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# *Emergency Contraceptives & Catholic Healthcare*

**A New Look at the Science and the Moral Question**



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## SUMMARY

The question of the licitness of providing “emergency contraceptives” to victims of sexual assault who present in the emergency rooms at Catholic hospitals is a critical matter for evaluating and developing appropriate protocols for sexual assault victims. An examination of the available scientific studies demonstrates that the most common emergency contraceptive—Plan B, generally administered to prevent ovulation—at times may fail to prevent conception from taking place and instead may prompt an early abortion. This necessitates answering the question of when, and under what circumstances, it is morally licit to provide contraceptive medications to sexual assault victims while avoiding the potential outcome of prompting an early abortion.

Consequently, in the present study we undertake a moral evaluation of this issue, articulating the conditions under which it would be morally licit to provide sexual assault victims with the emergency contraceptive Plan B, given what we know today of the effects of levonorgestrel (LNG), its active ingredient. Because the available body of scientific evidence indicates that LNG can at times work by preventing implantation of a newly conceived human embryo, and indicates no conclusive evidence that LNG never acts in that manner, we hold that the possibility of a chemical abortion will be present when Plan B is administered too close to the time of ovulation.

In developing our moral analysis, we address in depth the following four questions:

- (1) Is it morally licit for a sexual assault victim to intend to avoid conception?
- (2) Do statistical estimates of the likely incidence of actual chemical abortions occurring as a result of administering emergency contraceptives have a bearing on the moral evaluation of this issue?
- (3) How do possible ways of including or excluding the effects of emergency contraceptives in one’s intention bear on such a moral evaluation?
- (4) How does the imminent need to resist state mandates that jeopardize the free exercise of conscience in the practice of healthcare, especially in Catholic hospitals, bear on a moral evaluation?

We hold that, in addition to a pregnancy test, victims of sexual assault should be administered a urine-based ovulation test as a reasonable attempt to determine whether the victim is close to ovulation as judged by the presence of luteinizing hormone (LH surge) in the blood. Such urine testing is easy and inexpensive, and it does not submit the patient to an unreasonable burden. Only on the basis of a negative ovulation test (in addition to information regarding the patient’s own menstrual cycle, based on a thorough history and physical examination, which is appropriate for any victim of a sexual assault) can a healthcare professional then provide the patient with Plan B.

We argue that the resolution of this moral question should not be based on statistical modeling but that it must focus on the particular situation of the individual victim. Legislative mandates undermine religious liberties if they require administration of emergency contraceptives without allowing healthcare providers to make a proper determination for each victim that ovulation is not imminent. Catholic healthcare providers should neither accommodate, nor be compelled to accommodate, such unjust laws.



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## Emergency Contraception and Catholic Healthcare: A New Look at the Science and the Moral Question

### INTRODUCTION

The provision of sexual assault victims<sup>1</sup> with hormonal pregnancy prophylaxis, or “emergency contraceptives” (hereafter, EC),<sup>2</sup> continues to be a controversial topic within the Catholic healthcare system and among Catholic moral theologians faithful to the Church’s Magisterium. The controversy arises from what we know today of the mechanisms by which these hormonal drugs achieve their purpose of avoiding pregnancy. Central to the debate is the way scientists and moral theologians are to understand and evaluate the potential mode of action by which these hormones prevent an embryo from properly implanting in the womb (hereafter, the post-fertilization effect), thereby causing an early abortion. Scientific studies examining emergency contraceptive use cannot eliminate early abortion as one potential mode of action, although prevention of ovulation<sup>3</sup> is the most common effect of the drug levonorgestrel (LNG), the object of the present study.<sup>4</sup>

For Catholic healthcare institutions, this potential for causing an early abortion has serious implications for sexual assault treatment protocols. Although medical interventions aimed at blocking ovulation or blocking the rapist’s sperm from penetrating the victim to the point of fertilization are justified in situations of sexual assault, it is morally illicit for healthcare providers to offer treatment that would cause the abortion of a conceived child. Where state laws mandate<sup>5</sup> the provision of contraceptive drugs such as LNG after sexual assault, Catholic healthcare professionals in those states face the dilemma of either violating a specific and absolute moral norm or violating the law.

In the face of state mandates that require administration upon demand, with no religious or conscience protections, no state Catholic Conferences have publicized a refusal to comply. This leaves the door open to Catholic healthcare institutions’ administering LNG, commonly known by the trade name Plan B™, to sexual assault victims if a pregnancy test administered following the assault is negative. Pregnancy tests, however, will detect only an embryo who already has implanted in the womb—an event that happens five to twelve days<sup>6</sup> after conception.<sup>7</sup> It is widely known that a standard pregnancy test cannot detect a pre-implantation embryo. A positive pregnancy test administered within hours of a sexual assault would, therefore, indicate only the presence of an already existing pregnancy resulting from sexual relations prior to the sexual assault, and not from the sexual assault itself.

**1** For purposes of this paper, we define sexual assault (also referred to hereafter as “rape”) as “unwanted sexual intercourse.” See F. H. Stewart and J. Trussell, “Prevention of Pregnancy Resulting from Rape: A Neglected Preventive Health Measure,” *American Journal of Preventive Medicine* 19, no. 4 (November 2000): 228–229.

**2** This practice is more commonly referred to as “emergency contraception.” Since it is our conviction that the moral act here in question is not, in principle, the intrinsically immoral act called “contraception”—a point we clarify in depth at the beginning of Part II—we have preferred, throughout the present study as often as possible, to refer to the act in question as the provision of “emergency contraceptives” so as to reinforce the moral distinction between these two acts and to avoid sending the erroneous message that situations of sexual assault somehow constitute an exception to the absolute moral norm against contraception.

**3** For the purposes of this paper, ovulation is defined as the physical release or expulsion of the ovum from the ovarian follicle.

