No. 13-1144

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

CONESTOGA WOOD SPECIALTIES CORP., et al.

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services, et al.

Defendants-Appellees.

On Appeal from the United States District Court for the Eastern District of Pennsylvania
No. 12-06744 (Hon. Mitchell S. Goldberg)

AMICUS CURIAE BRIEF OF 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, JAMES TRUSSELL, SUSAN F. WOOD, DON DOWNING AND KATHLEEN BESINQUE IN SUPPORT OF DEFENDANTS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

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, James Trussell, Susan F. Wood, Don Downing and Kathleen Besinque have no parent corporations and no publicly held corporation own 10% or more of any *amicus* organization's stock. *Amici* have no further disclosures pursuant to 3d Cir. L.A.R. 26.1.1.

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

STATEMENT OF INTEREST OF AMICI[1]

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

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[1] Pursuant to Fed. R. App. Proc. 29(c)(4), *amici curiae* state that all parties have consented to the filing of this brief. Pursuant to Fed. R. App. Proc. 29(c)(5), *amici* state that no counsel for a party authored this brief in whole or in part; no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief; 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.

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.

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.

INTRODUCTION

Although Amici generally support the affirmance of the district court's decision, this brief is narrowly focused on ensuring the accuracy of the scientific record on a single issue: namely, that the emergency contraceptives ("EC") approved by the FDA and the Copper Intrauterine Device, CuT380A ("Cu IUD"), also effective for emergency contraception, are not "abortifacients."

Appellants erroneously assert that the Act mandates coverage of abortifacient drugs and that emergency contraceptives are abortifacients. *See. e.g.*, Dkt. ID# 003111198219 at 6 (asserting that the Mandate "requires Conestoga to provide and pay for an employee health plan that includes coverage, without cost-sharing, for all Food and Drug Administration-approved contraceptive methods, including abortion-inducing drugs . . ."); *id*. at 11 ("the Mandate will require Conestoga to provide coverage, without cost-sharing, for contraceptives, including abortion-inducing drugs . . ."). As explained by the district court, "[t]he Hahns specifically object to prescription plan coverage of 'Plan B,' commonly known as the 'morning after pill,' and 'Ella,' also known as the 'week after pill.'" A.10-11. Appellants fail to cite any scientific authority for their assertions that any FDA-approved contraceptives are abortifacients.

This Court has already been provided with considerable misinformation concerning the supposed "life-ending effects of emergency contraception." *See*,

e.g., Dkt. ID# 00311120549 at 5. Likewise, the public discourse on EC is infused with misleading rhetoric stemming from political or religious views. *Amici* seek to inform this Court of the objective scientific facts relevant to this issue.

ARGUMENT

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

A. Contraceptives v. Abortifacients: the Biology of Pregnancy

Understanding the difference between a contraceptive and abortifacient requires some familiarity with how various forms of contraception work to prevent pregnancy, which, in turns, 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 over the course of several days between 5-9 days following fertilization. Wilcox et al., *Timing of Sexual Intercourse in Relation to Ovulation. Effects on Probability of Conception*, 333 NEW ENG. J. MED. 1517 (1995); 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 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").[3]

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 has occurred, but before pregnancy is established, to prevent pregnancy. *See generally* Gemzell-Danielsson et al., *Emergency Contraception—Mechanisms of Action*, 87 CONTRACEPTION 300, 300 (2013) ("emergency contraception (EC) is defined as the use of any drug or device after an unprotected intercourse to prevent an unintended pregnancy")("Gemzell-

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[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* Diedrich, *et al*., *The role of the endometrium and embryo in human implantation*, 13 HUM. REPROD. UPDATE 365 (2007).

[3] Although Appellants and others may have differing personal views as to when life begins, the medical and scientific community define pregnancy as beginning upon implantation.

Danielsson et al."); *see also* 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 disturb an embryo already implanted in the uterine lining, which necessarily occurs after a pregnancy has been established. *See* COCHRANE LIBRARY, http://www.thecochranelibrary.com/view/0/index.html (search "Abortifacient Agents").

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 and have sometimes been referred to by the misnomer, "morning after pills."

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 effect an existing pregnancy. Gemzell-Danielsson et al. at 305. None, therefore are properly classified as abortifacients.

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, PLAN B, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf. 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 et al. at 301. Ella, which came on the market more recently in 2010, is also 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* Gemzell-Danielsson et al. at 305 (concluding that

"EC with a single dose of 1.5 mg LNG or 30 mg UPA acts through inhibition of or postponing ovulation") .[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 that the research indicates. Noe et al.; Novikova et al., *Effectiveness of Levonorgestrel Emergency Contraception Given Before or After Ovulation – A Pilot Study,* 75 CONTRACEPTION 112 (2007).[5]

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

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[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. Gabriela Noe et al., *Contraceptive Efficacy of Emergency Contraception With Levonorgestrel Given Before or After Ovulation*, 84 CONTRACEPTION 486 (2011)("Noe et al.").

