “all for the patient.”

**Christian Pharmacists Fellowship International** is a non-profit interdenominational fellowship of Christian pharmacists, whose members include Washington State pharmacists. CPFI is greatly concerned about its members' rights of conscience and their ability to exercise those rights in their professional practice. CPFI believes that pharmacists have a moral and legal responsibility to refuse to dispense a prescription that in the pharmacist's judgment might be harmful to the patient, either directly or indirectly. CPFI therefore opposes regulatory efforts to force pharmacists to dispense prescriptions against their best judgment and moral conscience. CPFI believes strongly in the sanctity of human life and supports the rights of Christian pharmacists, based upon Biblical principles and their moral convictions, to exercise their conscience within the realm of professional practice.

## SUMMARY OF THE ARGUMENT

Despite the plurality of views in our society about the moral status of the human being at the embryonic and fetal stages of development, the resolution of this case in favor of the Appellee Pharmacists' rights of conscience does not require this Court to decide the moral worth or legal rights of the human embryo prior to uterine implantation. This Court need only recognize that a pharmacist, like any healthcare provider, is a professional entitled to make a judgment to refrain from actions that violates his or her conscience as informed by both science and religion.

This brief presents the reasonable and scientifically supportable basis of the religious objections by the Appellee Pharmacists regarding the stocking and dispensing of drugs that have the capacity of terminating human life as one possible mechanism of action – specifically the so-called “emergency contraceptive” drugs known as Plan B and *ella*.

This brief is submitted partly in response to a reference in Intervenors' opening brief to this Court, in which they suggest, based on two non-medical newspaper articles, that Appellee Pharmacists' conscience objections are unreasonable as “contrary to the scientific evidence.”

The scientific evidence instead supports the Pharmacists' objections. The first section of this brief presents a concise survey of the relevant human

embryology establishing the biological humanity of the embryo whose life begins at sperm-egg fusion. This is followed by a review of the medical literature, FDA directives, and FDA-approved labeling on Plan B and *ella*— all of which Appellee-Pharmacists reasonably rely on to conclude that these drugs have the capacity to prevent implantation, thus destroying the life of a human embryo.

The second section of the brief demonstrates that the Pharmacists' objections are consistent with the Christian tradition that regards each individual human life as a unique moral being from conception. It presents a summary of the relevant religious beliefs regarding the sanctity of human life as found in the Bible and interpreted through the Catholic and many Protestant faith traditions.

Even if the scientific evidence did not support the reasonableness of the pharmacists' objections -- which it does -- the pharmacists "may believe what they cannot prove" and "may not be put to the proof of their religious doctrines or beliefs." *United States v. Ballard*, 322 U.S. 78, 87 (1944). The third section of the brief reviews Supreme Court and Ninth Circuit precedent that prohibits the courts from assessing the truth or falsity of a religious claimant's beliefs for purposes of adjudicating a religious liberty claim. *Id.* at 86; *Callahan v. Woods*, 658 F.2d 679, 685 (9th Cir. 1981). Sincerely held religious beliefs are protected even if others do not find them "acceptable, logical, consistent, or comprehensible." *Thomas v. Review Bd. of Ind. Emp't Sec. Div.*, 450 U.S. 707, 714 (1981); *United States v.*

*Zimmerman*, 514 F.3d 851, 853–54 (9th Cir. 2007). Of course, the First Amendment’s protection of sincerely held religious beliefs does not “turn on a judicial perception of the particular belief or practice in question.” *Thomas*, 450 U.S. at 715. Going beyond what the First Amendment requires, the Pharmacists have articulately explained their objections based on scientific evidence as well as a religious understanding that each individual human being is a unique moral being from conception.

## **ARGUMENT**

### **I. The Pharmacists’ Conscience Objections Regarding “Emergency Contraceptives” are Consistent with Scientific Evidence.**

As established in the district court’s findings of fact, the challenged regulations issued and enforced by the Washington State Board of Pharmacy have had a direct impact on Appellees’ livelihoods and families. FF ¶ 149. Appellee Pharmacists are Christians who understand the scientific fact that an individual human life begins at the moment of fertilization, when the female ovum and male sperm unite to begin the life of an individual human embryo. Their religious belief in the inherent dignity of every human life thus leads them to ascribe moral value to the pre-implantation human beings, such that their cooperation with the dispensation of drugs capable of destroying human life would be considered a grave evil.

