

Facts are Important Emergency Contraception (EC) and Intrauterine Devices (IUDs) are Not Abortifacients

Facts are very important, especially when discussing the health of the American public. Contrary to assertions made by some, emergency contraception and IUDs do not cause abortions, and therefore are not abortifacients. Here are the scientific facts.

Emergency contraception (EC) does not cause medical abortions. A woman can take mifepristone to cause a medical abortion, terminating an early existing pregnancy. EC however only works <u>before</u> a pregnancy is established. Review of the scientific evidence suggests that EC cannot prevent implantation of a fertilized egg. EC is not effective after implantation; it <u>cannot end a pregnancy</u> and is <u>not an abortifacient</u>.

Contraceptives v. Abortifacients

Understanding the difference between a contraceptive and an abortifacient requires an understanding of the biological processes leading to pregnancy and how various forms of contraception work to prevent pregnancy.

Fertilization: Occurs when a viable egg fuses 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.

Implantation: 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.¹²

Pregnancy: Is established only at the conclusion of implantation of a fertilized egg.³⁴ This scientific definition of pregnancy is also the legal definition of pregnancy, accepted by governmental agencies and all major U.S. medical organizations.⁵

Contraceptive: An agent which prevents fertilization of an egg or prevents implantation of a fertilized egg, preventing a pregnancy from taking place.ⁱ

Emergency contraception: A drug or device used after intercourse has occurred, but before pregnancy is established, to prevent pregnancy. EC works much like traditional contraceptives, but provides protection after-the-fact in the event of contraception failure (i.e. a broken condom) or unprotected sex, including sexual assault.⁶⁷ Plan B and ella are two FDA-approved emergency contraceptives.

Abortifacient: An agent that disturbs an embryo already implanted in the uterine lining, after a pregnancy has been established.⁸

ECs are Not Abortifacients

There is no scientific evidence that FDA-approved emergency contraceptives affect an existing pregnancy; no EC is classified as an abortifacient.

There are two types of EC pills available in the U.S.: 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

ⁱ 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)

1.5 mg LNG. LNG, which has long been approved at lower dosage levels for use in ordinary contraceptives, has been approved as EC since 1999 and is the most commonly used form of EC. Ella, which came on the market in 2010, contains 30 mg UPA and acts on human progesterone receptors.

LNG and UPA function primarily, if not exclusively, by inhibiting ovulation, thereby preventing fertilization from occurring. LNG and UPA do not affect implantation of a fertilized egg or harm or end an established pregnancy.⁹ UPA works later in the pre-ovulatory cycle, when LNG is no longer effective. The fact that UPA EC works when taken later than LNG EC does not mean that UPA EC prevents implantation. There is no scientific evidence that UPA EC affects implantation. LNG EC has been widely studied, and current scientific evidence shows that it works by preventing or disrupting ovulation, but is not effective after ovulation has already occurred.¹⁰

Opponents of EC frequently cite the FDA-approved product label for LNG products, which states that "it may inhibit implantation (by altering the endometrium)."¹¹ This product label has not been updated since the product was approved in 1999 and does not reflect current research, including recent studies showing that LNG does not cause changes to the endometrium (uterine lining) that would hamper implantation.¹²¹³

Another form of contraception approved by the FDA – the copper Intrauterine Device CuT380A (Cu-IUD) – is effective as an EC when inserted up to five days following intercourse. Copper ions released from the IUD create an environment that is toxic to sperm, preventing fertilization.¹⁴ Copper can also alter the endometrial lining, but studies show that this alteration can prevent implantation, but not disrupt implantation. **Because Cu-IUDs prevent rather than disrupt pregnancy, they too are properly classified as contraceptives, not abortifacients.¹⁵**

The American Congress of Obstetricians and Gynecologists (ACOG), representing nearly 58,000 ob-gyns and partners in women's health, supports robust, factual debates on issues of importance to the American people. We urge you to call on us for expert understanding of issues related to women's health.

¹ Wilcox et al., *Timing of Sexual Intercourse in Relation to Ovulation. Effects on Probability of Conception*, 333 NEW ENG. J.MED. 1517 (1995) ² Dunson et al., *Day-Specific Probabilities of Clinical Pregnancy Based on Two Studies With Imperfect Measures of Ovulation*, 14 HUM. REPROD. 1835 (1999)

³ OBSTETRIC-GYNECOLOGIC TERMINOLOGY: WITH SECTION ON NEONATOLOGY AND GLOSSARY OF CONGENITAL

ABNORMALITIES 299, 327 (E.G. Hughes, ed., F.A. Davis Co. 1972)

⁴ Statement on Contraceptive Methods (Am. Coll. of Obstetricians & Gynecologists, Wash., D.C., Jul. 1998)

⁵ See, e.g., 45 C.F.R § 46.202 (recognizing pregnancy as "the period of time from implantation to delivery")

⁶ Gemzell-Danielsson et al., *Emergency Contraception—Mechanisms of Action*, 87 CONTRACEPTION 300, 300

^{(2013) (&}quot;emergency contraception (EC) is defined as the use of any drug or device after an unprotected intercourse to prevent an unintended pregnancy")

⁷ 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.")

⁸ See COCHRANE LIBRARY, http://www.thecochranelibrary.com/view/0/index.html (search"Abortifacient Agents").

⁹ Gemzell-Danielsson et al. at 305; Access to Emergency Contraception, ACOG Comm. Op. 542, 120 OBSTET GYNECOL 1250 (2012)

¹⁰ Noe et al.; Novikova et al., *Effectiveness of Levonorgestrel Emergency Contraception Given*

Before or After Ovulation – A Pilot Study, 75 CONTRACEPTION 112 (2007)

¹¹ FDA, LABELING FOR PLAN B ONE STEP, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf

¹² Durand et al., On the Mechanisms of Action of Short-Term Levonorgestrel Administration in Emergency Contraception, 64 CONTRACEPTION 227, 233 (2001)

¹³ Noe et al. at 486-492

¹⁴ Gemzell-Daniellson et al. at 305

¹⁵ FDA, BIRTH CONTROL GUIDE, available at

http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM282014.pdf