No. 13-354

IN THE

Supreme Court of the United States

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,

Petitioners,

v.

HOBBY LOBBY STORES, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF OF *AMICI CURIAE* PHYSICIANS FOR REPRODUCTIVE HEALTH, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN SOCIETY FOR EMERGENCY CONTRACEPTION, ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS, AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, SOCIETY FOR ADOLESCENT HEALTH AND MEDICINE, AMERICAN MEDICAL WOMEN'S ASSOCIATION, NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH, SOCIETY OF FAMILY PLANNING, INTERNATIONAL ASSOCIATION OF FORENSIC NURSES, AMERICAN COLLEGE OF NURSE-MIDWIVES, JAMES TRUSSELL, SUSAN F. WOOD, DON DOWNING AND KATHLEEN BESINQUE IN SUPPORT OF PETITIONERS

B. ROBERT PILLER
JENNIFER BLASDELL
PHYSICIANS FOR REPRODUCTIVE HEALTH
55 West 39th Street,
Suite 1001
New York, NY 10018
(646) 366-1897

BRUCE H. SCHNEIDER
Counsel of Record
MICHELE L. PAHMER
STROOCK & STROOCK & LAVAN LLP
180 Maiden Lane
New York, NY 10038
(212) 806-5400
bschneider@stroock.com

Counsel for Amici Curiae

October 21, 2013

250178

TABLE OF CONTENTS

TABLE OF CITED AUTHORITIES

Page

CASES

STATUTES

OTHER AUTHORITIES

Page

Page

Cited Authorities

Page

Page

INTEREST OF *AMICI CURIAE*[1]

Amici curiae are physicians and other health care professionals with expertise in women's health, including reproductive health and contraception, with the common goals of disseminating current medical and scientific data concerning the method of action of various contraceptives that are frequently mischaracterized as abortificients and ensuring that the scientific distinction between contraceptives and abortifacients be recognized and preserved in judicial decisions on the issue.

Amici are cognizant that the public discourse on contraception generally, and emergency contraception in particular, is infused with misleading or charged rhetoric stemming from political or religious views. *Amici* seek to inform this Court of the objective scientific facts relevant to the method of action of the contraceptives at issue to aid this Court's determination as to whether to grant certiorari.

Physicians for Reproductive Health ("PRH") is a doctor-led national not-for-profit organization that relies upon evidence-based medicine to promote sound

---

1. Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part and no person other than *amici*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

Pursuant to Supreme Court Rule 37.2(a), *amici* also state that all parties were provided with ten-day written notice of their intent to file this brief and all parties have consented in writing to its filing.

reproductive health care policies. Comprised of physicians, PRH brings medical expertise to discussions of public policy on issues affecting reproductive health care and advocates for the provision of comprehensive reproductive health services as part of mainstream medical care. Ensuring the reasonable availability of contraceptives is one such aspect of comprehensive reproductive health care within PRH's objectives. As an organization of medical professionals, PRH is particularly sensitive to the need to ensure that public discourse concerning issues affecting reproductive health, as well as legislative and judicial decision-making, is based on medical and scientific facts and to prevent misinformation from forming the basis of reproductive health care policies. Based on its medical expertise, PRH seeks to highlight for the Court how certain FDA-approved contraceptives function and to dispel, based on scientific data, the notion that these contraceptives cause abortion and therefore are "abortifacients."

The American College of Obstetricians and Gynecologists (ACOG) is a non-profit educational and professional organization founded in 1951. With more than 57,000 members, ACOG is the leading professional association of physicians who specialize in the health care of women. ACOG's members represent approximately 90% of all board-certified obstetricians and gynecologists practicing in the United States. By virtue of the years of collective expertise of its physician members, ACOG recognizes that increased access to prescription contraceptives is an essential component of effective health care for women and their children.

The American Society for Emergency Contraception (ASEC) is a national organization which holds as its primary mission the promotion of access to and education about emergency contraception. ASEC supports collaboration among and represents a diverse group of stakeholders in the reproductive health community whose work includes a focus on emergency contraception. ASEC provides technical expertise to reproductive health organizations, including interpreting and explaining the scientific research about how emergency contraceptives work. ASEC's work is guided by a Steering Committee comprised of experts from leading reproductive health organizations.

