

# Statement on Emergency Contraception in Cases of Rape

Catholic Medical Association

The *Ethical and Religious Directives for Health Care Services* in directive 36 shows the concern Catholic hospitals should take in protecting a victim of rape from possible consequences of the assault, including pregnancy, as long as the agent used prevents ovulation or fertilization:

Compassionate and understanding care should be given to a person who is the victim of sexual assault. Health care providers should cooperate with law enforcement officials and offer the person psychological and spiritual support as well as accurate medical information. A female who has been raped should be able to defend herself against a potential conception from the sexual assault. If, after appropriate testing, there is no evidence that conception has occurred already, she may be treated with medications that would prevent ovulation, sperm capacitation, or fertilization. It is not permissible, however, to initiate or to recommend treatments that have as their purpose or direct effect the removal, destruction, or interference with the implantation of a fertilized ovum.<sup>1</sup>

Approximately 5 percent of women of childbearing age who are fertile and not using contraception at the time of an attack will become pregnant as a result of the assault. It is estimated that more than twenty thousand pregnancies result from rape in the United States annually.<sup>2</sup>

The standard emergency contraceptive used after rape is Plan B (levonorgestrel, or LNG-EC), 0.75 mg given within seventy-two hours of the sexual assault and then repeated twelve hours later, or 1.5 mg given in a single dose (Plan B One-Step). This drug was approved for use as an emergency contraceptive by the Food and Drug Administration in July 1999. The medical literature claims that the drug works primarily by preventing ovulation. According to the website for Plan B One-Step, however, “It is possible that Plan B One-Step may also work by preventing fertilization of an egg (the uniting of sperm with the egg) [or] preventing attachment (implantation) to the uterus (womb).”<sup>3</sup> In August 2006, Plan B was made available over the counter with restrictions, but as of October 2013, it is available to anyone of any age in the United States without prescription. It is only since 2000 that reliable studies have better elucidated the drug’s mechanisms of action.

## Definitions

To understand the mechanisms of action of LNG-EC and whether it is ethical to use it in cases of rape, it is important to understand when a woman is fertile. From Harvard data, we have learned that a woman has a six-day fertile window, which begins five days before ovulation (day - 5), includes the day of the LH (luteinizing hormone) surge (day -1) and ends on the day of ovulation (day 0).<sup>4</sup> Presumptive evidence of ovulation occurs with detection of the LH surge or, by serial ultrasound, detection of the collapse of the fully developed follicle. Intercourse outside of the fertile window will not result in a pregnancy. Maureen Condic has explained that, on the basis of biological criteria, “we can confidently conclude that a new cell, the zygote, comes into existence at the ‘moment’ of sperm–egg fusion, an event that occurs in less than a second.”<sup>5</sup>

For a drug to be *contraceptive*, it has to prevent the joining of the sperm with the egg. Postfertilization effects are those that occur after the egg and sperm join. If a drug acts against survival of the zygote to the blastocyst stage as it travels down the fallopian tube for four to five days, the drug is *interceptive*, and if it makes implantation difficult or impossible, it is *contragestive*. If it disrupts a previously implanted embryo, it is *abortifacient*. Administration of any drug to prevent ovulation that is also likely to act after fusion of the sperm and the egg (thus ending a human life) is morally illicit.

The anovulatory hormonal treatment component of the Saint Francis Medical Center protocol for sexual assault, also known as the Peoria protocol, was developed in the 1990s to provide for the administration of emergency contraception in cases of rape; it was intended for use in that hospital’s emergency room. The protocol was later adapted for use with Plan B. According to the protocol, if a woman’s menstrual history and findings on physical examination indicate that she is in the preovulatory phase of her menstrual cycle and if the urinary LH is negative and the serum progesterone level is less than 1.5 ng/ml, then Plan B is given in a single dose of 1.5 mg. If the woman is midcycle or in the early postovulatory phase by menstrual history or a positive urinary LH, or if she has a negative urinary LH with a serum progesterone level greater than or equal to 1.5 and less than 6.0 ng/ml—then Plan B is not given. If the woman is in the postovulatory phase and has a serum progesterone level of 6.0 ng/ml or higher, “the timing of the sexual assault could not have coincided with the presence of an ovum, [so] it is not unethical to prescribe Plan B

(levonorgestrel) for the psychological benefit of the woman who requests it.” Finally, if the woman is determined to be in the late postovulatory phase—having a menstrual history compatible with being less than seven days from the next period, a progesterone level of less than 6 ng/ml, and a negative urinary LH—Plan B could be prescribed if the woman requests it. The Peoria protocol is currently approved, with modifications, by the National Catholic Bioethics Center. The question to be answered is, does the Peoria protocol protect against the loss of human life when Plan B is given during the fertile window?

