ISSUE BRIEF

MYTH AND FACT: THE TRUTH ABOUT *ELLA* AND HOW IT WORKS

1) Myth: *Ella* is an "emergency contraceptive," just like Plan B, but it works longer and more effectively.

Fact: *Ella* works very differently than Plan B, which is also referenced as a "morning after pill." Plan B can prevent an embryo from implanting in the uterus, thereby causing its demise. However, Plan B cannot terminate an already implanted embryo, whereas *ella* can.[1] *Ella* is a different type of chemical compound than Plan B (Levonorgestrel). Plan B is a kind of progesterone, and progesterone is needed by the uterine lining to grow and feed the embryo. *Ella* is a selective progesterone receptor modulator (SPRM).[2] An SPRM blocks progesterone receptors and in doing so starves a developing baby of this needed protein. Until August, 2010, only one SPRM had been approved for drug use in the United States: RU-486 (Mifepristone) – a known abortifacient for first-trimester pregnancies. *Ella* and RU-486 function similarly, since they have similar chemical properties.[3]

2) Myth: *Ella* is not capable of causing abortions.

Fact: *Ella* can cause an abortion.[4, 5, 6, 7, 8] According to the European Medicines Agency (EMEA), the EU equivalent of the FDA, numerous studies show that *ella* causes abortions in animals, including rats, rabbits, guinea pigs and macaques (similar to monkeys). Additionally, the EMEA indicated that *ella* "is embryotoxic at low doses, when given to rats and rabbits"[9] and "[was] approximately equipotent at the dose levels of 10 and 30 mg/day in terminating pregnancies in guinea-pigs."[10] Given *ella*'s molecular similarity to RU-486 and this animal data, researchers have even concluded that a 30 milligram dose of *ella* will abort human pregnancies.[11]

3) Myth: *Ella* does not cause an abortion because it does not interrupt an established, implanted pregnancy.

Fact: *Ella* can cause the demise of an embryo that is already implanted in its mother's womb, in addition to preventing implantation after fertilization.[12] *Ella* also appears to have a powerful ovulatory blocking capability.

Issue Brief IF10G01
FAMILY RESEARCH COUNCIL
801 G STREET NW, WASHINGTON, D.C. 20001
202-393-2100 • *fax* 202-393-2134 • (800) 225-4008 *order line*
www.frc.org

4) Myth: *Ella* is safe for women's health.

Fact: The FDA looked at limited data on safety information[13] and should conduct further studies on the effect of *ella* on women's health. In addition to the studies considered during the approval process,[14] since *ella* works similarly to RU-486, there is compelling reason to believe that it will likely have similar side effects. It may cause excessive bleeding and increase vulnerability to infection. The FDA has admitted that 11 women died as a result of taking RU-486 since its approval.[15] It is possible that other serious side effects of RU-486 have occurred but have not been reported. Women who take *ella* should be aware of its potential side effects.

5) Myth: Since *ella* is only being approved for use for five days, it cannot interfere with a pregnancy, since implantation usually occurs between 6-10 days after fertilization.

Fact: Nothing would prevent providers from prescribing, or women from using, *ella* off-label. In fact, KwikMed, the official online provider for *ella,* states that the drug can be purchased without visiting a doctor to get a prescription.[16] Indeed, Planned Parenthood openly admits to providing emergency contraception beyond the 3-day FDA approved timeframe. Additionally, the Planned Parenthood website describes two off-label uses for RU-486: the organization prescribes the RU-486 abortion regimen at a lower dose than is approved by the FDA[17] and they prescribe it after the 49-day FDA approved timeframe.[18] The FDA is not able to prevent off-label and unapproved use of the drug. Once approved, the drug can be used off-label outside of FDA guidelines. Furthermore, issues surrounding informed consent arise because a woman in early pregnancy can unknowingly take *ella* within 5 days of a separate sexual encounter and unintentionally and unknowingly have an abortion because she believes emergency contraception will not harm an implanted fetus.

6) Myth: *Ella* is safe for women who are breastfeeding, and for their unborn and born children.