The Association of Reproductive Health Professionals (ARHP) is a non-profit membership organization that was founded by Alan Guttmacher in 1963 as the education arm of Planned Parenthood. ARHP translates good science into practice by producing accredited, evidence-based programs for health care professionals across a broad range of sexual and reproductive health topics. ARHP is the only association offering continuing medical education designed for an inter-professional audience. ARHP is committed to increasing access to emergency contraception and co-manages the Not-2-Late website and hotline with James Trussell and Princeton's Office of Population Research.

The American Society for Reproductive Medicine (ASRM) is a non-profit, multidisciplinary organization with members in all 50 states and more than 100 countries worldwide. Founded in 1944, ASRM is dedicated to the advancement of the art, science, and practice of reproductive medicine. ASRM pursues its mission by

supporting research, providing professional and patient education, developing practice and ethical standards in the field, and engaging in advocacy. As an organization of physicians, scientists, and other healthcare providers, ASRM seeks to clarify how certain contraceptive methods operate to ensure that patients are able to receive the most appropriate, individualized contraceptive care.

The Society for Adolescent Health and Medicine (SAHM) was founded in 1968 and is a multidisciplinary organization committed to improving the physical and psychosocial health and well-being of all adolescents through advocacy, clinical care, health promotion, health service delivery, professional development and research. In its pursuit of optimal adolescent health and developmentally-appropriate health care, SAHM believes that scientific research provides the evidence base for effective health promotion as well as prevention and treatment of illness and injury. SAHM believes prevention of unintended adolescent pregnancy requires a multifaceted approach that includes primary and secondary prevention methods. Because access to emergency contraceptive methods are essential components of secondary prevention efforts, SAHM seeks to ensure the accuracy of information regarding these safe and effective medications.

The American Medical Women's Association (AMWA) is a multispecialty organization comprised of physicians, residents, medical students, and health care professionals. AMWA functions at the local, national, and international level by providing and developing leadership, advocacy, education, expertise, mentoring, and strategic alliances to advance women in medicine and improve women's health.

The National Association of Nurse Practitioners in Women's Health (NPWH) is a non-profit educational and professional organization that was established over 30 years ago and is the leading professional association of nurse practitioners who specialize in the health care of women. The mission of NPWH is to ensure the provision of quality health care to women of all ages by nurse practitioners and to protect and promote women's rights to make their own health care choices. NPWH continues to advocate for access to contraceptives and education about emergency contraception.

The Society of Family Planning (SFP) is an academic society of researchers, clinicians and educators dedicated to improving sexual and reproductive health. Among its other activities, SFP promotes scientifically sound research by funding studies on family planning and fosters the advancement of clinical care through the development of evidence-based clinical guidelines. SFP also advances the creation of family planning knowledge to inform public policy. SFP maintains that promoting the most current research findings and medically accurate information about contraception, including emergency contraception, is a critical part of improving sexual and reproductive health.

The International Association of Forensic Nurses (IAFN) is an international non-profit membership organization comprised of forensic nurses working around the world and other professionals who support and complement the work of forensic nursing. Forensic nursing is the practice of nursing at the intersection of the health and legal systems, including the care of victims of violence and sexual assault. IAFN is dedicated to the use of evidence-based forensic nursing practices and

advocates for the availability of emergency contraception to victims of sexual assault who choose to use it as a means of preventing pregnancy.

The American College of Nurse-Midwives, (ACNM) is the professional organization for certified nurse-midwives and certified midwives. ACNM leads the profession through education, clinical practice, research and advocacy. ACNM advocates on behalf of women and families, its members, and the midwifery profession to eliminate health disparities and increase access to evidence-based, quality cares.