The Pharmacists therefore believe that dispensing Plan B or *ella* constitutes direct participation in the destruction of human life. This belief is based on the Pharmacists’ review of the medical literature, FDA directives, and FDA-approved labeling on Plan B and *ella*— all of which confirm that Plan B and *ella* can prevent implantation, thus destroying a fertilized egg known as a human embryo. PX 424, 502 (Plan B information); PX 451, 501 (*ella* Patient Information).

Despite the reasonableness of the facts undergirding the Pharmacists’ sincere religious beliefs and moral convictions, Intervenors’ opening brief suggests that their conscience objections are unreasonable, stating: “Plaintiffs refuse to dispense Plan B because they believe, *contrary to the scientific evidence*, that Plan B can cause a fertilized egg to fail to implant in the uterus, which they consider the taking of a life.”<sup>2</sup>

Intervenors launch this baseless claim based on a *New York Times* article which itself admits that the Federal Drug Administration (FDA) requires the drugs’ product packaging materials to reveal the capacity of emergency contraception to

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<sup>2</sup> Opening Brief of Intervenors-Appellants Judith Billings et al., at 14 n.1 (emphasis added).

For a rebuttal of the claims made in the *New York Times* article, see Donna Harrison, *The Times’s Convolution of Facts on Abortifacients*, National Review Online (June 6, 2012), available at <http://www.nationalreview.com/corner/301980/itimesi-s-convolution-facts-abortifacients-donna-harrison> (last checked November 9, 2012).



prevent implantation in the event fertilization occurs, as discussed in more detail below.

**A. 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 Pharmacists' conscientious objection to dispensing the objectionable drugs, 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). As discussed below, the State attempts to entangle and interchange these phases of development in an attempt to cast the Pharmacists' conscience objections as unreasonable.

### **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.**<sup>3</sup>

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<sup>3</sup> 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 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").

The established medical fact that “a unique individual” begins his or her life “at fertilization” is the factual foundation of the Pharmacists’ religious objection to dispensing a drug that has 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 postfertilization, 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 emotional reaction. It is a matter of observable, objective, scientific fact.*<sup>4</sup>

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<sup>4</sup> *Planned Parenthood of Ind. v. Comm’r*, 794 F. Supp.2d 892, 916–17 (S.D. Ind. 2011) (emphasis added).

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, 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.<sup>5</sup>

## 2. Implantation

Approximately five to six days *after* the human embryo's life has begun at fertilization, the human embryo (now at the "blastocyst" stage of development) begins the self-directed process of attaching to the uterine lining.<sup>6</sup> 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

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<sup>5</sup> 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).

<sup>6</sup> *E.g.*, Moore and Persaud, *supra* note 3, at 37.

drugs, the human embryo, now one week old, will not have the environment to continue its nourishment and growth.<sup>7</sup>

The Pharmacists' offer of proof in the district court includes an expert report of Bruce M. Carlson, M.D., Ph.D., a University of Michigan medical professor and author of two widely used textbooks of embryology. Dr. Carlson's report provides rebuttal to Intervenor's expert report of Dr. David Grimes, whose statements focused on whether emergency contraception causes post-*implantation* abortion.<sup>8</sup> Dr. Grimes' statements were found by Dr. Carlson to "miss the point of the plaintiffs' case, namely that from the time of fertilization the human embryo deserves full protection":

Because the plaintiffs believe that human life should be protected from the time of fertilization, the discussion of pregnancy's beginning upon implantation is irrelevant, because at the time of implantation the embryo has already been worthy of protection for approximately six days.<sup>9</sup>

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<sup>7</sup> 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 prevents the embryo's nourishment that can only be received in the environment of uterine implantation.

<sup>8</sup> Expert Report of Dr. David A. Grimes (Sept. 26, 2008) (Intervenor's Offer of Proof, Doc. 493-1, at 2–9).

<sup>9</sup> Expert Report of Dr. Bruce Coleman (October 30, 2008) (Plaintiffs' Offer of Proof Regarding Mechanism of Action of Emergency Contraceptives Related to their Religious Beliefs, Doc. 495 at 18–26).

Therefore, as explained by Dr. Carlson, “Regardless of the mechanism of action of Plan B, the plaintiffs’ concerns would only be assuaged if the scientific evidence showed that in no case does Plan B act by preventing implantation of an existing embryo.”<sup>10</sup>

**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.**

Drugs and devices with post-fertilization mechanisms of action are properly considered by Appellees to be life-ending since embryology establishes that a unique human life begins at fertilization. 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.<sup>11</sup>

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

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<sup>10</sup> *Id.* at 8.

