No. 15-862

In The Supreme Court of the United States

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

Petitioners,

v.

JOHN WIESMAN, Secretary of the Washington State Department of Health, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF *AMICUS CURIAE* OF AMERICAN ASSOCIATION OF PROLIFE OBSTETRICIANS & GYNECOLOGISTS, ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, CATHOLIC MEDICAL ASSOCIATION, CHRISTIAN MEDICAL ASSOCIATION, AND CHRISTIAN PHARMACISTS FELLOWSHIP INTERNATIONAL IN SUPPORT OF PETITIONERS

DENISE M. BURKE
AMERICANS UNITED FOR LIFE
655 15th Street NW, Suite 410
Washington, DC 20005
Tel: (202) 289-1478
Email:
Denise.Burke@AUL.org

NIKOLAS T. NIKAS
DORINDA C. BORDLEE
Counsel of Record
BIOETHICS DEFENSE FUND
3312 Cleary Avenue
Metairie, LA 70002
Tel: (504) 231-7234
Email:
DBordlee@BDFund.org

Counsel for Amici Curiae AAPLOG, et al.

February 4, 2016

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

QUESTION PRESENTED

Whether the Petitioner-Pharmacists' belief that it is immoral to participate in the taking of human life is informed by the *objective* medical science establishing (1) that a new, distinct, human being comes into existence at the moment of sperm-egg fusion, and (2) that the objectionable drugs, Plan B and *ella*, have the capacity to end the life of a new human being at the embryonic stage of development.

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are five national medical associations whose members include physicians, pharmacists and other healthcare professionals who have a profound interest in defending healthcare rights of conscience protected by the Free Exercise Clause of the First Amendment. *Amici* have an interest in this Court's restoration of the conscience rights of all healthcare professionals to refrain from practices that have the capacity to result in the taking of human life.

Their belief that it is gravely immoral to participate in the taking of human life is informed by the *objective* medical science establishing (1) that a new, distinct, human being comes into existence at the moment of sperm-egg fusion, and (2) that the objectionable drugs, Plan B and *ella*, have the capacity to end the life of a new human being at the embryonic stage of development.

Amici include the following medical associations, who set forth in this *amicus* brief the objective biological facts that inform the Petitioner-Pharmacists' moral values underlying their conscience objections:

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[1] No counsel for a party authored this brief in whole or in part. No person or entity other than *Amici*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. *Amici* file this brief with the required ten-day prior written notice, and with the written consent by all parties as evidenced by the blanket consent letter on file with the Clerk of Court.

American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") is a non-profit professional medical organization consisting of over 3,000 obstetrician-gynecologist members and associates. The American College of Obstetricians and Gynecologists (ACOG) recognizes AAPLOG as one of its largest special interest groups. AAPLOG exists to provide an evidence-based defense of both the pregnant mother and her unborn child. Members of AAPLOG affirm that physicians caring for pregnant women are responsible, as far as possible, for the well-being of both the mother and her unborn child at all stages of human development, from fertilization until completion of the postpartum period.

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

Catholic Medical Association ("CMA") is the largest association of Catholic physicians and healthcare professionals in the United States, with over 97 official guilds across the nation and over 2,000 members. CMA is a physician-led community of healthcare professionals that informs, organizes, and inspires its members, in steadfast fidelity to the teachings of the Catholic Church, to uphold the

principles of the Catholic faith in the science and practice of medicine. The CMA helps to educate the medical profession and society at large about issues in medical ethics, including healthcare rights of conscience, through its annual conferences and quarterly scholarly journal, *The Linacre Quarterly.* CMA members are challenged to be a voice of truth spoken in charity, to demonstrate how Catholic teachings on the human person, human rights and the common good intersect with and improve the science and practice of medicine, and to defend the sacredness and dignity of human life at all stages.

Christian Medical Association is a non-profit national organization of Christian physicians and allied healthcare professionals with over 17,000 members dedicated to a respect for the sanctity of human life, and to traditional, historical and Judeo-Christian medical ethics. In addition to its physician members, it also has associate members from a number of allied health professions, including nurses and physician assistants. Christian Medical Association provides up-to-date information on the legislative, ethical, and medical aspects of defending conscience in healthcare for its members and other healthcare professionals, as well as for patients, institutions, and students in training. Christian Medical Association manages the Freedom2Care.org coalition, which has 30,000 constituents to advance freedom of faith, conscience and speech.