James Trussell, Ph.D, is Professor of Economics and Public Affairs and Faculty Associate of the Office of Population Research at Princeton University. He is the author or co-author of more than 300 scientific publications, primarily in the area of reproductive health. His recent research has been focused in four areas: emergency contraception, contraceptive failure, the safety of contraception and abortion, and the cost-effectiveness of contraception. He has actively promoted making emergency contraception more widely available as an important step in helping women reduce their risk of unintended pregnancy; in addition to his research on this topic, he maintains an emergency contraception website (http://not-2-late.com) and designed and launched a toll-free emergency contraception hotline (1-888-NOT-2-LATE). Dr. Trussell received his B.S. degree in mathematics from Davidson College in 1971, a B.Phil. in economics from Oxford University in 1973, and a Ph.D. in economics from Princeton University in 1975. He is a senior fellow at the Guttmacher Institute, a member of the National Medical Committee of Planned Parenthood

Federation of America, and a member of the board of directors of the NARAL Pro-Choice America Foundation and the Society of Family Planning. He serves on the editorial advisory committees of Contraception and Contraceptive Technology Update.

Susan F. Wood, Ph.D., is associate professor of health policy at the George Washington University School of Public Health and Health Services where she directs the Jacobs Institute of Women's Health. Formerly, she was Assistant Commissioner of Women's Health at the FDA (2000-2005). She is both an expert in women's health, family planning and preventive services policy, and in FDA regulation. She has worked to support the scientific evidence and public health interest in women's health, family planning, and access to emergency contraception.

Don Downing, RPh, is a Clinical Professor at the University of Washington School of Pharmacy in Seattle. His major practice and training interests have included the development of the nation's first pharmacist-provided emergency contraception program and the first pharmacist-initiated on-going hormonal contraception services. In 2002 he was awarded the Washington State Pharmacists Association's Pharmacist of the Year Award and also the University of Washington School of Pharmacy's Alumni of the Year. In 2005 he was awarded the American Pharmacists Association's Academy of Pharmacy Practice and Management Distinguished Achievement Award for his efforts in contraception and other public health endeavors. In 2008 the Pharmacy Access Partnership named him Pharmacist Leader of the Year for his national work in improving contraceptive access.

Kathleen Besinque, Pharm.D., M.S.Ed., FASHP, FCSHP is an Associate Professor of Clinical Pharmacy and the Assistant Dean for Curriculum and Assessment at USC School of Pharmacy. She teaches in both the Doctor of Pharmacy program and the Academic Medicine program at USC. She received both a Doctor of Pharmacy degree and a Masters degree in Education from the University of Southern California and completed a residency in Ambulatory Care at the Veterans Affairs Outpatient Clinic in Los Angeles. Her clinical practice area is primary care women's health including emergency contraception and menopause therapies.

SUMMARY OF ARGUMENT

This Petition implicates several issues of national importance and the outcome of this case will affect countless Americans who obtain health insurance through their employers' group plan. This case arises at the intersection of several significant issues of widespread interest: health care, contraceptive coverage and the free exercise of religious belief. This case concerns the enforceability of an important provision of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat 119, which mandates that non-exempt employer group health plans provide preventive health services, including coverage of FDA-approved contraceptives (the "Mandate"). Respondents' challenge the Mandate and this Petition specifically addresses whether the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. 2000BB *et seq.,* allows a for-profit corporation to decline to provide its employees with the mandated contraceptive coverage based on the belief of the owner of the corporation that certain contraceptives prevent

implantation of a fertilized egg and that coverage of these contraceptives in the corporation's group health plan contravenes the owner's religious belief. The sincerity of the owner's belief that the use of such contraceptives would be wrong is not challenged.

However, as pointed out by the dissenting opinion of Chief Judge Briscoe, below, Respondents' *religious* objection to providing coverage for emergency contraceptives Plan B and ella, and for two intrauterine devices, ultimately is premised on Respondents' belief regarding a *scientific* matter; namely, their belief regarding how such contraceptives work. Petition App. at 131a-132a (noting that the connection between Respondents' religious beliefs and their objection to coverage of these contraceptives is "not one of religious belief, but rather of purported scientific fact, *i.e.*, how the challenged contraceptives operate to prevent pregnancy). Although Respondents' supposition as to the method of action of the challenged contraceptives form the basis of their challenge to the Mandate, the majority below declined to "wade into scientific waters here[.]"

In fact, Respondents' claim that Plan B and ella prevent implantation is not supported by current scientific data or by evidence in the record below. To the contrary, scientific research shows that Plan B and ella both function by inhibiting or postponing ovulation; they do not prevent fertilization or implantation. *See, e.g.,* K. Gemzell-Danielsson, *et al., Emergency Contraception—Mechanisms of Action,* 87 CONTRACEPTION 300, 305 (2013) ("Gemzell-Danielsson").