<sup>11</sup> 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).

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. . . .”<sup>12</sup> In other words, Dr. Trussell, although an advocate of “emergency contraception,”<sup>13</sup> 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.<sup>14</sup>

Moreover, a new drug classified by the FDA as “emergency contraception”—Ulipristal Acetate (*ella*)—is actually an abortion-inducing drug,

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<sup>12</sup> J. Trussell et al., *Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy*, Office of Population Research at Princeton University (June 2010).

<sup>13</sup> See Profile of Dr. James Trussell, *available at* <https://www.princeton.edu/~trussell/> (last visited Oct. 2, 2012).

<sup>14</sup> *Morr-Fitz, Inc. v. Quinn*, 2012 IL App (4th) 110398 (Ill. App. Ct. 2012) (quoting Trans. of Bench Trial at 91–92, 111).

because it can cause the death of an embryo after implantation. The post-fertilization 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 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.<sup>15</sup> Although called “contraception,” the FDA’s labeling acknowledges that Plan B can prevent implantation of a human embryo.<sup>16</sup> 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).**<sup>17</sup>

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<sup>15</sup> 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.

<sup>16</sup> Plan B Approved Labeling, *available at* [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2006/021045s011\\_Plan\\_B\\_P\\_RNTLBL.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_P_RNTLBL.pdf) (last visited Sept. 30, 2012).

<sup>17</sup> FDA, *FDA’s Decision Regarding Plan B: Questions and Answers* (updated Apr. 30, 2009), *available at* <http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm> (last visited Sept. 30, 2012).

The same explanation is provided by Duramed Pharmaceuticals, the manufacturer of Plan B One-Step. Duramed states that Plan B One-Step “works primarily by: 1) preventing ovulation; 2) possibly preventing fertilization by altering tubal transport of sperm and/or egg; 3) **altering the endometrium, which may inhibit implantation.**”<sup>18</sup>

**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.”<sup>19</sup> This means that though labeled as “contraception,” *ella* works the same way as RU-486. By blocking progesterone—

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30, 2012) (emphasis added).

<sup>18</sup> Duramed Pharmaceuticals, *How Plan B One-Step Works* (2010), available at <http://www.planbonestep.com/plan-b-prescribers/how-plan-b-works.aspx> (last visited Sept. 30, 2012) (emphasis added).

<sup>19</sup> 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).



a hormone necessary to build and maintain the uterine wall during pregnancy—an SPRM can either prevent a human embryo from implanting in the uterus, or it can abort a human embryo that has already implanted in the uterine lining by essentially starving it to death. Therefore, *ella* has the capacity to abort a pregnancy even under a definition that limits abortion to the time after the embryo implants in the uterus.<sup>20</sup>

Studies confirm that *ella* is toxic to a human embryo.<sup>21</sup> The FDA’s own labeling notes that *ella* may “affect implantation,”<sup>22</sup> 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

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<sup>20</sup> See Gacek, *Conceiving Pregnancy*, *supra* note 11. Because the semantics of what constitutes an “abortifacient” or “abortion-inducing” drug differ based on the underlying moral value ascribed to the pre-implantation human embryo, this brief focuses on the more precise question of when the life of the human embryo begins and how Plan B and *ella* end the life of the human embryo, whether before uterine implantation or after.

<sup>21</sup> 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](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf) (last visited Sept. 30, 2012).

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

progesterone) “including ulipristal acetate” can “impair implantation.”<sup>23</sup> While the study theorizes that the dosage used in its trial “might be too low to inhibit implantation,”<sup>24</sup> it states affirmatively “an additional postovulatory mechanism of action,” e.g. impairing implantation, “cannot be excluded.”<sup>25</sup>

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.”<sup>26</sup>

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

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<sup>23</sup> Glasier et al, *Ulipristal acetate versus levonorgestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis*, 375 THE LANCET 555, 555–62 (2010).

<sup>24</sup> *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* “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.*

<sup>25</sup> *Id.*

<sup>26</sup> Ralph P. Miech, *Immunopharmacology of Ulipristal as an Emergency Contraceptive*, 3 INT’L J. WOMEN’S HEALTH 391–397 (2011).