Fact: The FDA admits at least one case in which a baby exposed to *ella* in utero had visual development problems and delayed gross motor skills.[19] Despite this information, the FDA Advisory Panel did not suggest further studies on the potential for *ella* to produce birth defects, either for babies in utero or those drinking their mother's breast milk. Additionally, the EMEA stated that "Extremely limited data are available on the health of the foetus/new-born in case a pregnancy is exposed"[20] to the drug, as well as "it has not been possible to evaluate the teratogenic (birth-defect) potential of ulipristal acetate (*ella*)."[21]

---

[1]Hild et al., "CDB-2914: Anti-progestational/antiglucocorticoid Profile and Post-coital Anti-fertility Activity in Rats and Rabbits." 15 *Human Reproduction* (2000): 822-829, 824.

[2] FDA, "Background Document for Meeting of Advisory Committee for Reproductive Health Drugs (June 17, 2010),"http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Reproductive Health Drugs Advisory Committee/UCM215425.pdf, p. 10.

[3] VandeVoort et al., "Effects of Progesterone Receptor Blockers on Human Granulosa-Luteal Cell Culture Secretion of Progesterone, Estradiol, and Relaxin," 62 Biology of Reproduction (2000): 200-205, 200. In this article, ulipristal is referred to as "HRP-2000."

[4] Reel et al., "Antiovulatory and Postcoital Antifertility Activity of the Antiprogestin CDB-2914 When Administered as Single, Multiple, or Continuous Doses to Rats," 58 *Contraception* (1998): 129-136, p. 129.

[5] VandeVoort *et al.*, p. 200.

[6] Hild *et al.*, p. 824.

[7] G. Teutsch and D. Philibert, "History and Perspectives of Antiprogestins from the Chemist's Point of View," 9 *Human Reproduction* (1994)(suppl 1):12-31.

[8] B. Attardi, J. Burgenson, S. Hild, and J. Reel, "In vitro Antiprogestational/Antiglucocorticoid Activity and Progestin and Glucocorticoid Receptor Binding of the Putative Metabolites and Synthetic Derivatives of CDB-2914, CDB-4124, and mifepristone," *Journal of Steroid Biochemistry and Molecular Biology* 88 (2004): 277-88.

[9] European Medicines Agency, "CHMP Assessment Report for EllaOne," (Doc.Ref.: EMEA/261787/2009): p. 16, (http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf).

[10] European Medicines Agency, p. 10.

[11] D. Harrison and J. Mitroka, "Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health," Annals of Pharmacotherapy 45 (Jan. 2011): 115-9.

[12] American Association of Pro-Life Obstetricians and Gynecologists, "Re: Comment to Docket No. FDA–2010–N–0001 Advisory Committee for Reproductive Health Drugs; Notice of Meeting Ulipristal acetate tablets, (NDA) 22–474, Laboratoire HRA Pharma," http://www.aaplog.org/wp-content/uploads/2010/06/AAPLOG-Ulipristal-Comments_2010.pdf, p.3.

[13] The clinical safety database for ulipristal included 4,771 subjects, 2,764 of whom received the to-be-marketed formulation of a 30 mg micronized tablet of ulipristal. No deaths occurred and no unexpected adverse outcomes were observed in the clinical development program. The most common adverse reactions were nausea, headache, dysmenorrhea, abdominal pain, fatigue, and dizziness. Amenorrhea beyond 60 days of a subject's expected menses after ulipristal treatment was observed infrequently. Data on pregnancy outcomes after EC failure with ulipristal were too limited to draw any definitive conclusions regarding the effect of ulipristal on an established pregnancy or fetal development.

[14] FDA, p. 10.

[15] FDA, "Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011,"http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353, p. 1.

[16] "NEW ella® emergency contraception available by online prescription,"http://ella-kwikmed.com.

[17] Planned Parenthood Federation of America,"Mifepristone: Expanding Women's Options for Early Abortion in the United States," http://www.plannedparenthood.org/files/PPFA/fact_Mife_0910.pdf, p. 2.

[18] PPFA, "What is the Abortion Pill?", http://www.plannedparenthood.org/health-topics/abortion/abortion-pill-medication-abortion-4354.asp.

[19] FDA, Background Document, p. 45-46.

[20] European Medicines Agency, p. 41.

[21] European Medicines Agency, p. 16.