Equally unsupported is Respondents' characterization of any of the FDA-approved contraceptives or emergency contraceptives as "abortifacients." Petition App. at 5a (summarizing Respondents' objection to providing coverage for certain contraceptive services, including "drugs and devices that the plaintiffs believe to be abortifacients . . ."). Similarly, decisions in other lower courts addressing this same issue have also failed to preserve the scientific distinction between a contraceptive and an abortifacient, and have erroneously suggested that certain of the FDA-approved contraceptives that are covered by the Mandate are abortifacients. *See, e.g.*, *Conestoga Wood Specialties Corp. v. HHS*, 724 F.3d 377, 416 (3d Cir. 2013) ("the Hahns and Conestoga are being forced to pay for the offending contraceptives, including abortifacients . . ."); *Korte v. Sebelius*, No. 12-3841, 2012 WL 6757353, at *3 (7th Cir. Dec. 28, 2012) ("[t]he religious-liberty violation at issue here inheres in the coerced coverage of contraception, abortifacients, . . ."). Abortificient has a precise meaning in the medical and scientific community and it refers to the termination of a pregnancy. Contraceptives that prevent fertilization from occurring, or even prevent implantation, are simply not abortifacients regardless of an individual's personal or religious beliefs or mores.

As demonstrated herein, the weight of the scientific evidence establishes that the FDA-approved contraceptives and emergency contraceptive are not abortifacients. It is respectfully urged that the Court grant a writ of certiorari in this significant case and that any formulation of the issues for review accurately reflect the scientific record and maintain the proper distinction between a contraceptive and an abortifacient.

ARGUMENT

THE SCIENTIFIC EVIDENCE CONFIRMS THAT THE FDA-APPROVED FORMS OF EMERGENCY CONTRACEPTION ARE NOT ABORTIFACIENTS

As highlighted by Chief Judge Briscoe's opinion below, "there is no evidentiary support in the record for plaintiffs' allegations that the objected-to contraceptive drugs and devices actually have the potential to prevent implantation of fertilized eggs." Petition App. at 106a. And, as to this issue of science, not religious belief, "plaintiffs' allegations regarding the abortion-causing potential of the challenged drugs are subject not only to examination but evidentiary proof." *Id*. at 132a. First Amendment jurisprudence maintains a distinction between scientific facts which are verifiable, and matters of protected religious belief which are more personal. *See Founding Church of Scientology v. United States,* 409 F.2d 1146, 1164 (D.C. Cir. 1969) ("… in order to raise a religious defense to a charge of false statement …, the person charged with the alleged misrepresentation must have explicitly held himself out as making religious, as opposed to medical, scientific or otherwise secular, claims"), *on remand sub nom. United States v. Article or Device "Hubbard Electrometer,"* 333 F. Supp. 357, 362 (D.D.C. 1971) ("… the proof showed that many scientific claims permeate the writings and that these are not even inferentially held out as religious, either in their sponsorship or context."). As demonstrated below, there is a scientific distinction between a contraceptive and an abortifacient and the scientific record demonstrates that none of the FDA-approved contraceptives covered by the Mandate are abortifacients.

A. Contraceptives v. Abortifacients: the Difference Between Pregnancy Prevention and Pregnancy Termination

Understanding the difference between a contraceptive and abortifacient requires some familiarity with how various forms of contraception work to prevent pregnancy, which, in turn, requires a general understanding of certain biological processes leading to pregnancy. Fertilization occurs upon the fusion of a viable egg with viable sperm. Because sperm can remain viable in the female reproductive tract for approximately five days and an egg for up to one day, sexual intercourse can result in fertilization from five days before ovulation up to one day after. Following fertilization, the blastocyst (the fertilized egg) may implant into the lining of the uterus (the endometrium), which typically occurs, if at all, over the course of several days between 5-9 days following fertilization. A.J. Wilcox, *et al., Timing of Sexual Intercourse in Relation to Ovulation. Effects on Probability of Conception*, 333 New Eng. J. Med. 1517 (1995); D.B. Dunson, *et al*, *Day-Specific Probabilities of Clinical Pregnancy Based on Two Studies With Imperfect Measures of Ovulation*, 14 Hum. Reprod. 1835 (1999).[2] Pregnancy is established only upon the conclusion of such implantation. Obstetric-Gynecologic Terminology: With Section on Neonatology and Glossary of Congenital Abnormalities 299, 327 (E.G. Hughes, ed., F.A. Davis Co. 1972); *Statement on Contraceptive Methods* (Am. Coll. of