**4** This paper is limited to a discussion of the active ingredient in the most common modern emergency contraceptive, known as Plan B™ (Levonorgestrel, hereafter referenced as LNG). It does not address other forms of emergency contraceptives such as the Yuzpe regimen (a combination of synthetic estrogen and progestin). Nor does this paper address RU-486 as an emergency contraceptive, the abortifacient effect of which is well-documented. Also, ellaOne(R) (ulipristal acetate), approved by the US Federal Drug Administration in August 2010, can be effective up until five days post intercourse. It is a progesterone receptor modulator, attaching to progesterone receptors and thus blocking the effectiveness of progesterone. European Medicines Agency, “European Public Assessment Report for Ellaone: Summary for the Public,” p. 2. [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Summary\\_for\\_the\\_public/human/001027/WC500023671.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/001027/WC500023671.pdf) (accessed March 28, 2011). Natural progesterone prepares the endometrium for implantation. This fact, plus the length of time post intercourse that ulipristal acetate is effective, supports the fact that ulipristal acetate prevents implantation of the embryo. Ulipristal acetate is addressed in a later section.

**5** A complete listing of statutes that require the offering of emergency contraceptives following sexual assault is available at <http://www.ncbcenter.org/NetCommunity/Page.aspx?pid=481>.

**6** See Asgerally T. Fazleabas and J. Julie Kim, “What

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Makes an Embryo Stick?" *Science*, 299, no. 5605 (January 17, 2003): 355-356. Available at <http://www.sciencemag.org/cgi/content/summary/299/5605/355> or DOI: 10.1126/science.1081277 (accessed June 1, 2011). This statement is based on a study, as cited in the article, by S. D. Spandorfer et al., "Importance of the Biopsy [sic] Date in Autologous Endometrial Cocultures for Patients with Multiple Implantation Failures," *Fertility and Sterility* 77, no 6 (June 2002): 1209-1213, in which it was demonstrated that embryos created through IVF implanted at higher rates when they were co-cultured with endometrial cells obtained at 6 days after ovulation. Another article indicates that implantation occurs 6 to 7 days after fertilization (see M. S. M. van Mourik, N.S. Macklon, and C. J. Heijnen, "Embryonic Implantation: Cytokines, Adhesion Molecules, and Immune Cells in Establishing an Implantation Environment," *Journal of Leukocyte Biology* 85 (January 2009): 4-19). Another study indicates that implantation of a human embryo into the endometrium can occur only during a self-limited period between LH+7 to LH+11 (see H. Achache and A. Revel, "Endometrial Receptivity Markers: The Journey to Successful Embryo Implantation," *Human Reproduction Update* 12, no. 6 (November/December, 2006): 731-746). Given the commonly accepted timing for ovulation and then conception one to two days after the LH surge, these studies support the commonly reported and reasonable window for the timing of implantation of between 5 and 10-12 days after fertilization.

7 It is paramount to insist on the scientific fact that conception, the union of sperm and egg, is the starting point for a new, individual human life. Once conception takes place, the woman is pregnant. This clarification is important because some in the medical community now define "pregnancy" as beginning once the embryo implants in the mother's womb, 5-12 days after the embryo is engendered. See ACOG Committee on Terminology, *Obstetric-Gynecologic Terminology, with Section on Neonatology and Glossary of Congenital Anomalies*, ed. Edward Hughes (Philadelphia: F.A. Davis, 1972). Throughout this paper, "conception" and "pregnancy" are synonymous; once sperm and egg fuse together, the "moment of conception," a new human being exists. See Maureen Condic, *When Does Human Life Begin? A Scientific Perspective* (New York: Westchester Institute for Ethics & the Human Person White Paper, 2008). Available at [http://www.westchesterinstitute.net/index.php?option=com\\_content&view=article&id=351:white-paper&catid=64:white-papers&Itemid=113](http://www.westchesterinstitute.net/index.php?option=com_content&view=article&id=351:white-paper&catid=64:white-papers&Itemid=113).

Consequently, in this paper, we endeavor to do the following: In Part I, we engage in a thorough analysis of the best scientific studies available to date on the mechanisms by which LNG achieves its effects. In Part II, based on this scientific knowledge, we engage in a moral analysis of the propriety of including the provision of LNG in sexual assault protocols without the benefit of testing for ovulation. Specifically, we address the following questions:

- (1) Is it morally licit for a sexual assault victim to intend to avoid conception?
- (2) Do statistical estimates of the likely incidence of actual chemical abortions occurring as a result of administering EC have a bearing on the moral evaluation of this issue?
- (3) How do possible ways of including or excluding the effects of EC in one's intention bear on such a moral evaluation?
- (4) How does the imminent need to resist state mandates that jeopardize the free exercise of conscience in the practice of healthcare, especially in Catholic hospitals, bear on a moral evaluation?

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## PART I

### LEVONORGESTREL AND ITS MODE OF ACTION

Plan B was approved as an emergency contraceptive (a method of preventing pregnancy after intercourse) by the U. S. Food and Drug Administration (FDA) in 1999. At the time, it was available to women only and by prescription only. In 2006, the FDA approved the availability of Plan B without a prescription to anyone (man or woman) 18 years and older. In April 2009, the FDA announced that Plan B could be obtained over-the-counter by anyone who is age 17 or older. Men and women under age 17 still must have a prescription to obtain this drug.<sup>8</sup> Plan B is currently a one-pill regimen of 1.5 mg of a synthetic progestogen called levonorgestrel (LNG), which has been used in birth control pills for over 35 years.

### SCIENTIFIC STUDIES EXAMINING LNG'S MECHANISM OF ACTION

Most scientific studies of LNG demonstrate that the primary mode of action for the drug, if taken within 72 hours<sup>9</sup> of intercourse, is the prevention of ovulation.<sup>10</sup> However, the estimated effectiveness of this mode of action is disputed, and none of the available research on LNG and its mechanism of action conclusively answers the question of whether, when ovulation does occur and therefore potentially conception, there is any post-fertilization effect of the drug that may impede implantation of a developing embryo.<sup>11</sup>

It is reasonable to question if other mechanisms are at work, given the discrepancy between reported estimates of LNG's overall effectiveness in preventing pregnancy, versus its effectiveness in merely preventing ovulation: LNG's "total effectiveness" (at preventing pregnancy) is usually estimated at between 58% and 95% (depending on when the drug is administered relative to intercourse),<sup>12</sup> and its effectiveness in merely preventing ovulation is estimated at about 50%.<sup>13</sup>

One explanation for this discrepancy may be simple overestimation in several studies of LNG's total effectiveness in preventing pregnancy. This gap may also be explained, however, by other modes of action of LNG, including a post-fertilization effect, in which ovulation does occur and conception does take place in spite of the anovulatory action of LNG, but the newly conceived embryo is prevented from successfully implanting and developing in the uterus.

