

in the March-April 2008 issue of *Health Progress*, pages 50-51—“Reflective Process for Assessing Catholic Health Care Organizations’ Involvement with Philanthropic Organizations.”

Plan B – Update

Plan B (levonorgestrel)—the standard of care to prevent pregnancy in women who have been sexually assaulted—seems to be in the limelight again. It is one of the FDA-approved drugs included in the HHS mandate regarding preventive services for women under the ACA. Ella, or ulipristal, is the other FDA-approved drug for women who have been raped. Unfortunately, in the thousands of statements made regarding the mandate by a host of different people, these two drugs are usually lumped together. Most often, they are both described as “abortion-inducing drugs.” This nomenclature and the increased attention to Plan B in the current debate about the mandate and religious liberty in turn seem to be raising concerns among some about the drug’s use in Catholic hospitals. This debate—whether Plan B can be used in Catholic hospitals and under what circumstances—has been going on for years. It is still unresolved.

However, it needs to be said that levonorgestrel (LNG) is not ulipristal (Ella) and they should not be lumped together. Doing so betrays ignorance of the science and ultimately weakens one’s

claims and one’s position. All the scientific evidence on the mechanism of action of ulipristal points to its having an abortifacient effect if it does not prevent ovulation. Chemically, ulipristal is a cousin of RU486. It should not be used in a Catholic hospital even though it can be administered and be effective up to 120 hours after an act of unprotected sex.

The vast preponderance of scientific evidence on the mechanism of action of levonorgestrel, especially more recent scientific studies, suggests that it does not have an abortifacient effect, that is, it does not make the endometrium unreceptive to the implantation of an embryo. The conclusions of a few of the more recent studies were summarized in “Ethical Currents” in the Spring 2011 issue of *Health Care Ethics USA* (19, no. 2, pp. 28-30). Here is a further update.

- M. Durand and colleagues, in a paper published in the December 2010 issue of *Contraception* (“Hormonal Evaluation and Midcycle Detection of Intrauterine Glycodelin in Women Treated with Levonorgestrel as in Emergency Contraception,” 82, pp. 526-33), studied the effects of levonorgestrel (LNG) on hormonal behavior and on the secretory pattern of intrauterine glycodelin at the midcycle of ovulatory women. Thirty women were administered LNG approximately two days prior to the LH surge when LNG is less likely to

prevent or delay ovulation. They found that in women who had ovulated despite taking LNG during their preovulatory stage, “the apparently normal E₂ and P₄ production during the luteal phase suggested a normal luteinization and corpus luteum function in LNG-ov cycles, which agree with the lack of deleterious effects of this hormonal contraceptive regimen on the endometrium” (532). In other words, LNG, when it is taken close to the LH surge and is therefore unlikely to prevent ovulation, seems not to disrupt normal hormonal levels that are necessary for healthy development of the endometrium. In addition, the presence of glycodelin-A, which is capable of inhibiting sperm-oocyte interaction, “may in part contribute to explaining the contraceptive effect of this progestin...” (532).

- V. Suarez and colleagues in a 2010 issue of *Revista Peruana de Medicina Experimental y Salud Publica* (“Effect of Levonorgestrel in the Ovulation, Endometrium, and Spermatozoa for Emergency Oral Contraception,” 27, no. 2, 222-230), published the results of a review of 22 articles out of 444 on the mechanism of action of levonorgestrel. They found that the “main mechanism of action of levonorgestrel given at the doses recommended for EOC is the inhibition or retardation of ovulation” and that “no morphological or

molecular alterations in the endometrium that could interfere with the implantation of a fertilized egg have been demonstrated.” They also found that “there is no actual scientific evidence available supporting that the use of levonorgestrel for EOC is abortive” (222).

- Finally, the International Federation of Gynecology & Obstetrics and the International Consortium for Emergency Contraception issued a statement in March 2012 in response to the question: how do levonorgestrel-only emergency contraceptive pills (LNG ECPs) prevent pregnancy? They go on to say that “the evidence shows that LNG ECPs”:
 - Prevent or delay ovulation as their main mechanism of action by inhibiting the LH surge thereby impeding follicular development and maturation and/or the release of the egg itself.
 - Do not inhibit implantation.:
 - Two studies resulted in pregnancies in women who took LNG on or after the day of ovulation;
 - Several studies have shown that LNG produces no

histological and biochemical changes in the endometrium;

- One study showed that LNG did not prevent the attachment of human embryos to a simulated (in vitro) endometrial environment;
- Animal studies have demonstrated that LNG did not prevent implantation of the fertilized egg in the endometrium.

In light of these studies, current language regarding implantation should not be included in LNG ECP labeling. That LNG ECPs have no effect on the endometrium explains why they are less effective the later they are taken.

- May affect sperm:
 - There are contradictory results; this warrants further studies.

Does not have an effect on an established pregnancy.

- Two studies found that LNG has no effect on an established pregnancy even at very early stages.

Readers may obtain the complete statement as well as references to the particular studies supporting the conclusions at http://www.cecinfo.org/UserFiles/File/IC_EC_FIGO_MoA_Statement_March_2012.pdf.

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