



Secretariat of Pro-Life Activities

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June 17, 2010

Margaret Hamburg, M.D.
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Building 32
Silver Spring, MD 20993

Dear Dr. Hamburg:

I am writing because of grave concern over the FDA's current process for approving the drug Ulipristal (with the proposed trade name of Ella) for use as an "emergency contraceptive." The decision to hold an advisory committee hearing on the drug today, without broad public input or a full record on the drug's safety for women or their unborn children, does not demonstrate an understanding of the new medical and moral issues it presents.

Concerns have been raised over other drugs considered for "emergency contraception," such as the "Plan B" regimen, because they might act not only to prevent ovulation but also to prevent implantation of the developing embryo in his or her mother's womb. However, such drugs were thought to have no post-implantation effects. Ulipristal is a close analogue to the abortion drug RU-486, with the same biological effect – that is, it can disrupt an established pregnancy weeks after conception has taken place.¹

This drug is contraindicated for women who are or may be pregnant. Yet its proposed use here is targeted precisely at women who may already have conceived, as it would be administered within five days *after* "unprotected" sex or contraceptive failure. No existing pregnancy test can exclude the possibility that a new life has been conceived in this time frame. Indeed, advocates praise this drug as an advance precisely because it seems to retain its full efficacy five days after intercourse – that is, after the opportunity to prevent fertilization has passed.

Millions of American women, even those willing to use a contraceptive to prevent fertilization in various circumstances, would personally never choose to have an abortion. They would be ill served by a misleading campaign to present Ulipristal simply as a "contraceptive." In fact, FDA approval for that purpose would likely make the drug available for "off-label" use simply as an abortion drug – including its use by unscrupulous men with the intent of causing an early abortion without a woman's knowledge or consent. Such abuses have already occurred in the case of RU-486, despite its warning labels and limited distribution.

For many years, Congress has acted to ensure that the federal government does not fund abortion, and does not endanger or destroy the early human embryo even in the name of important medical research. This Administration, like many before it, has voiced support for federal laws to ensure that no one is involved in abortion without his or her knowledge or consent. And the Administration's support for broad access to contraception has been defended as serving the goal of reducing abortions. Plans for approving a known abortion-causing drug as a "contraceptive" for American women is not consistent with the stated policy of the Administration on these matters.

Please know that I appreciate any attention the FDA can give to these serious concerns, and I will follow the Administration's further discussion and actions on this issue with great interest.

Sincerely,



Cardinal Daniel N. DiNardo
Chairman, Committee on Pro-Life Activities
United States Conference of Catholic Bishops

ⁱ Documentation on this and other medical aspects of the issue is cited in testimony submitted to the FDA by the American Association of Pro-Life Obstetricians and Gynecologists, available at www.aaplog.org/?page_id=808.