In addition to the cascade of hormonal changes that take place throughout the reproductive cycle and upon which LNG may have an effect, LNG's mode of action may interfere with various steps of the reproductive process and prevent pregnancy, as noted by Croxatto.<sup>14</sup> The following list combines the steps of the reproductive process at which LNG's mode of action might have an effect, according to Croxatto (the information about the time range of the various events in an idealized 28-day cycle is adapted from a graphic representation by Ralph P. Miech<sup>15</sup>):

- Follicle maturation – occurs during the pre-ovulatory phase, from day 6 to day 12 of the cycle.<sup>16</sup>

<sup>8</sup> Information about the FDA's approval of Plan B is available at <http://www.fda.gov/cder/drug/infopage/planB/default.htm> (accessed November 14, 2010).

<sup>9</sup> The manufacturer's webpage for Plan B One-Step states that if administered within 72 hours after sexual intercourse, "Plan B® One-Step works primarily by: Preventing ovulation[,] Possibly preventing fertilization by altering tubal transport of sperm and/or egg[,] Altering the endometrium, which may inhibit implantation." See <http://planbonestep.com/plan-b-prescribers/how-plan-b-works.aspx>. Our paper is written specifically with regard to the potential cases of women who would present within that 72-hour time frame after sexual assault. We recognize that there are cases in which women present beyond that window, who, in our opinion, would not be candidates for LNG.

<sup>10</sup> Arguments supporting other mechanisms of preventing fertilization pertain to the impact of EC on cervical mucus and sperm capacitation. (Marta Durand et al., "On the Mechanisms of Action of Short-Term Levonorgestrel Administration in Emergency Contraception," *Contraception* 64, no. 4 (October 2001): 227-234.) LNG, as a progestin, thickens cervical mucus, which significantly impairs sperm motility. This effect has been cited as one potential mode of action in preventing pregnancy. There have been satisfactory authoritative refutations of this point. Sperm can reach the fallopian tubes within minutes of ejaculation; and they are capacitated as early as 5 hours after entering the female reproductive tract. (See Donald R. Coustan, Ray V. Haining, Jr., and Don B. Singer, eds., *Human Reproduction: Growth and Development* (Boston: Little, Brown and Company, 1995), 22; D. S. F. Settlage, M. Motoshima, and D. R. Tredway, "Sperm Transport From the External Cervical OS to the Fallopian Tubes in Women: A Time and Quantitation Study," *Fertility and Sterility*, 24 (1973): 655–661, referenced in L. Speroff, et al., *Clinical Gynecologic Endocrinology and Infertility* (Baltimore: Williams and Wilkins, 5th edition, 1994), p. 232: "Uterine contractions propel the sperm upward, and in the human they can be found in the tube five minutes after insemination.") The effects of EC on cervical mucus and sperm capacitation can take up to nine hours. E. Kesserü et al. found that there is a decrease in sperm mobility beginning in five hours, and an increase in cervical mucus viscosity beginning in nine hours, after 0.4 mg administration of LNG. (E. Kesserü, F. Garmendia, N. Westphal and J. Parada, "The Hormonal and Peripheral Effects of D-Norgestrel in Postcoital Contraception," *Contraception* 10, no. 4 (October 1974): 411–424). Thus, taking LNG at any time after the coital act is complete cannot change the cervical mucus soon enough to prevent sperm motility if fertile mucus is present. Furthermore, Gemzell-Danielsson and Marions conclude that data indicate that "levonorgestrel or mifepristone in doses relevant for emergency contraception have no direct effect on sperm function." (Kristina Gemzell-Danielsson and Lena Marions, "Mechanisms of Action of Mifepristone and Levonorgestrel When Used for Emergency Contraception," *Human Reproduction Update* 10, no. 4 (July–August 2004): 342.) They observe that the effects reported by Kesserü et al. are probably seen when LNG is used as a regular contraceptive, but are unlikely

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to be its main action. Thus, any such effects of LNG on sperm function are from daily ingested oral contraceptives, not from the single dose EC administered within a sexual assault protocol.

11 The actual drug label for Plan B One-Step states that the drug “may inhibit implantation (by altering the endometrium).” This statement has led many to believe that this mode of action—preventing the implantation of an embryo—has been conclusively verified since it is information that is part of the official, FDA-approved product label. However, for some drug products, the FDA-approved labeling may include information that has not been conclusively verified, but that the agency and/or the manufacturer believes may be relevant to the decision whether to prescribe or use the product.

12 See a complete review of the literature in R. Mikolajczyk and J. Stanford, “Levonorgestrel Emergency Contraception: A Joint Analysis of Effectiveness and Mechanism of Action,” *Fertility and Sterility* 88 (February 23, 2007): 565-571.

13 *Ibid.*, 565-571. The study authors estimate that LNG is 49% effective at preventing ovulation if taken within 24 hours of intercourse, but effectiveness for ovulation disruption drops when LNG is taken longer than 24 hours after intercourse.

14 Croxatto lists these steps as “discrete steps of the reproductive process whose theoretical interference by EC could prevent pregnancy.” H. B. Croxatto et al., “Mechanism of Action of Hormonal Preparations Used for Emergency Contraception: A Review of the Literature,” *Contraception* 63, no. 3 (March 2001): 111-121.

15 See Gerald J. McShane, “Postcoital Anovulatory Hormonal Treatment: An Overview of the Medical Data,” in *Catholic Health Care Ethics: A Manual for Practitioners*, 2nd ed., ed. Edward J. Furton with Peter J. Cataldo and Albert S. Moraczewski (Philadelphia: The National Catholic Bioethics Center, 2009), 126. Reprinted with permission of The National Catholic Bioethics Center.

16 The timing noted in this list of discrete steps in the reproductive cycle assumes an idealized 28-day cycle. Actual cycles in women are more variable as to the timing of various pituitary, ovarian, and uterine events, even in the context of cycles that are 28 days in length.

17 The period from fertilization to implantation can be anywhere from 5 to 12 days.

18 Andrea D. Shields, “Pregnancy Diagnosis,” *E-Medicine from MedMD* (April 20, 2009), <http://emedicine.medscape.com/article/262591-overview> (accessed June 25, 2010).