## **Research**

A series of studies by Marta Durand et al. in 2001, 2005, and 2010 looked specifically at the effects of LNG-EC when given on carefully timed days of the cycles of forty-five women who had previously been sterilized. In the 2001 study, Durand et al. found that if the drug was given more than four days before ovulation, it prevented ovulation 80 percent of the time. In those women who received the drug within the three-day window before the LH surge, ultrasound findings showed that all ovulated, but they had deficient progesterone production and shorter luteal phases, which would affect zygote survival.<sup>6</sup> The women who received LNG-EC on the day of the LH surge (day -1) or after ovulated, and the drug had no effect on the luteal phase or progesterone levels. LNG-EC had no effect on the histologic features or dating of the endometrium, which is no longer a determinant of successful implantation.<sup>7</sup>

Many factors have to be present in the endometrium for successful implantation. In the 2005 and 2010 studies, Durand et al. looked at progesterone levels and glycodelin-A levels when the drug was given on days -5 and -4 as well as day -1 and day +1.<sup>8</sup> Glycodelin-A is a progesterone-mediated substance that is normally present in high amounts at the time of implantation. One of its functions is to suppress the mother’s immune system so that the blastocyst is not recognized as a foreign body. Durand et al. found that LNG-EC administered prior to the LH surge altered the luteal phase secretory pattern of glycodelin in serum and endometrium and significantly lowered serum progesterone levels in the luteal phase. Levels of glycodelin-A were low at the time of implantation, preventing the suppression of the mother’s natural killer cells. This could result in a postfertilization effect. They concluded that a premature elevation of glycodelin-A in response to a spike in

progesterone early in the cycle could account for the lack of clinical pregnancies in women who ovulated.<sup>9</sup>

These findings were confirmed in two large studies by Gabriela Noé et al. (2010 and 2011). Seeking emergency contraception after intercourse, 388 women received LNG-EC followed by serial vaginal ultrasound examinations and serum hormone testing on the day the drug was given and for five days after. The researchers found that when the drug was given during the fertile window, it was 70 percent effective at preventing a clinical pregnancy. It had no effect when taken on the day of ovulation or after. In the 87 women treated prior to ovulation, 71 percent ovulated, yet no clinical pregnancies were detected. Noé et al. concluded that mechanisms other than suppression of ovulation prevented pregnancy in these women.<sup>10</sup> In a follow-up study of 393 cycles, they found that LNG-EC given the day of ovulation or later did not prevent pregnancy, but it did prevent pregnancy when given on days -5 to -1 even though 80 percent of the women were ovulating.<sup>11</sup>

Some articles have contradicted the findings of these large, well-done studies by Durand and Noé, but the contradictory studies are limited because of their small sample size<sup>12</sup> or the timing of administration of the drug (on the day of the LH surge or later).<sup>13</sup> It has also been proposed that in the women who ovulate, the ovum may be dysfunctional because lower LH levels result in an egg that is not capable of being fertilized.<sup>14</sup> Proponents of this theory rely on in vitro studies in which high doses of progesterone were not given, whereas with the administration of Plan B they are.<sup>15</sup> In a study of Macaque monkeys given synthetic progesterone prior to ovulation, the LH surge was blunted but 40 percent of the oocytes achieved fertilization and early embryonic development.<sup>16</sup>

In fact, we may never know the exact mechanisms by which LNG-EC acts; however, we conclude that LNG-EC is a poor anovulant through most of the fertile window. Proposing that the ovum is not capable of being fertilized is a weak argument. There is no in vivo test to determine whether fertilization has taken place, so we should err on the side of life.