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.<sup>27</sup>

In short, the FDA-approved “contraceptive” *ella* can work by ending an established pregnancy.

## **II. The Pharmacists’ Objections are Consistent with the Christian Tradition That Regards Each Individual Human Life as a Unique Moral Being from Conception.**

### **A. The traditional Christian understanding that the unborn child is a unique moral being from conception is rooted in the scriptures.**

The belief that each individual human life is a unique moral being lies at the heart of Christian tradition. In a section entitled “The Beginning of Life and Abortion,” the editors of the most widely representative, currently available study Bible conclude:

The witness of Scripture, as confirmed by the testimony of the early church, is that every human being, from conception through natural death, is to be respected as a person created in the image of God, whose life has special dignity by virtue of his or her relationship to the Creator. Like the early church, Christians should be known as a

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<sup>27</sup> See Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs, June 17, 2010, *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf> (last visited Sept. 30, 2012).

people who protect, nurture, and cherish children as gifts from the Lord (Ps. 127:3).

*ESV Study Bible, English Standard Version 2539* (Crossway Books 2008).

Yale Professor Kenneth Latourette noted that the early Church prohibited “[t]he destruction of young life, either by abortion or infanticide.” KENNETH SCOTT LATOURETTE, *A HISTORY OF CHRISTIANITY: BEGINNINGS TO 1500* 248 (2d ed., 1975).<sup>28</sup> Instead, “Jesus himself had set the example” that “[c]hildren were to be held in tender regard.” *Id.*<sup>29</sup>

The Church’s traditional protection of unborn children derives from numerous scriptures. For example, the account of Mary’s visit to her pregnant cousin Elizabeth while carrying Jesus in her womb depicts an unborn baby as a unique moral being. In his gospel, Luke records:

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<sup>28</sup> An in-depth, contextual discussion of early Christians’ attitudes toward abortion may be found in Michael J. Gorman, *ABORTION & THE EARLY CHURCH: CHRISTIAN, JEWISH & PAGAN ATTITUDES IN THE GRECO-ROMAN WORLD* (1982).

<sup>29</sup> For example, Jesus’ disciples rebuked parents for “bringing babies to Jesus to have him touch them.” *Luke* 18:15. But “Jesus called the children to him and said, ‘Let the little children come to me, and do not hinder them, for the kingdom of God belongs to such as these.’” *Luke* 18:16-17. “And he took the children in his arms, put his hands on them and blessed them.” *Mark* 10:16. When the disciples asked Jesus who was greatest in the Kingdom of Heaven, he responded, “[W]hoever humbles himself like this child is the greatest in the kingdom of heaven. And whoever welcomes a little child like this in my name welcomes me.” *Matthew* 18:4-5. Jesus then warned, “But if anyone causes one of these little ones who believe in me to sin, it would be better for him to have a large millstone hung around his neck and to be drowned in the depths of the sea.” *Matthew* 18:6. (Citations are to the New International Version.)

When Elizabeth heard Mary's greeting, the baby leaped in her womb, and Elizabeth was filled with the Holy Spirit. In a loud voice she exclaimed: "Blessed are you among women, and blessed is the child you will bear! But why am I so favored that the mother of my Lord should come to me? As soon as the sound of your greeting reached my ears, the baby in my womb leaped for joy."

*Luke* 1:41-45. In this passage, an adult woman acknowledges the unborn Jesus' spiritual status as her Lord, while the unborn John the Baptist "leap[s] for joy" at the sound of Mary's voice.

The Christian belief is also rooted in the Bible's foundational teaching that each human is created in, and so bears, God's own image: "So God created man in his own image, in the image of God he created him; male and female he created them." *Genesis* 1:27. The psalmist King David praised God, saying: "[F]or you created my inmost being; you knit me together in my mother's womb. I praise you because I am fearfully and wonderfully made." *Psalms* 139:13-14. The prophet Jeremiah records God telling him that "[b]efore I formed you in the womb I knew you, before you were born I set you apart." *Jeremiah* 1:5. See *Isaiah* 49:1 ("Before I was born the Lord called me.")

The Scriptures' prohibition on the taking of human life rests in part on the teaching that humans are made in God's image. In the first book of the Bible, *Genesis* 9:6, God prohibits the shedding of another human's blood "for in the image of God has God made man." Man's likeness to God undergirds ethical teaching in the New Testament as well, for example, when unkind speech is

condemned: “With the tongue we praise our Lord and Father, and with it we curse human beings, who have been made in God’s likeness.” *James* 3:9. The Sixth Commandment instructs, “You shall not murder.” *Exodus* 20:13; *Deuteronomy* 5:17.