- The ovulatory process – up through at least day 9 of the cycle, the pituitary gland releases increasing amounts of the hormone that stimulates the growth of the immature ovarian follicle; this event, along with the release by the pituitary gland of the luteinizing hormone (LH) on or about day 12 of the cycle (peaking on day 13, as evidenced by a positive urine or blood LH test), stimulates ovulation on day 14; the ovulatory phase ends with ovulation, signaling the luteal phase.
- Luteal phase – from day 15 to day 28, the endometrium is prepared for implantation of an embryo by progesterone secreted by the corpus luteum, which develops from the ruptured ovarian follicle, until implantation, at which time the placenta begins to produce progesterone (in addition to that from the corpus luteum) and eventually takes over this function entirely later in the first trimester.
- Sperm migration – sperm migrate into and through the fallopian tube; this phase includes adhesion of spermatozoa to the epithelium, which is needed for them to acquire and maintain their fertilizing capacity.
- Fertilization – occurs in the distal fallopian tube.
- Zygote development – begins in the fallopian tube; the zygote is transported through the fallopian tube, which takes 5 to 7 days (day 21 of the cycle).
- Pre-implantation – development of the endometrium by progesterone from the corpus luteum preparing for endometrial receptivity; uterine retentiveness of free laying morula or blastocyst for 3 to 4 days (up to day 25 of the cycle<sup>17</sup>), with the blastocyst’s signaling, adhesion, and invasiveness accomplishing implantation.
- Implantation of the blastocyst – human chorionic gonadotropin hCG is secreted by the trophoblast of the implanted blastocyst, as evidenced by a positive serum or urine pregnancy test as soon as eight days after fertilization.<sup>18</sup>

*Any effect of LNG that makes the reproductive system inhospitable to a newly conceived, living embryo would be an abortifacient.*

Any effect of LNG that makes the reproductive system inhospitable to a newly conceived, living embryo would be an abortifacient. The scientific studies that have examined LNG do not offer a conclusive answer about whether potential post-fertilization effects exist, but certain substantive scientific findings raise significant moral concerns that LNG may have a post-fertilization mechanism. Below is a summary of findings from the scientific research that is currently available:

*(a) The closer to ovulation the drug is administered, the more likely ovulation is to occur.*

Croxatto et al. measured the dominant follicle when LNG was administered and observed the ovulatory process in the ensuing five days. Ovulation was prevented in 89% of cycles where the follicle measured 12-14 mm, but ovulation

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was prevented in only 38% of cycles where the follicle measured 15-17 mm, and in only 10% of cycles where the follicle measured 18 mm.<sup>19</sup> In a Durand et al. study, all participants (n = 8) ovulated who received LNG in the late follicular phase (immediately before the LH surge). That study concluded that “anovulation results from disrupting both normal development and hormonal activity of the growing follicle” when LNG is given preovulatory.<sup>20</sup> In a study by Hapangama et al., 7 of 12 women who took LNG before the LH peak ovulated; 5 of them took LNG on the day before the LH surge, and one on the day of the surge.<sup>21</sup> A study by Tirelli et al. found that one woman who took LNG after the LH surge had already begun ovulating normally and had a normal-length luteal phase. However, the study did not determine whether or not any of the women who took LNG during the peri-ovulatory phase (defined within the Tirelli study as from one day before to one day after expected ovulation) ultimately ovulated.<sup>22</sup>

*(b) Ovulatory dysfunction with follicular rupture may follow administration of LNG, meaning that an egg is released, but the follicular rupture is preceded by a blunted or absent LH peak (which would affect the normal progesterone secretory function of the corpus luteum), or rupture is followed by low-serum progesterone.*

The corpus luteum provides essential hormonal support for the developing embryo from implantation until the placenta takes over, at about 11 weeks gestation. Natural progesterone is necessary to support the pregnancy and to prevent the uterine lining from shedding. Croxatto et al. determined that all cycles with “ovulatory dysfunction” following LNG administration (defined within the study as “follicular rupture not preceded by an LH peak or preceded by a blunted LH peak, or not followed by elevation of serum [progesterone] over 12 nmol/L”) also had a blunted or absent follicle-stimulating hormone (FSH) peak, significantly lower estradiol levels, and significantly lower progesterone concentration—all of which are “deviations of the normalcy required for the success of the reproductive process.”<sup>23</sup>

In related studies, Durand et al. found that women who ovulated after LNG was administered in the late follicular phase all had significantly lower daily serum P4 (progesterone) concentrations.<sup>24</sup> In a later study, Durand found that progesterone levels were significantly lower in the luteal phase when LNG was given two to four days prior to the LH surge. Durand concluded that “LNG administration prior to LH surge does not always prevent ovulation, but it has deleterious effects on [progesterone] production by the corpus luteum.”<sup>25</sup> As stated earlier, in the Hapangama et al. study, 7 of 12 women who took LNG before the LH surge ovulated, but all of them had a reduced total luteal phase LH concentration, and a shorter luteal phase than did the women with the control cycles. As noted by Hapangama et al., “Basal levels of LH are essential for the normal secretory function of the corpus luteum.”<sup>26</sup>

- <sup>19</sup> Horacio Croxatto et al., “Pituitary-ovarian Function Following the Standard Levonorgestrel Emergency Contraceptive Dose or a Single 0.75-mg Dose Given on the Days Preceding Ovulation,” *Contraception* 70 (2004): 442-450.  
<sup>20</sup> Durand et al., “On the Mechanisms,” 227.  
<sup>21</sup> Dharani Hapangama, Anna F. Glasier, and David T. Baird, “The Effects of Peri-Ovulatory Administration of Levonorgestrel on the Menstrual Cycle,” *Contraception* 63 (2001): 123-129.  
<sup>22</sup> Alessandra Tirelli, Angelo Cagnacci, and Annibale Volpe, “Levonorgestrel Administration in Emergency Contraception: Bleeding Pattern and Pituitary-Ovarian Function,” *Contraception* 77 (2008): 328-332.  
<sup>23</sup> Croxatto et al., “Pituitary-ovarian Function,” 448.  
<sup>24</sup> Durand et al., “On the Mechanisms,” 227-234.  
<sup>25</sup> Marta 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 (2005): 455.  
<sup>26</sup> Hapangama et al., “The Effects of Peri-Ovulatory,” 128.

