July 28, 2010

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
Rockville, MD 20687

Dear Commissioner Hamburg:

On June 17, 2010, the Reproductive Health Drugs Advisory Committee met regarding the approval of Ulipristal Acetate, marketed as *ella.* We have significant concerns that *ella* poses a danger to women and their children and we ask that you do not approve this drug for use in the United States.

The drug is deceptively portrayed as a five day "emergency contraception." There is evidence, however, that Ulipristal Acetate (ella) prevents implantation after fertilization and may also kill or injure the unborn child after implantation.

Ulipristal Acetate and the abortion drug Mifepristone (RU-486) are both selective progesterone receptor modulators (SPRM). SPRMs block progesterone, which is necessary to maintain pregnancy[i] thus starving an unborn baby of the nutrients it needs to continue life.

Given *ella*'s similar chemical makeup to RU-486, women deserve to see evidence demonstrating that *ella* will not destroy or harm an unborn child and that *ella*'s modes of action do *not* include abortion, especially in light of studies that show *ella* causes abortions in animal studies. FDA materials admit that data is "too limited to draw any definitive conclusions regarding the effect of ulipristal on an established pregnancy or fetal development."[ii]

During the FDA advisory committee meeting a representative from Planned Parenthood (PPFA) openly admitted that they distribute PlanB/NextChoice beyond the time frame approved by the FDA (their website also indicates they distribute RU-486 past the time frame approved by the FDA), so there is a compelling indication that *ella* could be provided off-label to either intentionally or unintentionally induce an abortion. The FDA must also adequately address potential off-label use and the possibilities of adverse effects to women and their children if taken off-label. This includes ensuring that any approved dose or higher doses cannot be used to induce an abortion. Women also have a right to know about the health risks to themselves and their children if *ella* is taken off-label.

In addition, we have significant concerns about the health risks *ella* poses to women. Since *ella*'s chemical make-up and mode of action are very similar to RU-486, which causes serious adverse health risks such as severe bleeding, ruptured tubal pregnancies, serious infections, and even death, further study is necessary to ensure *ella* is safe for women, particularly if it is used off-label. The FDA summary indicates that the

clinical study was too limited to draw any meaningful conclusions about risks associated with tubal pregnancy.[iii] Limited to no data is available about *ella*'s effect on minors or its interaction with other drugs, such as hormonal birth control.

While data on pregnancy outcomes are limited, what information is available suggests that unborn children who survive *ella* may be seriously impacted. In particular, it is troubling that the advisory panel did not discuss or address the case of 1 of the 6 subjects who carried her baby to term after taking *ella* and reported the baby had optic nerve hypoplasia and developmental delay. More information is needed on the adverse effects *ella* can have on unborn children.

We do commend the FDA panel for requesting more information as to the risk *ella* might pose to breastfeeding infants. Research in animals showed that traces of *ella* could be found in breast milk. Little is known of the effects that it could have on infants who are breastfeeding and the FDA must also ensure proper research and labeling to inform nursing mothers of the risks involved.

In light of these serious concerns, we believe that *ella* should not be approved and should not be categorized as "emergency contraception." At a bare minimum, the FDA must provide women with informed consent and ensure transparent labeling about the serious risks associated with off-label use clearly indicated, specifically, with the label including a "black box warning." Women deserve to know the truth about the harm that *ella* can cause to themselves and their unborn children.

Sincerely,

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Gene Mills
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Louisiana Family Forum Action

Dr. Dennis Sullivan
Director
Center for Bioethics
Cedarville University

Matthew Staver
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[i] "Ulipristal acetate prevents progesterone from occupying its receptor, thus the gene transcription normally turned on by progesterone is blocked, and the proteins necessary to begin and maintain pregnancy are not synthesized." European Medicines Agency, "CHMP Assessment Report for EllaOne," (Doc.Ref.: EMEA/261787/2009), p. 8.
[ii] FDA Background Document for Meeting of Advisory Committee for Reproductive Health Drugs NDA 22-474 Ulipristal Acetate (Proposed trade name: ELLA) HRA Pharma (June 17, 2010), pg 10-11.
[iii] FDA Background Document for Meeting of Advisory Committee for Reproductive Health Drugs NDA 22-474 Ulipristal Acetate (Proposed trade name: ELLA) HRA Pharma (June 17, 2010), pg 46.
*Affiliations for Identification Purposes Only