A recurrent scriptural injunction is to choose life rather than death. In one such passage, God explains that He has “set before you life and death, blessings and curses. Now choose life, so that you and your children may live and that you may love the Lord your God, listen to his voice, and hold fast to him.” *Deuteronomy* 30:19-20.

**B. Various Christian faith traditions affirm that each individual human life is a unique moral being from conception.**

These biblical passages have been understood by many Christian faith traditions to signify that the moral value of every human life begins at conception. Consequently, participation in the use of drugs that end life after conception, such as Plan B and *ella*, contravene the teaching that each individual human life is a unique moral being from conception. It is widely known 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).

For example, in recent testimony before Congress, the President of the Lutheran Church—Missouri Synod “object[ed] to the use of drugs and procedures used to take the lives of unborn children,” such as *ella* and Plan B, which “violates our stand on the biblical teaching of the sanctity of life, which is a matter of faith and conscience.”<sup>30</sup> Similarly, the medical director at a Reformed Christian college testified that its health clinic’s medical staff “write prescriptions that include contraception for a variety of reasons, including the prevention of pregnancy. However, abortifacient agents are not prescribed, nor are they covered in our health care plan. The advocacy of these agents is profoundly inconsistent with the belief system of our college and our religion.”<sup>31</sup> The senior vice president for a university affiliated with Churches of Christ similarly related its view that *ella* and

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<sup>30</sup> *Lines Crossed: Separation of Church and State: Has the Obama Administration Trampled on Freedom of Religion and Freedom of Conscience?: Hearing Before the H. Comm. on Gov’t Oversight*, 112<sup>th</sup> Cong. (Feb. 16, 2012) (statement of Rev. Dr. Matthew C. Harrison, President, Lutheran Church -- Missouri Synod), available at [http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12\\_Full\\_HC\\_Mandate\\_Harrison.pdf](http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12_Full_HC_Mandate_Harrison.pdf) (last visited Nov. 16, 2012).

<sup>31</sup> *Id.* (statement of Laura Champion, M.D., Medical Director and Physician, Calvin College), available at <http://oversight.house.gov/wp-content/uploads/2012/03/2-16-12-Full-Champion-FINAL.pdf> (last visited Nov. 16, 2012).

Plan B act as abortifacients that destroy human life in violation of the university's religious beliefs.<sup>32</sup>

The president of a Baptist university testified that the university “believe[s], based on the Bible, that life begins at conception” and that the Baptist “faith and the most recent science tells us that these drugs cause abortions” and “interfere with a human embryo.”<sup>33</sup> In a 2003 resolution, the Southern Baptist Convention declared that “[t]he Bible affirms that the unborn baby is a person bearing the image of God from the moment of conception.”<sup>34</sup> The Convention reiterated that its confessional statement, *The Baptist Faith and Message*, “affirms that children ‘from the moment of conception, are a blessing and heritage from the Lord’; and further affirms that Southern Baptists are mandated by Scripture to ‘speak on behalf of the unborn and contend for the sanctity of all human life from conception

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<sup>32</sup> *Id.* (statement of Dr. Allison Dabbs Garrett, Senior Vice President for Academic Affairs, Oklahoma Christian University), *available at* [http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12\\_Full\\_HC\\_Mandate\\_Garrett.pdf](http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12_Full_HC_Mandate_Garrett.pdf) (last visited Nov. 16, 2012).

<sup>33</sup> *Id.* (statement of Dr. Samuel Oliver, President of East Texas Baptist University), *available at* [http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12\\_Full\\_HC\\_Mandate\\_DubOliver.pdf](http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12_Full_HC_Mandate_DubOliver.pdf) (last visited Nov. 16, 2012).