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- 27 Durand et al., "On the Mechanisms," 227-234.  
28 Hapangama et al., "The Effects of Peri-Ovulatory," 123-129.  
29 Tirelli et al., "Levonorgestrel Administration," 328-332.  
30 Durand et al., "On the Mechanisms," 227-234.  
31 Lena Marions et al., "Effect of Emergency Contraception with Levonorgestrel or Mifepristone on Ovarian Function," *Contraception* 69 (2004): 373-377.  
32 Idris A. Okewole et al., "Effect of Single Administration of Levonorgestrel on the Menstrual Cycle," *Contraception* 75 (2007): 375.  
33 Durand et al., "Late Follicular Phase," 451-457.

*(c) The luteal phase is shorter after administration of LNG.*

The luteal phase is the period between ovulation and menstruation, during which the uterine lining prepares to nourish an embryo, should one implant. As stated earlier, the embryo takes anywhere from 5-12 days after conception to travel through the fallopian tube and implant in the uterus. If the luteal phase is too short, the uterine lining sheds before the embryo can implant. Durand et al. found that of 15 women who were administered LNG in mid-follicular phase, the 3 women who ovulated from that group had significantly shorter luteal phases than the women in the control cycles, as did all 8 women who received LNG in the late follicular phase.<sup>27</sup> Again, as Hapangama et al. found, all 12 women who took LNG prior to the LH surge showed a significantly shorter luteal phase.<sup>28</sup> Tirelli's study, in which women self-reported the dates of their cycle stage, found that all the women who took LNG during the follicular phase had a significantly shorter overall cycle length, but women who took LNG during the peri-ovulatory phase did not have shorter cycle length. This study did not specifically discuss luteal phase length but only cycle length.<sup>29</sup>

*(d) Progesterone concentrations in the luteal phase are lower after LNG is taken in the late follicular phase.*

As stated earlier, in one of Durand et al.'s studies, all 8 participants who received LNG in the late follicular phase (prior to LH surge) ovulated and had significantly lower daily serum P4 concentrations compared to their control cycles.<sup>30</sup> Marions et al. also found that median values of P4 were significantly lower than those of the control cycles after LNG treatment was administered two days before the expected LH surge; two women (of 7 in the study) had no rise in progesterone levels.<sup>31</sup> Okewole et al. observed shorter luteal phases in their sample of 6 women who took LNG one day before the expected day of ovulation and found that LNG altered progesterone production by the corpus luteum, suggesting that "LNG might have caused premature degeneration of the corpus luteum."<sup>32</sup>

*(e) LNG alters glycodelin secretion.*

Glycodelin is a secretory progesterone-regulated glycoprotein in the endometrium. It is a potent inhibitor of sperm-zona binding and is, therefore, normally absent during the peri-ovulatory phase; but it becomes highly expressed in the last week of the luteal phase, wherein its inhibitory activity on the immune cells may play a role in fetomaternal defense mechanisms. Durand et al. found that LNG alters glycodelin secretion in two important phases of the cycle: (1) It increases earlier than in control cycles in the luteal phase, where it might inhibit sperm-zona binding (though this action requires glycodelin levels several orders of magnitude higher than those found in the study); (2) later in the luteal phase, glycodelin concentration is significantly lower than in controls, and unlike in the controls, it declines (perhaps indicating a weakened immunosuppressive microenvironment at the implantation site, inhibiting implantation of a developing embryo).<sup>33</sup>

## EVALUATION OF STUDIES EXPLORING LNG AND HISTOLOGICAL CHANGES IN THE ENDOMETRIUM

The studies discussed above offer findings that suggest there may be a post-fertilization effect of LNG that could lead to the destruction of a living human embryo. A number of studies, on the other hand, conclude that LNG has no post-fertilization effect, often citing the studies and arguments which we will now respond to at length.

One particular study by Novikova et al.<sup>34</sup> was designed specifically to determine whether LNG has a post-fertilization effect. Ninety-nine women who had intercourse one time in cycle days -5 to -2 (before ovulation) were studied. Among the 34 women who took LNG before or on the day of ovulation, there were zero pregnancies, whereas 4 would have been expected. Among the 17 women who had intercourse during the fertile period but who took LNG after ovulation, 3 or 4 pregnancies could have been expected, and 3 were observed. The study authors suggest that this data supports the theory that LNG does not have a post-ovulatory effect, but the authors also acknowledge that the small sample size does not enable them to make a definitive statement about the potential post-ovulatory effects of LNG. The significance of their conclusions are twofold: (1) the study supports what we have already stated—that the effectiveness of EC in preventing ovulation declines as it is administered closer to the timing of ovulation; thus, it should not be administered once ovulation has been initiated; and (2) the study does not have the number of subjects to reach a definitive conclusion on the post-fertilization effect.

*The effectiveness of EC in preventing ovulation declines as it is administered closer to the timing of ovulation; thus, it should not be administered once ovulation has been initiated.*

Another in vivo research report also claims that the impact of LNG on the endometrium is insufficient to prevent implantation. Landgren et al. studied the proliferative activity of the endometrium after it had been exposed to large doses of LNG at different stages of the cycle.<sup>35</sup> They concluded that

[t]he main endometrial effects observed in this study, a decrease in number and diameter of glands when [LNG] was administered on cycle days 2, 4, 6, and 8 or 9, 11, 13, and 15, indicate that the proliferative activity of the endometrium is suppressed when [LNG] is administered during the follicular phase. When administered in the secretory [luteal] phase, [LNG] does not induce any significant endometrial changes.<sup>36</sup>

The significance of this study is that days 13 and 15 are ones during which the cascade of events that initiate ovulation have begun, and the presence of a positive LH surge may be detected. Therefore a positive LH test indicates that LNG cannot prevent ovulation. Thus, if LNG is administered in the presence of a positive LH

<sup>34</sup> Natalia Novikova et al., "Effectiveness of Levonorgestrel Emergency Contraception Given Before or After Ovulation: A Pilot Study," *Contraception* 75 (2007): 112-118. In this study, ovulation was calculated by analyzing serum LH, estradiol and progesterone levels to estimate timing of ovulation within a  $\pm 24$ -hour period and accuracy of about 80%.

<sup>35</sup> B.M. Landgren et al., "The Effect of Levonorgestrel Administered in Large Doses at Different Stages of the Cycle on Ovarian Function and Endometrial Morphology," *Contraception* 39 (1989): 275-289.

<sup>36</sup> Landgren et al., "The Effect of Levonorgestrel," 286-287.