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

Petitioner-Pharmacists believe that they have a religious and moral duty to refrain from the taking of human life. Informing this sincerely held religious belief and moral conviction that forms the basis of their conscientious objection is objective medical science establishing (1) that a unique, individual human being comes into existence at the moment of sperm-egg fusion (known as conception or fertilization), and (2) that the objectionable drugs, Plan B and *ella*, have the capacity to end the life of a new human being.

More specifically, the Petitioner-Pharmacists conscience objections are based on their sincerely held religious beliefs that each individual human being is entitled to dignity and protection from the moment of conception/fertilization until natural death. The Ninth Circuit erred by failing to recognize the distinction between the *objective* scientific facts that inform Petitioner-Pharmacists' conscience objections and their religious beliefs about the moral value of every human life from the moment that life begins, as determined by the scientific facts. This led the Ninth Circuit to erroneously reject the Pharmacists' asserted "right to refrain from taking human life" as not "objectively" established. *Stormans v. Wiesman*, 794 F.3d 1064, 1086 (9th Cir. 2015).

This brief on behalf of *Amici* medical associations presents the objective and scientifically supportable facts that inform the religious objections by the Petitioner-Pharmacists in regard to the stocking and dispensing of drugs that have the capacity to terminate the life of a human being at the embryonic stage of development as one possible mechanism of action – specifically the so-called "emergency contraceptive" drugs known as Plan B and *ella*.

The *amicus* brief begins by presenting a concise survey of human embryology and establishing that the biological humanity of a new embryonic human being begins at the moment of sperm-egg fusion (fertilization). The next section includes a review of the medical literature, FDA directives, and FDA-approved labeling on Plan B and *ella* – all of which

Petitioner-Pharmacists reasonably rely on to conclude that these drugs have the capacity to destroy the life of a human being at the earliest stages of development.

The Ninth Circuit erred in disregarding the district court's factual findings and adopting an exceptionally narrow interpretation of the Free Exercise Clause that upsets the longstanding national consensus on the issue of conscience protections in healthcare. *Amici* respectfully urge this Court to grant the petition for writ of *certiorari*.

ARGUMENT

I. The Pharmacists' Conscience Objections Regarding "Emergency Contraceptives" are Consistent with Objective Scientific Evidence.

As established in the district court, the Petitioner-Pharmacists are Christians who inform their consciences with objective scientific facts establishing that every individual human being comes into existence at the moment of fertilization, when the female ovum and male sperm unite to begin the unique and separate life of an individual human embryo. Their sincerely held religious belief in the inherent dignity of every human life thus leads them to ascribe moral value to pre-implantation human beings, such that their cooperation with the dispensation of drugs

capable of destroying those early human lives would be considered a grave evil.[2]

The Pharmacists' conscience objections that dispensing the so-called "emergency contraceptives" Plan B or *ella* constitutes immoral direct participation in the destruction of human life is based on the Pharmacists' objective 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* are known to have the capacity to prevent a new human being whose life began at fertilization from implanting in the uterine lining, thus causing the death of the new human embryo.

Despite the objectivity of the facts undergirding the Pharmacists' sincere religious beliefs and moral convictions, the Ninth Circuit disregarded the district court's factual findings and adopted an exceptionally narrow interpretation of the Free Exercise Clause that upsets the longstanding national consensus on the issue of conscience protections in healthcare.

More specifically, the Ninth Circuit failed to recognize the distinction between the "objective" scientific

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[2] The district court 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.*

facts that inform Petitioner-Pharmacists' conscience objections and the Pharmacists' religious beliefs about the moral value of every human life from the moment that life begins, as determined by the scientific facts. This led the Ninth Circuit to disregard the Pharmacists' asserted fundamental liberty interest in the "right to refrain from taking human life," and to erroneously dismiss it as not "objectively" established. *Stormans v. Wiesman*, 794 F.3d 1064, 1086 (9th Cir. 2015).[3] If left standing, this new standard would eviscerate the ability of Christian pharmacists and other healthcare providers to serve others via their vocations in accord with their sincerely held religious beliefs and moral convictions that respect the sanctity of human life.