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

implantation and has no adverse effect on a pregnancy." Gemzell-Danielsson et al. 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)." FDA, LABELING FOR PLAN B ONE STEP, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf (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. 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 et al. 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, F*ood 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. Trussell & 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 et al. at 305 ("EC with […] LNG or […] UPA […] does not prevent fertilization or implantation" of a fertilized egg).

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;

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[6] 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); Stratton et al., *Endometrial Effects of a Single Early Luteal Dose of the Selective Progesterone Receptor Modulator CDB-2914*, 93 FERTILITY STERILITY 2035 (2010).

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 et al. at 305; *Access to Emergency Contraception*, ACOG Comm. Op. 542, 120 OBSTET GYNECOL 1250 (2012). Neither, therefore, is an abortifacient.

Another form of contraception approved by the FDA – the copper Intrauterine Device CuT380A (Cu-IUD) – has also proven effective as EC when inserted up to five days following intercourse. Copper ions released from the IUD create an environment that is toxic to sperm. Gemzell-Daniellson et al. at 305. The Cu-IUD affects the motility and viability of sperm and impairs their fertilizing capability. *Id.* Copper can also alter molecules present in the endometrial lining, however studies indicate that the alteration of the endometrial lining prevents rather than disrupts implantation. *Id*. Because Cu-IUDs prevent rather than 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. Although UPA and mifepristone are in the same class of drugs (anti-progestins), their chemical composition and mechanisms of action 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. 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

Further evidence that emergency contraceptives are not abortifacients is their lack of effect on pregnancies and their reduced efficacy to prevent pregnancy post-ovulation. Studies demonstrate a marked decline in the efficacy rate of emergency contraceptive pills the longer the interval between intercourse and treatment. *See* Piaggio et al., *Timing of Emergency Contraception With Levonorgestrel or the Yuzpe Regimen*, 353 THE LANCET 721, 721 (1999) (finding that "efficacy of [...] treatments declined with increasing time since unprotected intercourse"). That efficacy rates decline in this manner provides complementary evidence that the

primary, and perhaps only, method of action of EC pills is on pre-fertilization functions. When taken post-ovulation, LNG has not been shown to have a statistically significant effect on preventing pregnancy at all, "indicating that no reproductive process subsequent to ovulation is interfered with by LNG-EC." Noe at 491.[7] If LNG prevented implantation or caused abortion, there would be no explanation for its decline in efficacy when taken post-ovulation. *Id*.

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 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 et al.; *see also* 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

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[7] LNG blocks or delays the luteinizing hormone (LH) surge, which triggers the ovulatory process. Once the process has been triggered by the LH surge, LNG cannot prevent follicular rupture and release of the egg. Brache et al., *Immediate Preovulatory Administration of 30 mg Ulipristal Acetate Significantly Delays Follicular Rupture*. 25 HUM. REPROD. 2256 (2010) ("Brache et al.").

surge. Brache et al. Once again, this diminished efficacy of UPA when taken at a point too late to stop ovulation is incompatible with the assertion that it prevents implantation or causes abortion.

CONCLUSION

The medical and scientific record establishes that emergency contraceptives approved by the FDA and the copper intrauterine device CuT380A do not interfere with pregnancy and are not abortifacients, as they are not effective after a fertilized egg has successfully implanted in the uterus. The Court's decision in this case should, consistent with the scientific data, ensure this proper distinction between contraceptives and abortifacients.

Dated: New York, New York
April 22, 2013

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CERTIFICATION OF COMPLIANCE PURSUANT TO FRAP 32(a)(7)(C), L.A.R. 31.1(c), and L.A.R. 46.1(e)

This *amicus* brief complies with the type-volume limitation of Fed. R. App. P. 29(b) and 32(a)(7)(B) because it contains 4,086 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), as it has been prepared in a 14-point, proportionally spaced typeface, Times New Roman, by using Microsoft Word 2007.

The text of the electronic brief is identical to the text of the paper copies.

The electronic brief has been scanned for viruses using Microsoft Forefront Endpoint Protection and found to be virus-free.

The undersigned counsel is a member of the bar of this Court.

Dated: April 22, 2013

/s/ Bruce H. Schneider
Bruce H. Schneider

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2013, I electronically filed the foregoing brief with the Clerk of this Court by using the appellate CM/ECF system and caused ten copies to be delivered to the court by overnight mail. The participants in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

Dated: April 22, 2013

/s/ Bruce H. Schneider
Bruce H. Schneider