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37 C.X. Meng et al., "Effects of Oral and Vaginal Administration of Levonorgestrel Emergency Contraception on Markers of Endometrial Receptivity," *Human Reproduction* 25, no. 4 (April 2010): 881.

38 Wilder Alberto Palomino, Paulina Kohen, and Luigi 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*, published online, November 10, 2009.

39 Lena Marions et al., "Emergency Contraception with Mifepristone and Levonorgestrel: Mechanism of Action," *Obstetrics and Gynecology* 100 (2002): 65-71; quote from Abstract.

40 *Ibid.*, 65-71.

41 Gabriela Noé et al., "Contraceptive Efficacy of Emergency Contraception with Levonorgestrel Given Before or After Ovulation," *Contraception* 81, no. 5 (2010): 414.

41 *Ibid.*, 419-420.

42 H.M. Behre et al., "Prediction of Ovulation by Urinary Hormone Measurements with the Home Use ClearPlan Fertility Monitor: Comparison with Transvaginal Ultrasound Scans and Serum Hormone Measurements," *Human Reproduction* 15 (Dec 2000): 2478-2482.

test, with the inability to prevent ovulation at that point, and the changes in the endometrium occur—which this study identified when LNG is administered prior to ovulation—the possibility of a post-fertilization effect (on the endometrium) is present, and LNG should not be administered. On cycle days 2 through 11, in the absence of a positive LH test, there is sufficient moral certitude that ovulation can be suppressed by the administration of LNG.

Additionally, two recent studies of endometrial receptivity markers after exposure to LNG may erroneously be viewed as resolving this issue. However, even the researchers of these studies equivocate in their conclusions. Meng et al. conclude, "Although the expression of PR [progesterone receptor] and LIF [leukaemia inhibitory factor] was affected by high-dose oral levonorgestrel, it seems unlikely that these changes would be enough to prevent implantation."<sup>37</sup> Palomino et al. found that "[t]he histologic assessment revealed small areas of glandular atrophy and intense stromal decidualization in only 3 of 12 biopsies [25 percent] from subjects who received LNG through the oral route."<sup>38</sup> Of significance is the fact that neither study had even as many as 15 subjects exposed to oral LNG.

A similar study of endometrial receptivity by Marions et al. concluded that "[t]he mode of action of emergency contraception with mifepristone or levonorgestrel is *primarily* due to inhibition of ovulation rather than inhibition of implantation" [emphasis added].<sup>39</sup> Of importance is the small sample size of 12 participants, 6 in each treatment group, with the LNG treatment group being treated in two phases, one before and one after ovulation. In the LNG treatment group, the changes demonstrated in endometrial receptivity markers were not reported to be significant by the researchers. However, one participant demonstrated a reduced staining of COX-2 in glandular cells; the endometrium was out of phase in two women treated after ovulation (but one biopsy was taken a day early); in another participant there was a reduced expression of COX-2 in glandular epithelial cells; and in another participant there was a reduced expression of COX-2 in luminal epithelial cells. Significantly, the authors also found that treatment with LNG before ovulation inhibited the luteinizing hormone surge.<sup>40</sup> Such a finding supports our recommendation that the appropriate time to administer LNG, for its only confirmed effectiveness as EC, is before ovulation.

Additionally, a study by Noé et al. concludes that LNG prevents pregnancy only when taken before fertilization. It acknowledges that "[s]tudies on the impact of LNG-EC on endometrial parameters involved in endometrial receptivity are not consistent, and current knowledge on cellular and molecular markers of endometrial receptivity in the human is insufficient to resolve this controversy."<sup>41</sup> In this study, of the 87 women who took LNG before ovulation (1 to 5 days before the day of ovulation), 62 (71%) of them ovulated, but none of them became pregnant—clearly suggesting a post-ovulation effect. It remains unclear in this study how many women who ovulated received LNG before the LH surge. The LH surge occurs 1 to 2 days before ovulation,<sup>42</sup> and the subjects were treated with LNG 1 to 5 days before



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ovulation. That is a critical factor, since research has demonstrated that LNG cannot prevent ovulation in the presence of such a surge. If the Noé et al. study is replicated and also finds that 71% of women treated with LNG-EC 1 to 5 days before ovulation actually ovulated and none of them conceived, then such findings would indicate a possible post-fertilization effect of LNG. Furthermore, such a replication would need to be more precise as to what day the LNG-EC was administered prior to ovulation and what evidence of an LH surge existed for each subject. We argue that an LH test is necessary to use LNG-EC licitly, precisely because research indicates that it does effectively prevent ovulation if used prior to the LH surge. However, if LNG is administered at or after the surge, there is a reasonable possibility of a post-fertilization/abortifacient effect.

Noé et al. also “postulate that increased cervical mucus viscosity caused by LNG impedes the migration of sperm...”<sup>43</sup> However, as cited earlier, this assertion has been refuted by other researchers. Sperm reach the fallopian tubes in minutes and are capacitated within 5 hours.<sup>44</sup>

Furthermore, Noé et al. report that among the 35 women who had unprotected intercourse during fertile cycle days and who took LNG on the day of ovulation or immediately thereafter, the number of observed pregnancies was very similar to the number that would have been expected if LNG had not been administered. This could support their conclusions of no endometrial effect if LNG is administered during or after ovulation. The question to ask is—why then administer such high doses of a medication when there is no difference in pregnancy rates with the LNG administered at this time? Our position is that LNG can prevent ovulation, and thus conception, when administered before, but not after, the LH surge is detected. Thus, a simple test for the absence of the LH surge would provide the moral certitude required for the licit administration of LNG as EC.

Proponents of Plan B frequently argue that LNG is a progestin, the same class that includes progesterone, which renders the endometrium more receptive to implantation and assists in maintaining pregnancies. While true as stated, the claim is factually incomplete. LNG is a synthetic progestin, not the naturally occurring steroid progesterone, which prepares the endometrium for implantation and helps maintain a pregnancy. Progestins that are not derived from the naturally occurring steroid progesterone are not used in pregnancy and are, in fact, contraindicated in pregnancy because their effects in humans are not uniformly the same as those of progesterone.<sup>45</sup>

Those arguing that the effects of LNG on the endometrium are insufficient to alter implantation often cite animal studies or in vitro studies, such as the Lalitkumar et al. study,<sup>46</sup> none of which replicate the human condition. The purpose of the Lalitkumar study was to investigate the effect of LNG and mifepristone on the attachment of human embryos to an in vitro endometrial construct. The researchers concluded, “Levonorgestrel did not impair the attachment of human embryos to

<sup>43</sup> Noé et al., “Contraceptive Efficacy,” 419-420.