<sup>34</sup> Southern Baptist Convention Resolution, *On Thirty Years of Roe v. Wade*, June 2003, *available at* <http://sbc.net/resolutions/amResolution.asp?ID=1130> (last visited Nov. 13, 2012).



to natural death.”<sup>35</sup> The Convention’s Ethics and Religious Liberty Commission has described *ella* and Plan B as “destroy[ing] a developing human being prior to, or even after, implanting in the mother’s womb.”<sup>36</sup>

In its Statement of Faith, the American Anglican Council affirms that “[a]ll human life is a sacred gift from God and is to be protected and defended from conception to natural death.”<sup>37</sup>

While Protestants and Catholics typically may part company on the permissibility of contraceptive use solely to prevent conception, many Protestants share the Catholic understanding that Plan B and *ella* unacceptably act to end human life. In 2008, Pope Benedict XVI approved the *Instruction Dignitas Humanae on Certain Bioethical Questions* prepared by the Church’s Congregation for the Doctrine of the Faith, which begins: “The dignity of a person must be recognized in every human being from conception to natural death.”<sup>38</sup> The *Instruction* further imparts:

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<sup>35</sup> *Id.*

<sup>36</sup> Ethics and Religious Liberty Commission of the Southern Baptist Convention, *On the Obama Administration’s Abortion Rule*, Feb. 7, 2012, available at <http://erlc.com/documents/pdf/20120207-landduke-abortion-hhs.pdf> (last visited Nov. 13, 2012).

<sup>37</sup> <http://www.americananglican.org/statement-of-faith/> (last visited Nov. 13, 2012).

<sup>38</sup> [http://www.vatican.va/roman\\_curia/congregations/cfaith/documents/](http://www.vatican.va/roman_curia/congregations/cfaith/documents/)

Alongside methods of preventing pregnancy which are, properly speaking, contraceptive, that is, which prevent conception following from a sexual act, there are other technical means which act after fertilization, when the embryo is already constituted, either before or after implantation in the uterine wall. . . . [A]nyone who seeks to prevent the implantation of an embryo which may possibly have been conceived and who therefore either requests or prescribes such a pharmaceutical, generally intends abortion.<sup>39</sup>

Pope Benedict XVI had previously reaffirmed the sanctity of human life from conception, including in the pre-implantation stage.<sup>40</sup> In an *Instruction* approved by Pope John Paul II, the Congregation earlier had affirmed that a “human being must be respected – as a person – from the very first instant of his existence.”<sup>41</sup>

In its guidance for Catholic health care workers, *Ethical and Religious Directives for Catholic Health Care Workers*, the United States Conference of Catholic Bishops teaches that “[e]very procedure whose sole immediate effect is

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rc\_con\_cfaith\_doc\_20081208\_dignitas-personae\_en.html (last visited Nov. 13, 2012).

<sup>39</sup> *Id.* at ¶ 23.

<sup>40</sup> Speech to the 12th General Assembly of the Pontifical Academy of Life, [www.vatican.va/holy\\_father/benedict\\_xvi/speeches/2006/february/documents/hf\\_b-en-xvi\\_spe\\_20060227\\_embrione-umano\\_en.html](http://www.vatican.va/holy_father/benedict_xvi/speeches/2006/february/documents/hf_b-en-xvi_spe_20060227_embrione-umano_en.html) (last visited Nov. 13, 2012).

<sup>41</sup> Congregation for the Doctrine of the Faith, *Instruction for Respect for Human Life in its Origin and on the Dignity of Procreation Replies to Certain Questions of the Day* (1987), available at [http://www.vatican.va/roman\\_curia/congregations/cfaith/documents/rc\\_con\\_cfaith\\_doc\\_19870222\\_respect-for-human-life\\_en.html](http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html) (last visited Nov. 18, 2012).

the termination of pregnancy before viability is an abortion, which, in its moral context, includes the interval between conception and implantation of the embryo.”<sup>42</sup> Leading Catholic legal scholar John Garvey, President of Catholic University of America, testified before Congress that the Church teaches “that abortion is a grave wrong because ‘[h]uman life must be respected and protected absolutely from the moment of conception.’”<sup>43</sup>

Furthermore, the Catholic bishops’ *Ethical Directives* provide that: “Catholic health care institutions are not to provide abortion services, even based upon the principle of material cooperation.”<sup>44</sup> The Pope has urged Catholic pharmacists to stand for the right “not to collaborate either directly or indirectly by

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<sup>42</sup> United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Workers*, ¶ 45 (5<sup>th</sup> ed., Nov. 17, 2009) (“*Ethical Directives*”), available at <http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf> (last visited Nov. 16, 2012).