A. Embryology establishes that the life of a new human being begins at fertilization, and that implantation is simply a later but necessary event instituted by the new human organism for the purpose of nourishment.

To clearly understand the basis of the Pharmacists' conscientious objection to dispensing the

[3] *See generally*, Brief *Amicus Curiae* of Christian Legal Society in support of Petitioners (to be filed Feb. 5, 2016) setting forth the argument that courts in free exercise cases do not second-guess the truth of the claimant's belief, and that at any rate the belief in this case is based on a reasonable conclusion from objective scientific evidence.

objectionable drugs, it is necessary to distinguish "fertilization" (which marks the beginning of an individual human life) from uterine "implantation" (a later event in the self-directed life of the human embryo that is the standard marker for determining that a woman is pregnant).

In their filings in the Ninth Circuit, the Respondents and Intervenors entangled and interchanged these two separate phases of development in the life of the individual human being in their attempt to cast the Pharmacists' conscience objections as unreasonable. To be clear, Petitioner-Pharmacists' religious beliefs and moral convictions attach to the moral status of the human life that comes into existence at the moment of fertilization, with the later event of implantation of the human embryo into the uterine wall simply being a necessary condition of that human being's continued life cycle.

1. Fertilization

As universally stated in medical embryology textbooks used in United States medical schools, each individual human life has its origin at the moment of fertilization. For example:

> **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**.

Keith L. Moore and T.V.N. Persuad, THE DEVELOPING HUMAN: CLINICALLY ORIENTED EMBRYOLOGY 11 (10th ed. 2015) (emphasis added).

> Fertilization, the uniting of egg and sperm, takes place in the oviduct. After the oocyte finishes meiosis, the paternal and maternal chromosomes come together, resulting in the formation of a zygote containing a single diploid nucleus. **Embryonic development is considered to begin at this point.**

Schoenwolf, G.C., LARSEN'S HUMAN EMBRYOLOGY 14 (5th ed. 2015) (emphasis added).

> Although life is a continuous process, fertilization . . . is a critical landmark because, under ordinary circumstances, **a new genetically distinct human organism is formed** when the chromosomes of the male and female pronuclei blend in the oocyte.

O'Rahilly, R. and Miller, F., HUMAN EMBRYOLOGY AND TERATOLOGY 8 (3rd ed. 2001) (emphasis added).

The universally accepted scientific fact about the beginning of each individual human life is also recognized in a myriad of peer-reviewed scientific literature. *See, e.g.,* Wilding, M., et al., *Maternal non-Mendelian inheritance of a reduced lifespan? A hypothesis*, 31(6) Journal of Assist. Reprod. Genet. 637-43 (Jun. 2014) ("**Since a new individual** is derived from the fusion of a single sperm and egg, we tested. . . .") (emphasis

added); Gadella B.M., Boerke A., *An update on post-ejaculatory remodeling of the sperm surface before mammalian fertilization*, 85(1) Theriogenology 113-24 (Jan. 1, 2016) ("The fusion of a sperm with an oocyte to form **new life** is a highly regulated event.") (emphasis added).[4]

Therefore, the objective scientific observation 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. The Petitioner-Pharmacists are simply acting in accord with the objective fact that "[b]ased on universally accepted scientific criteria" every human being begins his or her life "as a new cell, the human zygote, which

[4] *See also*, Kashir, J., Nomikos, M., Swann, K., Lai F.A., *PLCζ or PAWP: revisiting the putative mammalian sperm factor that triggers egg activation and embryogenesis*, 21(5) MOL. HUM. REPROD. 383-88 (May 2015) ("In mammals, egg activation is initiated by multiple cytosolic Ca(2+) transients (Ca(2+) oscillations) that are triggered following delivery of a putative sperm factor from the fertilizing sperm. The identity of this 'sperm factor' thus holds much significance, **not only as a vital component in creating a new life**, but also for its potential therapeutic and diagnostic value in human infertility.") (emphasis added).

comes into existence at the moment of sperm-egg fusion, an event that occurs in less than a second."[5]

While no one objects to the destruction of ordinary human cells for biomedical research or any other purpose, the destruction of *human beings* to obtain biological material for research is a matter of grave moral and legal consequence.[6] As a matter of logic, there must be some non-arbitrary scientific criteria to determine when living human gamete cells give rise to a new individual human being.