<sup>44</sup> Coustan et al., *Human Reproduction*, 22.

<sup>45</sup> Northwest Center for Reproductive Sciences, Fact Sheet Progesterone Supplementation Patient Information (May 2005), 2. Note: Hydroxyprogesterone caproate, a synthetic form of the hormone progesterone, was approved by the U.S. Federal Drug Administration to help reduce the risk for preterm delivery in pregnant women who have a history of spontaneous birth. See <http://www.endocrinetoday.com/view.aspx?rid=80296#jump> (accessed February 25, 2011).

<sup>46</sup> P. G. L. Lalitkumar et al., “Mifepristone, but not Levonorgestrel, Inhibits Human Blastocyst Attachment to an In Vitro Endometrial Three-Dimensional Cell Culture Model,” *Human Reproduction* 22 (2007): 3031-3037.

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47 Ibid., 3031.

48 Achahe and Ariel, "Endometrial Receptivity Markers," 731.

49 C. E. Selick et al., "Fertilization and Early Embryology: Embryo Quality and Pregnancy Potential of Fresh Compared with Frozen Embryos—Is Freezing Detrimental to High Quality Embryos?" *Human Reproduction* 10, no. 2 (1995): 392–395.

50 C. Simón et al., "Cytokines and Embryo Implantation," *Journal of Reproductive Immunology* 39, vols.1–2 (August 1998): 117–131.

51 S. D. Spandorfer et al., "An Analysis of the Effect of Age on Implantation Rates," *Journal of Assisted Reproduction and Genetics* 17, no. 6 (July 2000): 305.

52 John D. Aplin and Susan J. Kimber, "Trophoblast-Uterine Interactions at Implantation," *Reproductive Biology and Endocrinology* 2, no. 48, published online July 5, 2004, <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=471567>.

the in vitro endometrial construct."<sup>47</sup> But many unanswered questions remain in this research. The small sample raises serious questions about interpretation of the findings. Furthermore, this study demonstrated that more of the control (untreated) embryos successfully implanted (10) than did not (7), and fewer of the LNG-exposed embryos successfully implanted (6) than did not (8). While the difference in rates of implantation is not statistically significant at this sample size, one should not conclude that this study has demonstrated that there is no post-fertilization effect with LNG.

The Lalitkumar research design also raises a number of questions. The endometrial tissue used as a cell culture was from 11 women between the ages of 22 and 40 years, at luteinizing hormone (LH) days +4 and +5. Research has demonstrated that "even though the blastocyst can implant in different human tissues, surprisingly in the endometrium, this phenomenon can occur only during a self-limited period spanning between days 20 and 24 of a regular menstrual cycle (day LH+7 to LH+11)."<sup>48</sup> The question needs to be asked whether more of the control group embryos, untreated with any substance, would have implanted if they had been in tissue taken from donors within this self-limited window. The ability to state whether or not there is a significant difference in implantation rates among untreated/treated groups must first be grounded in a research design that provides for accurate baseline data. Thus, there is a question concerning how closely this study replicated the in vivo conditions of implantation.

No information about the qualities of the embryos was provided beyond the fact that the embryos had been cryopreserved for five or more years. Cryopreservation of embryos has a detrimental effect on embryo quality. However, cryopreservation of high-quality embryos does not have detrimental effects on their implantation or pregnancy potential, even though there is a decline in embryo quality.<sup>49</sup> No embryo gradation is provided in the Lalitkumar study, nor is there a report of any attempt to assign embryos to control or treated groups based on similar qualities, parental origins, or age of mother. Such factors as age of the mother could have an effect on embryo quality. The embryo assignment to groups was random, but no control for these or other variables was reported. Researchers tell us that the embryo is responsible for one-third of implantation failures,<sup>50</sup> so without information on the quality of the embryos in this study, no helpful determinations of causality can be made.

As noted above, a maternal age beyond 35 years affects implantation rates, with a linear decrease in implantation rates of 2.77% per year.<sup>51</sup> There is no information on how the age of the endometrial donor affected the assignment of tissue for the 3 endometrial cell culture sites, if at all. Blastocyst implantation studies in animals are indicating that receptivity to implantation is largely maternally controlled.<sup>52</sup> There was no reported attempt to control tissue used by age of donor, so that each area of the endometrial construct used for implantation was formed by an equal amount of tissue representative of the total donor group. The study reports that the endometrial tissue was "minced." This could indicate that tissue from 40-year-old donors was

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combined with that of all younger donors, but no age breakdown of the 11 donors used is provided. No information is provided on the exact ages of the women, and no information is provided on endometrial tissue donor assignment, except that the age range of the donors was between 22 and 40 years.

The researchers of this study report that “there is very limited information about the concentration of mifepristone or levonorgestrel at the endometrial cellular level when given orally for fertility control.”<sup>53</sup> However, they conclude that “the dosage of these drugs used in this study is sufficient enough to inhibit the action of progesterone as shown by earlier studies (Catalano et al., 2003).” But Catalano et al. identified key pathways responsible for endometrial receptivity using RU-486.<sup>54</sup> Human endometrial biopsies were cultured in the presence of estradiol and progesterone, with or without RU-486. The results indicated that two important endometrial signaling pathways controlling gene expression are altered by RU-486. Endometrial receptivity to the implanting embryo is affected by steroids, and the identified genes are likely to be involved in this mechanism. However, while the progestin LNG is a synthetic progesterone, RU-486 (mifepristone) contains no estrogen or progesterone. The Catalano study makes no reference to the progestin LNG. It is unclear what dosing parameters were used in the Lalitkumar study to simulate the in vivo action of LNG.