2. Not all blastocysts implant. The limited data available suggests that even under optimal conditions and timing, no more than 40% of blastocysts eventually implant in the endometrium. See K. Diedrich,*et al.*, *The Role of the Endometrium and Embryo in Human Implantation*, 13 Hum. Reprod. Update 365 (2007).

Obstetricians & Gynecologists, Wash., D.C., Jul. 1998). The scientific definition of pregnancy is also the legal definition of pregnancy, accepted by governmental agencies and all major U.S. medical organizations. *See, e.g.,* 45 C.F.R § 46.202 (recognizing pregnancy as "the period of time from implantation to delivery").

In the medical literature, a "contraceptive" refers to that which prevents fertilization of an egg or prevents implantation of a fertilized egg – in other words, it prevents a pregnancy from taking place. "Emergency contraception" (EC) refers to a drug or device that is used after intercourse, but before pregnancy, to prevent pregnancy from occurring. *See generally* Gemzell-Danielsson at 300 ("emergency contraception (EC) is defined as the use of any drug or device after an unprotected intercourse to prevent an unintended pregnancy"); *see also* H.B. Croxatto *et al., Mechanism of Action of Hormonal Preparations Used for Emergency Contraception: A Review of the Literature,* 63 CONTRACEPTION 111, 112 (2001) ("emergency contraception is used after coitus but before pregnancy has become established."). An "abortifacient," by contrast, works to terminate a pregnancy, which necessarily occurs after an embryo has implanted in the uterine lining. *See* COCHRANE LIBRARY, http://onlinelibrary.wiley.com/cochranelibrary/search/mesh/quick (search "Abortifacient Agents").[3]

3. Although Respondents and others may have differing personal views as to when life begins, the medical and scientific communities define pregnancy as beginning upon implantation. While personal beliefs may dictate individual choices and values, they cannot alter established scientific standards and terminology: abortion refers to the termination of a pregnancy. Thus, the term "abortifacient" refers to – and should only be used in connection with – drugs or devices that end a pregnancy, not those that prevent it.

EC is contraception that is effective within a specified window *after* intercourse to prevent pregnancy. EC works much the same way as traditional contraceptives, but provides protection after-the-fact in the event of contraception failure (such as a broken condom) or unprotected sex, including in the case of sexual assault. Plan B and ella are among the emergency contraceptives approved by the FDA.

B. FDA-Approved Emergency Contraceptives are not Abortifacients

Given the established scientific demarcation between contraceptives and abortifacients at the point of pregnancy – with contraceptives preventing pregnancy and abortifacients ending a pregnancy that has occurred - we turn to the specific mechanism of action of each of the approved emergency contraceptives as established by the medical and scientific literature. At the outset, we note that, as discussed below, there is no scientific evidence that emergency contraceptives available in the United States and approved by the FDA affect an existing pregnancy. Gemzell-Danielsson at 305. None, therefore, is properly classified as an abortifacient.

By way of explanation, there are two types of emergency contraceptive pills (ECPs) available in the United States: those containing levonorgestrel (LNG) and those containing ulipristal acetate (UPA). Plan B, Plan B One-Step, Next Choice One Dose and others are hormonal pills containing 1.5 mg LNG, a synthetic version of the naturally-occurring hormone progesterone. FDA, Labeling for Plan B One Step, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf ("Plan B Label"). LNG, which has long been approved

at lower dosage levels for use in ordinary contraceptives, has also been approved as emergency contraception since 1999 and is presently the most commonly used form of emergency contraception. Gemzell-Danielsson at 301. Ella, which came on the market more recently in 2010, is an oral pill containing 30 mg UPA, which acts on human progesterone receptors. As established by the weight of the scientific evidence, LNG and UPA function primarily, if not exclusively, by inhibiting ovulation, thereby preventing fertilization from occurring. *See id.* at 305.[4]