These criteria are cogently presented in a white paper authored by Maureen Condic, Ph.D., *When Does Life Begin: A Scientific Perspective* (2008),[7] and

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[5] Condic, M.L., *When Does Human Life Begin? A Scientific Perspective* ix (Westchester Institute 2008), *available at* http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf. All internet citations throughout this brief were last checked January 28, 2016.

[6] *See* YUVAL LEVIN, IMAGINING THE FUTURE: SCIENCE AND AMERICAN DEMOCRACY (2008); Robert P. George and Christopher Tollefson, EMBRYO (2008); *see also* Albert R. Jonsen, THE BIRTH OF BIOETHICS 90-100 (1998), recounting the history of the 1974 legislation that created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged to conduct a "comprehensive study of the ethical, legal, and social implications of advances in biomedical research" involving human subjects. The Commission ultimately produced *The Belmont Report*, which became the basis for federal regulations at 45 C.F.R. 46, Subpart A "to cover all biomedical researchers who received federal funds for their work" including protection for human fetuses.

[7] *Supra*, n.5.

updated in 2014.[8] The Condic white paper provides a concise yet comprehensive survey of the foundational question of when, as a matter of developmental biology, the life of a new human being begins. The conclusions unambiguously support the factual premise underlying Pharmacists' conscience objections. After all, their objection to the challenged requirement to stock and dispense Plan B and *ella* are coherent only if the drugs are capable of taking the life of a human being and not a mere collection of human cells.

Specifically, the review of modern embryology found in the Condic white paper provides this Court with the objective conclusions of two central questions regarding the biological beginning of human life: (1) in the course of sperm-egg interaction, when is a new cell formed that is distinct from either sperm or egg? and (2) is this new cell a distinct individual human organism (i.e., a new human being), or merely a new kind of human cell?[9]

Based on universally accepted scientific criteria, the white paper sets forth the unequivocal conclusion that a new single-cell organism, the human zygote, comes into existence at a precise moment of sperm-egg fusion, an event that occurs in less than a second.

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[8] *See also*, Condic, M.L., *When Does Human Life Begin? The Scientific Evidence and Terminology Revisited*, 8 UNIV. OF ST. THOMAS JOURNAL OF LAW AND PUBLIC POLICY 44, 46 (2014), *available at* https://www.stthomas.edu/media/schooloflaw/pdf/jlpp/volume8no1/CondicArticle.pdf.

[9] *Id.* at 5.

Upon formation, the human zygote immediately initiates a complex sequence of events that establish the molecular conditions required for its own self-directed development. The behavior of the one-cell human embryo and its molecular composition are radically unlike that of either sperm or egg separately, and are characteristic of a human organism.[10]

As the human embryo matures over the next hours and days, it continues to meet the distinguishing feature of an organism or being: self-directed interaction of parts in the context of a coordinated whole.[11] In contrast, collections of human cells (such as skin cells) carry on the activities of cellular life, yet fail to exhibit the coordinated interactions directed towards any higher level of organization that are unique to a human organism. Unlike a human embryo, collections of skin or other somatic cells do not establish the complex, interrelated cellular structures (tissues, organs, and organ systems) that exist in a whole, living human being.[12]

Thus, from the beginning, "the human embryo is a living, individuated human being. 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

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[10] *Id.* at 7.

[11] *Id.* at 6.

[12] *Id.*

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."[13]

In addition to scientists and developmental biologists, other prominent Jewish and Christian theologians, philosophers and scholars have recognized that a human embryo from the moment of fertilization 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.[14]

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[13] Expert Report of Maureen L. Condic, as quoted in *Planned Parenthood of Ind. v. Comm'r*, 794 F.Supp.2d 892, 916-17 (S.D. Ind. 2011).