<sup>43</sup> See *supra* note 30 (statement of John Garvey, President of Catholic University of America, at 4, quoting Catechism of the Catholic Church 2270), available at [http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12\\_Full\\_HC\\_Mandate\\_Garvey\\_Complete.pdf](http://oversight.house.gov/wp-content/uploads/2012/02/2-16-12_Full_HC_Mandate_Garvey_Complete.pdf) (last visited Nov. 16, 2012).

<sup>44</sup> *Ethical Directives*, ¶45, available at <http://www.ncbcenter.org/document.doc?id=147> (last visited Nov. 16, 2012).

supplying products for the purpose of decisions that are clearly immoral such as, for example, abortion or euthanasia.”<sup>45</sup>

By no means intended to be comprehensive, these examples illustrate that the Catholic Church and many Protestant Christian denominations including Lutheran, Reformed, Baptist, and Anglican traditions, share a common understanding that human life should be respected from the moment of conception. The Appellee Pharmacists reasonably rely on both science and religion to conclude that each individual human life is a unique moral being to be protected and respected from conception.

### **III. Because the Constitution Constrains Government Officials from Determining the Truth or Falsity of Sincerely Held Religious Beliefs, the Courts Must Accept a Religious Claimant’s Beliefs as True for Purposes of Adjudicating a Religious Liberty Claim.**

The Pharmacists’ beliefs regarding the mechanisms of action of Plan B and *ella* are based upon the current scientific information. The Pharmacists’ religious understanding that each individual human life is a unique moral being from conception is rooted in Christian tradition and accords with many Christian denominations’ understanding that human life begins at conception and that Plan B and *ella* destroy that unique individual life.

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<sup>45</sup> *Address of His Holiness Benedict XVI to Members of the International Congress of Catholic Pharmacists* (Oct. 29, 2007), available at [http://www.vatican.va/holy\\_father/benedict\\_xvi/speeches/2007/october/documents/hf\\_ben-xvi\\_spe\\_20071029\\_catholic-pharmacists\\_en.html](http://www.vatican.va/holy_father/benedict_xvi/speeches/2007/october/documents/hf_ben-xvi_spe_20071029_catholic-pharmacists_en.html) (last visited Nov. 17, 2012).

Even if the Pharmacists' beliefs were not anchored in current scientific information, or firmly held by other Christians, the courts would still be required to defer to the pharmacists' own understandings of the tenets of their religious faith. It is axiomatic that the Constitution prohibits the courts from determining "[t]he truth or verity of . . . religious doctrines or beliefs." *Ballard*, 322 U.S. at 86; *see Callahan*, 658 F.2d at 685. In establishing this rule, the Supreme Court explained that "the First Amendment precludes" such an inquiry because "the law knows no heresy, and is committed to the support of no dogma." *Ballard*, 322 U.S. at 86 (quoting *Watson v. Jones*, 13 Wall. 679, 728 (1871)). "When the triers of fact undertake" to determine the truth of religious doctrines or beliefs, "they enter a forbidden domain." *Id.* at 87.

"Freedom of thought, which includes freedom of religious belief, is basic in a society of free men." *Id.* at 86 (citing *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943)). For that most basic of reasons, religious individuals, such as the Pharmacists here, "may believe what they cannot prove" and "may not be put to the proof of their religious doctrines or beliefs." *Id.* at 87. This freedom of thought and religious beliefs "embraces *the right to maintain theories of life and of death* and of the hereafter which are rank heresy" to others. *Id.* at 86 (emphasis added).

But even if the Pharmacists' beliefs were not eminently reasonable and well-grounded, they would nonetheless be protected because "religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection." *Thomas*, 450 U.S. at 714; *see also Zimmerman*, 514 F.3d at 853–54. Religious beliefs are protected even if they are but recently adopted. *Hobbie v. Unemployment Appeals Comm'n of Fla.*, 480 U.S. 136, 144 (1987). They are protected whether they are "derived from revelation, study, upbringing, gradual evolution, or some source that appears entirely incomprehensible." *Callahan*, 658 F.2d at 687. "Courts should not undertake to dissect religious beliefs" even when "the believer admits that he is 'struggling' with his position or because his beliefs are not articulated with the clarity and precision that a more sophisticated person might employ." *Thomas*, 450 U.S. at 715.