LNG EC has been widely studied, and current evidence shows that it works by preventing or disrupting ovulation, but is not effective after ovulation has already occurred. Indeed, if LNG EC were effective in preventing the implantation of a fertilized egg, pregnancy rates among women who took it after ovulation had occurred would most certainly be lower than the research indicates. *See* Noe at 491; N. Novikova *et al.*, *Effectiveness of Levonorgestrel Emergency Contraception Given Before or After Ovulation – A Pilot Study,* 75 CONTRACEPTION 112 (2007).[5]

---

4. Some studies have suggested that Plan B and/or ella increase cervical mucosal viscosity, which could impede the migration of sperm in the reproductive tract, or increase alkanization of the reproductive tract, which immobilizes sperm. These incidental effects of ECPs create an environment inhospitable to fertilization; they still do not have a post-fertilization effect. See, e.g., G. Noe *et al.*, *Contraceptive Efficacy of Emergency Contraception With Levonorgestrel Given Before or After Ovulation*, 84 CONTRACEPTION 486 (2011) ("Noe").

5. Progesterone inhibits ovulation, but once fertilization has occurred, it actually supports pregnancy. A.S. Penzias, *Luteal Phase Support*, 77 FERTILITY AND STERILITY 318 (2002).

UPA EC (ella) is highly effective in preventing ovulation because UPA EC works later in the pre-ovulatory cycle, when LNG EC is no longer effective. The fact that UPA EC works when taken later than LNG EC does not mean that UPA EC prevents implantation. Indeed, there is no evidence that UPA EC affects implantation: "EC with a single dose of 1.5 mg LNG or 30 mg UPA acts through inhibition of or postponing ovulation but does not prevent fertilization or implantation and has no adverse effect on a pregnancy." Gemzell-Danielsson at 305.

Opponents of emergency contraception frequently cite the FDA-approved product label for LNG EC products, which states that "it *may* inhibit implantation (by altering the endometrium)." PLAN B LABEL at 4 (emphasis added). The product label has not been updated since the product was originally approved in 1999 and it does not reflect the most current research. In fact, later studies have led to the conclusion that LNG does not cause changes to the endometrium (uterine lining) that would hamper implantation. M. Durand *et al.*, *On the Mechanisms of Action of Short-Term Levonorgestrel Administration in Emergency Contraception*, 64 CONTRACEPTION 227, 233 (2001) (study of LNG-exposed tissue "strongly suggest[s] the apparent preservation of endometrial structures thought to be associated with implantation capabilities."); Noe at 486-492 (concluding that LNG-EC, when used after ovulation "is completely unable to prevent pregnancy *because it has no effect on subsequent reproductive processes, including implantation of the embryo*") (emphasis added). *See also* U.S. Gov't Accountability Office, GAO-06-109, *Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive*

Drug Plan B Was Unusual, at 12-13 (November 2005) ("Research has shown that levonorgestrel-only hormonal emergency contraception, such as Plan B, interferes with prefertilization events. . . . ECPs, including Plan B, do not interfere with an established pregnancy.").

There is no scientific evidence showing that either LNG or UPA ECPs are able to prevent implantation of a fertilized egg. While the chemical compound found in ella has been shown to have some effect on the endometrium when higher or repeated doses are taken,[6] whether, in fact, ella has an effect sufficient to prevent implantation of a fertilized egg is unknown and assertions that ella works in this way are speculative at best. As stated by *amicus* James Trussell, Ph.D., "the best evidence is that the ability of levonorgestrel and ulipristal acetate ECPs to prevent pregnancy can be fully accounted for by mechanisms that do not involve interference with post-fertilization events," such as implantation. J Trussell & E.G. Raymond, A Last Chance to Prevent Unintended Pregnancy, at 7 (2013), *available at http://ec.princeton.edu/questions/ec-review.pdf*; *see also* Gemzell-Danielsson at 305 ("EC with [...] LNG or [...] UPA [...] does not prevent fertilization or implantation" of a fertilized egg).