[14] 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/1995/01/001-the-inhuman-use-of-human-beings.

The Ramsey Colloquium signatories include Leon R. Kass, M.D., who was at that time with the University of Chicago, Committee on Social Thought, as well as Hadley Arkes, Amherst

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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.[15] Uterine implantation is necessary for the human embryo's continued development because it provides nourishment from surrounding maternal tissues.[16]

Thus, if a human embryo is unable to attach to the uterus due to the mechanism of the objectionable

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College; Matthew Berke, First Things; Gerard Bradley, Notre Dame Law School; Fr. James T. Burtchaell, Congregation of the Holy Cross; Fr. Francis Canavan, Fordham University; Rabbi David G. Dalin, West Hartford, CT; Midge Decter, Institute on Religion and Public Life; Thomas S. Derr, Smith College; Fr. Ernest Fortin, Boston College; Jorge Garcia, Rutgers University; Rabbi Marc Gellman, Dix Hills, NY; Robert P. George, Princeton University; Mary Ann Glendon, Harvard Law School; Stanley Hauerwas, Duke University; John Hittinger, Professor of Philosophy, CO; Russell Hittinger, Catholic University of America; Rev. Robert W. Jenson, St. Olaf College; Ralph McInerny, University of Notre Dame; Fr. Richard John Neuhaus, Institute on Religion and Public Life; Rabbi David Novak, University of Virginia; Michael Novak, American Enterprise Institute; James Nuechterlein, First Things; David Singer, American Jewish Committee; George Weigel, Ethics and Public Policy Center; and Robert L. Wilken, University of Virginia. Institutional affiliations given for identification purposes only.

[15] *See* embryology textbooks cited in Section A(1), *supra*.

[16] *See, e.g.*, Burton, G.J., et al., *Nutrition of the human fetus during the first trimester – a review*, PLACENTA, Suppl. A:S70-7 (Apr. 2001).

drugs, the human embryo, now one week old, will not have the environment necessary to provide for continued nourishment and growth. 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 being at the embryonic stage of development any less human when a drug prevents the embryo's nourishment that can only be received in the environment of uterine implantation.

The Pharmacists' offer of proof in the district court included an expert report of Bruce M. Carlson, M.D., Ph.D., a University of Michigan medical professor and author of two widely used textbooks on embryology. Dr. Carlson's report provides rebuttal to Intervenors' expert report of Dr. David Grimes, whose statements focused on whether emergency contraception causes post-*implantation* abortion.[17] Dr. Grimes' statements were found by Dr. Carlson to "miss the point of the plaintiffs' [Petitioner-Pharmacists'] 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

[17] Expert Report of Dr. David A. Grimes (Sept. 26, 2008) (Intervenors' Offer of Proof, Doc. 493-1, at 2-9).

> embryo has already been worthy of protection for approximately six days.[18]

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."[19]

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 Petitioner-Pharmacists 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 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/conception.

This is because the FDA's relevant criterion is whether the drugs can work by preventing "pregnancy" – a term that describes the state of the woman

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[18] Expert Report of Dr. Bruce Coleman (Oct. 30, 2008) (Plaintiffs' Offer of Proof Regarding Mechanism of Action of Emergency Contraceptives Related to their Religious Beliefs, Doc. 495 at 18-26).

[19] *Id.* at 18.

– which they define as beginning at "implantation," not fertilization.[20]

Moreover, as will be discussed below, with the approval of the drug *ella* in 2010, the FDA definition of "contraception" now encompasses a drug or device that has the capacity to 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. . . ."[21] In other words, Dr. Trussell, although an advocate of "emergency contraception,"[22] understands that the scientific difference between a drug that prevents fertilization/conception of a new human embryo and one that may also prevent implantation of that human embryo into the uterine lining is significant enough that it must be disclosed to a potential user.

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[20] 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.

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

[22] *See* Profile of Dr. James Trussell, *available at* https://www.princeton.edu/~trussell/ (Trussell "has actively promoted making emergency contraception more widely available. . . .").