Of course, the Appellee Pharmacists have coherently explained their objections, grounding them in both science and faith. Protection of those beliefs does not "turn upon a judicial perception of the particular belief or practice in question." *Id.* at 714. The fact that some other religious persons, even other Christians, may differ with their position does not alter the First Amendment's protection of the Pharmacists' religious beliefs. As the Supreme Court has observed, "[i]ntrafaith differences . . . are not uncommon among followers of a

particular creed, and the judicial process is singularly ill equipped to resolve such differences in relation to the Religion Clauses.” *Id.* at 715.

Quite simply, “[c]ourts are not arbiters of scriptural interpretation.” *Id.* at 716. At bottom, “[p]articularly in this sensitive area, it is not within the judicial function and judicial competence to inquire whether” the Pharmacists or other Christians with different religious understandings “more correctly perceive[] the commands of their common faith.” *Id.* See *Frazee v. Ill. Dept. of Emp’t Sec.*, 489 U.S. 829, 833–834 (1989).

Of course, the courts may appropriately assess whether religious claimants’ *sincerely* hold their religious beliefs. See, e.g., *Shakur v. Schriro*, 514 F.3d 878, 885 (9th Cir. 2008). But the court below correctly found that the Pharmacists hold “the sincere religious belief that life begins at conception” and that “emergency contraceptives Plan B and *ella* . . . can also prevent a fertilized egg from adhering to the wall of the uterus (implanting).” *Stormans v. Selecky*, 844 F. Supp. 2d 1172, 1176 (W.D. Wash. 2012). The court below found that the pharmacists “are Christians who believe that all of human life is uniquely and inherently precious because it is created by God in His image” and that “dispensing Plan B or *ella* constitutes direct participation in the destruction of human life.” *Stormans v. Selecky*, 854 F. Supp. 2d. 925, 962 (W.D. Wash. 2012) (Finding No. 149). For that

reason, the Pharmacists’ “religious beliefs prevent them from stocking or delivering Plan B or *ella*.” *Id.* The court also found that:

Plaintiffs' religious beliefs prevent them from taking part in the destruction of innocent human life, and Plaintiffs believe that human life begins at the moment of fertilization. Plaintiffs have reviewed the labeling, FDA directives and other literature regarding the mechanism of action of Plan B and *ella* (“emergency contraceptives”) and believe that emergency contraceptives can prevent implantation of a fertilized ovum. Accordingly, Plaintiffs' religious beliefs forbid them from dispensing these drugs.

*Id.* at 932 (Finding No. 11).<sup>46</sup> The court below correctly deferred to the Pharmacists’ own understanding of their religious beliefs.

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<sup>46</sup> This conclusion accords with other courts’ treatment of pharmacists’ religious consciences regarding Plan B and *ella*. See, e.g., *Vandersand v. Wal-Mart Stores, Inc.*, 525 F. Supp. 2d 1052, 1057 (C.D. Ill. 2007); *Menges v. Blagojevich*, 451 F. Supp. 2d 992 (C.D. Ill. 2006); *Morr-Fitz v. Quinn*, --- N.E.2d ---, 2012 IL App 4<sup>th</sup> 110,398 \*1-2, 5-6 (Ill. App. Ct., Sept. 22, 2012) (“The individual plaintiffs believe life begins at conception, emergency contraception may act as an abortifacient, and the dispensing of such medication is against their religious beliefs.”)



## CONCLUSION

For the reasons stated herein and for the reasons stated in Appellees' brief, *Amici* respectfully request that this Court affirm the District Court's permanent injunction.

Respectfully submitted,

/s/ Dorinda C. Bordlee

Kimberlee Wood Colby  
Center for Law & Religious Freedom  
CHRISTIAN LEGAL SOCIETY  
8001 Braddock Road, Suite 302  
Springfield, VA 22151  
Tel: (703) 894-1087  
Fax: (855) 257-9801

Nikolas T. Nikas  
Dorinda C. Bordlee  
*Counsel of Record*  
BIOETHICS DEFENSE FUND  
6811 E. Voltaire Avenue  
Tel: (480) 483-3597  
Fax: (480) 483-3658

*Counsel for Amici Curiae*

Dated: November 20, 2012

## CERTIFICATE OF COMPLIANCE

I hereby certify that:

This brief complies with the typeface requirement of Fed. R. App. P. 32(a)(7)(B) because it contains 5031 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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/s/ Dorinda C. Bordlee

Dated: November 20, 2012

## CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on November 20, 2012.

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/s/Dorinda C. Bordlee  
Dorinda C. Bordlee  
Counsel for *Amici Curiae*