6. P. Stratton *et al.*, *A Single Mid-Follicular Dose of CDB-2914, a New Antiprogestin, Inhibits Folliculogenesis and Endometrial Differentiation in Normally Cycling Women,* 15 Hum. Reprod. 1092 (2000); P. Stratton *et al., Endometrial Effects of a Single Early Luteal Dose of the Selective Progesterone Receptor Modulator CDB-2914*, 93 Fertility and Sterility 2035 (2010).

In any event, even if LNG or UPA did, in fact, inhibit implantation (which the evidence does not support), such effects would necessarily be pre-pregnancy; they would not transform LNG or UPA EC into abortifacients. Critically, LNG and UPA, when given for EC, have "no adverse effect on pregnancy." Gemzell-Danielsson at 305; *Access to Emergency Contraception*, ACOG Comm. Op. 542, 120 Obstet Gynecol 1250 (2012). Neither, therefore, is an abortifacient.

In addition to objecting to the two ECPs based on the erroneous claim that they prevent implantation, Respondents also object to coverage of two intrauterine devices (IUDs) approved as contraceptives by the FDA. Here, again, Respondents' scientific assumptions are faulty.

The first type of IUD is a levonorgestrel-releasing intrauterine system (LNG-IUS). LNG-IUS works primarily by thickening the cervical mucus, thereby preventing sperm from reaching the egg. M.F. Natavio, *et al., Temporal Changes in Cervical Mucus After Insertion of the Levonorgestrel-Releasing Intrauterine System,* 87 Contraception 430-31 (2013). *See also* Radha A. Lewis, *et al. Effects of the Levonorogestrel-Releasing Intrauterine System on Cervical Mucus Quality and Sperm Penetrability,* 82 Contraception 491,495 (2010) (cervical mucus shown impenetrable by sperm in all LNG-IUS users in study, corroborating the primary contraceptive role of cervical mucus of the LNG-IUS). In addition, an LNG-IUS may also prevent ovulation, as the levonorgestrel released by the device has been shown to impair ovulation. I. Barbosa *et al.*, *Ovarian function after seven years' use of a levonorgestrel IUD,* Adv Contracept. 1995;11:85-95.

The second form of contraception approved by the FDA is the copper Intrauterine Device (Cu-IUD). Copper ions released from the IUD create an environment that is toxic to sperm. Gemzell-Daniellson at 305. The Cu-IUD affects the motility and viability of sperm and impairs their fertilizing capability. *Id.* In addition to its use as ordinary contraception, the Cu-IUD has also proven effective as emergency contraception when inserted up to five days following intercourse. When used as emergency contraception, the Cu-IUD could also act to prevent implantation, due to copper's effect of altering molecules present in the endometrial lining. *Id.* However, studies show that the alteration of the endometrial lining prevents rather than disrupts implantation. *Id.* at 304.). The Cu-IUD, just like any IUD, can produce an inflammatory response in the reproductive tract and uterus that is toxic for sperm and oocytes (eggs). M.E. Ortiz *et al,* H. *Copper-T Intrauterine Device and Levonorgestrel Intrauterine System: Biological Bases of their Mechanism of Action.* 75 Contraception 528 (2007). Critically, because neither IUD has been shown to disrupt pregnancy, they too are properly classified as contraceptives, not abortifacients. *See* FDA, Birth Control Guide, *available at* http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM282014.pdf ("Birth Control Guide").

Emergency contraceptive drugs LNG and UPA should not be confused with the drug mifepristone, sold as Mifeprex in the United States and formerly known as RU-486. Opponents of contraception, including certain *amici curiae* appearing in the circuit court on behalf of Respondents, often cite to the fact that UPA and mifepristone are in the same class of drugs (anti-progestins) to suggest that ella is an abortifacient in the

same manner as mifepristone. This claim is not supported by the scientific record. Both the chemical composition and the mechanisms of action of mifepristone and UPA differ. Moreover, mifepristone as contained in Mifeprex is taken at a materially greater dose and in combination with another drug, misoprostol. At the dosage used to induce abortion (200-600 mg), mifepristone acts to change the lining of the uterus, causing any implanted embryo to dislodge. M.D. Creinin *et al.*, *Medical Abortion in Early Pregnancy,* Management of Unintended and Abnormal Pregnancy 111, 111-135 (Maureen Paul et al., eds., Wiley-Blackwell 2009). Mifeprex, when combined with misoprostol, is effective at inducing abortion through the ninth week of gestation. *Medical Management of Abortion,* ACOG Practice Bulletin 67, 160 Obstet Gynecol 871, 872 (2005). Given its effect on a pregnancy, Mifeprex is clearly an abortifacient. Notably, Mifeprex is not on the list of FDA-approved contraceptives. *See* Birth Control Guide.