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.[23]

Moreover, a relatively new drug classified by the FDA as an "emergency contraception" – Ulipristal Acetate (*ella*) – is actually an abortion-inducing drug, because it can cause the death of a human embryo after implantation, the accepted marker for the beginning of pregnancy. The mechanisms of action of each common type of "emergency contraception" are discussed in more detail below.

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

In 1999, the FDA first approved the distribution of "emergency 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.[24] Although called "contraception," the

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

[24] In 2013, the Food and Drug Administration approved Plan B as a nonprescription drug for women who have the potential to bear children, pursuant to a federal court ruling in a suit brought by the Center for Reproductive Rights that was not

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FDA's labeling acknowledges that Plan B can prevent implantation of a human embryo.[25] 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[26] from attaching to the womb (implantation)**.[27]

On its website, the same explanation is provided by Duramed Pharmaceuticals, the manufacturer of Plan B One-Step:

> HOW PLAN B ONE-STEP® WORKS
>
> . . . .

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appealed by the Obama administration. This ruling meant that teenagers could purchase Plan B over the counter, without a prescription. Before this ruling, women under age 17 needed a prescription to buy Plan B. FDA News Release, *FDA Approves Plan B One-Step emergency contraception for use without a prescription for all women of child-bearing potential* (Jun. 20, 2013), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm.

[25] Plan B Approved Labeling, 12.1 *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf (Plan B "may inhibit implantation (by altering the endometrium).").

[26] *Amici* medical associations emphasize that "fertilized egg" is a non-scientific euphemism for the early human embryo.

[27] 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 (emphasis added).

It works mainly by:

Stopping the release of an egg from the ovary

It is possible that Plan B One-Step® may also work by:

Preventing fertilization of an egg (the uniting of sperm with the egg)

Preventing attachment (implantation) to the uterus (womb)[28]

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."[29]

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[28] Duramed Pharmaceuticals, *How Plan B One-Step Works* (2016), *available at* http://www.planbonestep.com/howitworks.aspx (emphasis added).

[29] D.J. Harrison & J.G. Mitroka, *Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone*

(Continued on following page)

This means that though labeled as "contraception," *ella* works the same way as RU-486. By blocking progesterone – a hormone necessary to build and maintain the uterine wall during pregnancy – an SPRM can either prevent a 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 human embryo implants in the uterus.[30]

i. FDA labeling and directives

The FDA's own labeling notes that *ella* may "affect implantation,"[31] and advises against the use of *ella* in the case of known or suspected pregnancy. A study funded by *ella*'s manufacturer, HRA Pharma, explains that SPRMs (drugs that block the hormone progesterone) "including ulipristal acetate" can "impair

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Receptor Modulators and Misoprostol in Reproductive Health, 45 ANNALS PHARMACOLOTHERAPY 115, 115-19 (2011).

[30] *See* Gacek, C., *Conceiving Pregnancy*, *supra* note 19. 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.

[31] *ella* Labeling Information, 12.1, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.

implantation."[32] While the study theorizes that the dosage used in its trial "might be too low to inhibit implantation,"[33] it states affirmatively "an additional postovulatory mechanism of action," e.g., impairing implantation, "cannot be excluded."[34]

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."[35]

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

[33] *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.*

[34] *Id.*

[35] Ralph P. Miech, *Immunopharmacology of Ulipristal as an Emergency Contraceptive*, 3 INT'L J. WOMEN'S HEALTH 391-97 (2011).

In fact, *ella*'s deadliness is confirmed by its high rate of "effectiveness." Notably, at the FDA advisory panel meeting for *ella*, panelist Dr. Scott Emerson, a professor of biostatistics at the University of Washington, raised the point that the low pregnancy rate for women taking *ella* four or five days after intercourse suggests that the drug must have an "abortifacient" quality.[36]

In short, the FDA-approved "contraceptive" *ella* can work by ending an established pregnancy – meaning a pregnancy as defined by the stage of embryonic development in which the embryo implants by its own self-directed, self-organizing action into the uterine lining.[37]

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[36] *See* Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs 157-58 (Jun. 17, 2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf.