Studies have also demonstrated that, unless given at very high doses, LNG-EC has no effect on cervical mucus, sperm motility, or the ability of sperm to fertilize the ovum.<sup>17</sup> We conclude that LNG-EC does not prevent ovulation and fertilization when given during the fertile window, and therefore its administration prior to ovulation in cases of rape is not morally licit. Thus, the Peoria

protocol cannot be safely followed, because LNG-EC cannot be given prior to ovulation without having a possible postfertilization effect on a new human life.

Two other FDA-approved emergency contraceptives, available by prescription only, are ulipristal acetate, also known as Ella, and the copper IUD (intrauterine device). Ulipristal 30 mg, a second-generation selective progesterone receptor modulator, can be administered up to 120 hours after intercourse. Since ulipristal, like mifepristone (RU-486), has a direct effect on progesterone-mediated processes, it cannot be used in cases of rape because of its postfertilization or abortifacient effect. Likewise, insertion of a copper IUD up to 120 hours after intercourse does not prevent ovulation or fertilization and would prevent a clinical pregnancy by the prevention or disruption of implantation.

### **Ethical Discussion**

According to the Congregation for the Doctrine of the Faith's instruction *Dignitas personae*,

In order to promote wider use of interceptive methods, it is sometimes stated that the way in which they function is not sufficiently understood. It is true that there is not always complete knowledge of the way that different pharmaceuticals operate, but scientific studies indicate that *the effect of inhibiting implantation is certainly present*. ... It must be noted, however, that anyone who seeks to prevent the implantation of an embryo which may possibly have been conceived, and who therefore either requests or prescribes such a pharmaceutical, generally intends an abortion. ... Therefore, the use of means of interception and contragestion fall within the sin of abortion and are gravely immoral.<sup>18</sup>

To say that it is licit to use a particular drug after rape to prevent conception, certain criteria have to be met with moral certitude. The criteria include the three moral fonts of an action:

- *The object chosen* must be good and must not involve any evil. In this case, the woman is acting in self-defense against the sexual assault by an unjust aggressor, and the object is to utilize a drug that will delay or prevent ovulation beyond the five days of sperm survival in order to protect the woman's ovum from coming into contact with the rapist's sperm, so that conception does not occur. The drug will thus prevent fertilization but will not have any postfertilization effects that are interceptive, contragestive, or abortifacient.

- *The end in view or the intention* has to be good or morally neutral. In this case the end is good since the goal is to avoid a pregnancy that would result from an act of violence and that the woman has no obligation to seek.
- *The circumstances of the action* must support the goodness of the act. Critical circumstances in this case are that the act at issue was not a marital act and that it is possible to test the woman to see if the drug, when given at this time in her cycle, will have any postfertilization effects detrimental to the survival of a conceptus if conception has already occurred.

At this time, the research findings appear to show clearly that these criteria are not met when Plan B is given according to the Peoria protocol during the fertile window and prior to the LH surge, or when any of the other FDA-approved emergency contraceptives are administered.

While those who developed the Peoria protocol did so with moral integrity according to the facts known to them at the time, and while they are to be commended for their efforts to care for women traumatized by rape, the facts known now require that use of the Peoria protocol be suspended. Further research is needed to find a drug that can be used after sexual assault to prevent conception without taking a human life.

Certainly we must have compassion for the woman who has been raped. Yet we must be mindful that a human life that may have been conceived cannot be attacked or destroyed but must be protected and preserved. Therefore we must refrain from acting violently against an innocent human life as the currently approved drugs and devices are known to do. To administer these contraceptives is to choose evil to achieve a good end. No matter how good the end might be, using evil means to achieve it is never morally permissible.

So if conception does result from a rape, the truly compassionate response is to walk with the woman through the resultant pregnancy, supporting her in the physical and emotional challenges that she faces. In such a difficult situation, her traumatic circumstances may turn into a life-giving and healing experience if she is enfolded in love and care. Authentic health care is only health care if it adheres to these principles. Those engaged in the vocation of Catholic health care are called to take the lead in promoting these principles and so minister to all persons the light of the Gospel of life.