C. Reduced Efficacy of ECPs Upon Delayed Use Demonstrates that ECPS are not Abortifacients

Further evidence that emergency contraceptives are not abortifacients is their lack of effect on pregnancies and their reduced efficacy to prevent pregnancy when taken post-ovulation. Some studies demonstrate a marked decline in the efficacy rate of emergency contraceptive pills the longer the interval between intercourse and treatment. *See* G. Piaggio *et al.*, *Timing of Emergency Contraception With Levonorgestrel or the Yuzpe Regimen,* 353 The Lancet 721, 721 (1999). Moreover, when taken post-ovulation, LNG has been shown to have no effect on preventing pregnancy at all, "indicating that no

reproductive process subsequent to ovulation is interfered with by LNG-EC." Noe at 491.

LNG works by blocking or delaying the luteinizing hormone (LH) surge, which triggers the ovulatory process; however, once that process has already been triggered by the LH surge, LNG cannot prevent follicular rupture and release of the egg. V. Brache *et al.*, *Immediate Preovulatory Administration of 30 mg Ulipristal Acetate Significantly Delays Follicular Rupture*. 25 HUM REPROD. 2256 (2010) ("Brache "). If LNG prevented implantation (or caused abortion), it would remain effective when taken post-ovulation. Noe at 491.

Ella's UPA has been shown to still be effective at delaying ovulation when taken later in the pre-ovulation period. This is because while LNG is effective at preventing ovulation only when taken *before* the LH surge, UPA EC is still effective at preventing pregnancy even when taken after the LH surge has begun, but before the LH peak. Brache; *see also* A.L. Glasier *et al.*, *Ulipristal Acetate Versus Levonorgestrel for Emergency Contraception: A Randomised Non-Inferiority Trial and Meta-Analysis*. 375 THE LANCET 555 (2010) (in a meta-analysis, the pregnancy rate for users of UPA was 65% lower than for users of LNG within the first 24 hours after intercourse and 42% lower within the first 72 hours). Although UPA has a wider window of effectiveness than LNG, it still does not prevent release of the egg, and, therefore, is not effective, if taken after the peak of the LH surge. *See* Brache. Once again, this diminished efficacy of UPA when taken at a point too late to stop ovulation is incompatible with the assertion that ella prevents implantation or causes abortion.

CONCLUSION

The medical and scientific record establishes that the emergency contraceptives approved by the FDA, as well as the approved intrauterine devices, do not interfere with pregnancy and are not abortifacients, because they are not effective after a fertilized egg has successfully implanted in the uterus. The Court should grant the petition for writ of certiorari and, in formulating any questions for review, should maintain the medical and scientific distinction between contraceptives and abortifacients.

Dated: New York, New York
October 21, 2013

Respectfully submitted,

B. Robert Piller
Jennifer Blasdell
Physicians For
Reproductive Health
55 West 39th Street,
Suite 1001
New York, NY 10018
(646) 366-1897

Bruce H. Schneider
Counsel of Record
Michele L. Pahmer
Stroock & Stroock
& Lavan LLP
180 Maiden Lane
New York, NY 10038
(212) 806-5400
bschneider@stroock.com

Attorneys for Amicus Curiae Physicians for Reproductive Health, American College of Obstetricians and Gynecologists, American Society for Emergency Contraception, Association of Reproductive Health Professionals, American Society for Reproductive Medicine, Society for Adolescent Health and Medicine, American Medical Women's Association, National Association of Nurse Practitioners in Women's Health, Society of Family Planning, International Association of Forensic Nurses, American College of Nurse-Midwives, James Trussell, Susan F. Wood, Don Downing and Kathleen Besinque