[37] Despite the objective science as established by both the manufacturers and other supporters of "emergency contraceptive," the ideological denial of the drugs' mechanisms of action persist. For example, the 2012 opening brief of the Intervenors at the appellate level suggested that the Pharmacists' 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." Opening Brief of Intervenors-Appellants Judith Billings et al., at 14 n.1 (emphasis added).

Intervenors leveled this accusation based on a *New York Times* article which itself admits that the Federal Drug Administration

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ii. Peer-reviewed medical literature

Studies confirm that *ella* is toxic to a human embryo.[38]

Beyond review articles, there are four important original research articles examining the effects of dose- and time-specific provision of *ella* (also known as UPA, and CBD-2914 in the medical literature), all confirming that *ella* is toxic to a human embryo.[39]

(FDA) requires the drugs' product packaging materials to reveal the capacity of "emergency contraception" to prevent implantation in the event fertilization occurs. 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 (Jun. 6, 2012), *available at* http://www.nationalreview.com/corner/301980/timess-convolution-facts-abortifacients-donna-harrison.

[38] *See, e.g.*, 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.

[39] Stratton, P., Hartog, B., Hajizadeh, N., Piquion, J., Sutherland, D., Merino, M., Lee, Y.J., and Nieman, L.K., *A Single Mid-Follicular Dose of CDB-2914, a New Antiprogestin, Inhibits Folliculogenesis and Endometrial Differentiation in Normally Cycling Women*, 15(5) HUMAN REPRODUCTION 1092-99 (2000); Passaro, M., Piquion, J., Mullen, N., et al., *Luteal phase dose response relationships of the antiprogestin CDB-2914 in normally cycling women*, 18(9) HUMAN REPRODUCTION 1820-27 (2003); Brache, V., Cochon, L., Jesam, C. et al., *Immediate Pre-Ovulatory Administration of 30 mg Ulipristal Acetate Significantly Delays Follicular Rupture*, 25(9) HUMAN REPRODUCTION 2256-63 (2010); Stratton, P., Levens, E., Hartog, B., et al., *Endometrial Effects of a Single Early Luteal Dose of the Selective Progesterone Receptor Modulator CDB-2914*, 93(6) FERTILITY AND STERILITY 2035-41

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These studies, which were cited by the manufacturer in its own FDA application, demonstrate that *ella* is capable of interfering with progesterone production by the ovary, needed for the woman's body to sustain the conditions needed for the human embryo's continued life. The studies confirm that *ella* interferes with the action of progesterone on the lining of the uterus, causing human embryos who have not yet implanted to be unable to do so, and further causing the death of human embryos who have implanted. [40]

CONCLUSION

The district court correctly deferred to the Petitioner-Pharmacists' own understanding of their sincerely held religious beliefs as informed by the objective scientific facts. The Ninth Circuit's decision reversing that decision sets a dangerous new precedent that disregards medical science and undermines the conscience rights of all healthcare professionals.

(Apr. 2010). CDB-2914 is a selective progesterone modulator similar in structure and function to UPA. *See* Passaro, et al., 2003, at 1821.

[40] For a more in depth analysis of these studies, *see* Brehany, J., Ph.D., *No consensus on ella*, 41(2) ETHICS & MEDICS (Feb. 2016), *available at* http://ncbcenter.org/document.doc?id=923 ("Below I question whether a relevant consensus exists and argue that the scientific evidence militates against, rather than in favor of, use of UPA/*ella* by Catholic providers.").

Amici medical associations respectfully urge this Court to grant the petition for writ of *certiorari*.

Respectfully submitted,

NIKOLAS T. NIKAS
DORINDA C. BORDLEE
Counsel of Record
BIOETHICS DEFENSE FUND
3312 Cleary Avenue
Metairie, LA 70002
Tel: (504) 231-7234
Email:
DBordlee@BDFund.org

DENISE M. BURKE
AMERICANS UNITED FOR LIFE
655 15th Street NW, Suite 410
Washington, DC 20005
Tel: (202) 289-1478
Email:
Denise.Burke@AUL.org

Counsel for Amici Curiae AAPLOG, et al.

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