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### Notes

1. U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (Washington, DC: USCCB, 2009), dir. 36.
2. M. M. Holmes et al., "Rape-Related Pregnancy: Estimates and Descriptive Characteristics from a National Sample of Women," *American Journal of Obstetrics and Gynecology* 175.2 (August 1996): 320–325; see also F. Stewart and J. Trussell, "Prevention of Pregnancy Resulting from Rape: A Neglected Preventive Health Measure," *American Journal of Preventive Medicine* 19.4 (November 2000): 228–229. Holmes et al. estimate that thirty-two thousand pregnancies resulted from rape annually, whereas Stewart and Trussell put the figure at twenty-five thousand.
3. Teva Women's Health, "How Plan B One-Step Works," *Plan B One-Step*, accessed December 9, 2015, <http://www.planbonestep.com/howitworks.aspx>.
4. A. J. Wilcox, C. R. Weinberg, and D. D. Baird, "Timing of Sexual Intercourse in Relation to Ovulation: Effects on the Probability of Conception, Survival of the Pregnancy, and Sex of the Baby," *New England Journal of Medicine* 333.23 (December 7, 1995): 1517–1521.
5. M. L. Condic, *When Does Human Life Begin? A Scientific Perspective* (Thornwood, NY: Westchester Institute for Ethics and the Human Person, 2008), 5.
6. M. Durand et al., "On the Mechanisms of Action of Short-Term Levonorgestrel Administration in Emergency Contraception," *Contraception* 64.4 (October 2001): 227–234.
7. It was previously thought that, to be effective, emergency contraceptives acted by modifying the histologic features of the endometrium, but this is no longer the case.
8. M. Durand et al., "Late Follicular Phase Administration of Levonorgestrel as an Emergency Contraceptive Changes the Secretory Pattern of Glycodelin in Serum and Endometrium during the Luteal Phase of the Menstrual Cycle," *Contraception* 71.6 (June 2005): 451–457.
9. M. Durand et al., "Hormonal Evaluation and Midcycle Detection of Intrauterine Glycodelin in Women Treated with Levonorgestrel as in Emergency Contraception," *Contraception* 82.6 (December 2010): 526–533.
10. G. Noé et al., "Contraceptive Efficacy of Emergency Contraception with Levonorgestrel Given Before or After Ovulation," *Contraception* 81.5 (May 2010): 414–420.
11. G. Noé et al., "Contraceptive Efficacy of Emergency Contraception with Levonorgestrel Given Before or After Ovulation," *Contraception* 84.5 (November 2011): 486–492.
12. L. Marions et al., "Effect of Emergency Contraception with Levonorgestrel or Mifepristone on Ovarian Function," *Contraception* 69.5 (May 2004): 373–377.

13. W. A. Palomino, P. Kohen, and L. Devoto, "A Single Midcycle Dose of Levonorgestrel Similar to Emergency Contraceptive Does Not Alter the Expression of the L-selectin Ligand or Molecular Markers of Endometrial Receptivity," *Fertility and Sterility* 94.5 (October 2010): 1589–1594.
14. N.P.G. Austriaco, "Levonorgestrel, Luteinizing Hormone Levels, and Oocyte Quality," letter, *National Catholic Bioethics Quarterly* 14.2 (Summer 2014): 201–203.
15. W. M. Verpoest et al., "Relationship between Midcycle Luteinizing Hormone Surge Quality and Oocyte Fertilization," *Fertility and Sterility* 73.1 (January 2000): 75–77.
16. S. M. Borman et al., "Progesterone Promotes Oocyte Maturation, but Not Ovulation, in Nonhuman Primate Follicles without a Gonadotropin Surge," *Biology and Reproduction* 71.1 (July 2004): 366–373.
17. W. Yeung et al., "The Effects of Levonorgestrel on Various Sperm Functions," *Contraception* 66.6 (December 2002): 453–457; and K.S. Brito et al., "The In Vitro Effect of Emergency Contraception Doses of Levonorgestrel on the Acrosome Reaction of Human Spermatozoa," *Contraception* 72.3 (September 2005): 225–228.
18. Congregation for the Doctrine of the Faith, *Dignitas personae, On Certain Bioethical Questions* (Boston: Pauline Books and Media, 2008), n. 23, original emphasis.

1/11/2016: Final text per page proofs from *Catholic Health Care Ethics: A Manual for Practitioners*, 3rd ed., ed. Edward Furton (Philadelphia: National Catholic Bioethics Center), forthcoming. Figure and table call-outs removed.