In sum, one cannot conclude that the Lalitkumar in vitro study has replicated the in vivo environment for the following reasons: 1) the dosage of LNG that mimics the in vivo state cannot be validated; 2) the condition, grade, and quality of the embryos are not reported or addressed; 3) the age of the mother of each of the embryos used is not addressed; and 4) the control of the age of the endometrial biopsy donors in relationship to each implantation site is not addressed. The study’s most glaring defect, of course, is the small sample size. Despite the fact that the research demonstrated no statistical difference in implantation rates between the control group and the LNG group, more of the control group embryos implanted than did not implant; and, on the other hand, more of the LNG-treated embryos did not implant than did implant. It would be a gross oversimplification to determine that this study has resolved the question of the effects of LNG on the implantation of embryos.<sup>55</sup>

Others who deny the post-fertilization effect of LNG hypothesize that, since LNG’s effectiveness drops significantly the longer the delay after coitus, it cannot be an abortifacient at any time in the cycle. One such author reasons, “Furthermore, several investigators have shown that the effectiveness of Plan B drops dramatically if given more than two days after coitus. This result is the exact opposite of what would be expected to happen if the agent interfered with implantation of the embryo—if that were the case, Plan B would become more effective as time passes after coitus and the moment of implantation approaches.”<sup>56</sup> In fact, the Canadian Plan B Web page states that it is “95% effective within 24 hours of unprotected sex” and “85% effective between 25 and 48 hours.”<sup>57</sup> While it is a fact that the effectiveness of LNG decreases the longer one is post-coitus, the Web page contains no disclaimer

<sup>53</sup> Lalitkumar, “Mifepristone, but not Levonorgestrel,” 3036.

<sup>54</sup> R. D. Catalano et al., “The Effect of RU486 on the Gene Expression Profile in an Endometrial Explant Model,” *Molecular Human Reproduction* 9, no. 8 (August 2003): 465–473.

<sup>55</sup> Excerpts with permission from The National Catholic Bioethics Center: Marie T. Hilliard, “Colloquy: Plan B’s Abortifacient Effect,” *The National Catholic Bioethics Quarterly* 8, no. 1 (Spring 2008): 9–12.

<sup>56</sup> Sandra E. Reznik, “Plan B’: How It Works: Science Shows It Is Not an Abortifacient,” *Health Progress* 91, no. 1 (January–February 2010): 60.

<sup>57</sup> Plan B: The Morning After Pill, “What it Isn’t,” <http://www.planb.ca/not.html> (accessed April 4, 2011).

58 Ibid.

59 Mikolajczyk and Stanford, "Levonorgestrel Emergency Contraception," 565-571.

60 Ibid.

61 Ibid.

in terms of where a woman is in her cycle. Even if one were to accept the author's reasoning, one is left to ask about the purpose of administering high doses of LNG at a time when it purportedly has no effect.

*There is agreement that the research is not definitive on whether the effect of LNG on the endometrium is sufficient to prevent implantation.*

In summary, there is agreement that the research is not definitive on whether the effect of LNG on the endometrium is sufficient to prevent implantation. However, due to the fact that LNG's effectiveness is as high as 58% between 49 and 72 hours post coitus,<sup>58</sup> that the sperm reach the fallopian tubes within minutes, that the research demonstrates that LNG used as EC cannot act fast enough to have an impact on sperm function, and that ovulation cannot be stopped once there is an LH surge, the evidence is strong for a post-fertilization effect. Even if one denies such an effect, there would be no sound medical reason to administer LNG if it cannot stop ovulation. Testing to determine where a woman is in her cycle (i.e., for the presence of an LH surge) represents sound medical practice, as well as a willingness to have moral certitude that LNG can accomplish the one agreed-upon reason for its administration: to prevent ovulation. Choosing not to know this, by omitting such testing, constitutes negligence.

## SIGNIFICANT OBSERVATIONS REGARDING THE SCIENTIFIC STUDIES

### *(1) Estimates differ on the "effectiveness" of LNG*

There are various estimates of the effectiveness of LNG in preventing pregnancy, ranging from 58% to 95% effective, depending on the timing of its administration after intercourse.<sup>59</sup> The wide range in estimates of effectiveness presents a special problem for understanding whether ovulation disruption alone can account for the effectiveness of LNG, whether effectiveness has simply been overestimated, or whether there are other modes of action, including post-fertilization effects, which help to explain the total effectiveness of LNG.

Based on combined data from multiple clinical studies, in order to develop a true range of effectiveness for LNG, Mikolajczyk and Stanford developed a model that simulated follicular growth, known day-specific probabilities of conception, and known disruption of ovulation by LNG. They report a wide discrepancy between total effectiveness (preventing pregnancy), which has been estimated in various studies at between 58% and 95% (depending on when the drug is administered relative to intercourse), and its effectiveness in merely preventing ovulation, which has been estimated at between 8% and 49%, depending on the timing of administration relative to intercourse.<sup>60</sup> They concluded that the gap between the effectiveness of LNG, as estimated from clinical studies and from what can be attributed to the disruption of ovulation, may be explained both by an overestimation in various studies of actual clinical effectiveness and by mechanisms of action other than ovulation disruption (including post-fertilization mechanisms).<sup>61</sup>

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*(2) Animal studies*

Some animal studies demonstrate that LNG will not prevent establishment of pregnancy once fertilization has taken place (demonstrated in Cebus monkeys<sup>62</sup> and in rats<sup>63</sup>). Nonetheless, results from non-human studies do not necessarily extrapolate to human studies, as demonstrated in the case of the intra-uterine device, which had markedly different mechanisms of action in animals than in humans.<sup>64</sup>

*(3) Timing of Administration of LNG*

An important and consistent finding from the studies discussed above is that LNG prevents ovulation at a much greater rate when it is administered prior to the LH surge, but that ovulation occurs at a much higher rate when LNG is administered closer to the LH surge (though it may be marked by ovulatory dysfunction).

*If ovulation is more likely to occur when LNG is administered very close to, or during, the LH surge ... but ovulatory dysfunction or other mechanisms of action from the drug prevent implantation of a newly conceived embryo, then LNG would act as an abortifacient.*

If ovulation is more likely to occur when LNG is administered very close to, or during, the LH surge (in the late follicular or peri-ovulatory phases), but ovulatory dysfunction or other mechanisms of action from the drug prevent implantation of a newly conceived embryo, then LNG would act as an abortifacient. Therefore, if LNG has an abortifacient effect when ovulation occurs, such an effect is most likely to occur when LNG is administered in the late follicular or peri-ovulatory phases (very close to, or during, the LH surge).

<sup>62</sup> M. Ortiz et al., "Post-Coital Administration of Levonorgestrel does not Interfere with Post-Fertilization Events in the New-World Monkey *Cebus paella*," *Human Reproduction* 19 (2004): 1352-1356.

<sup>63</sup> A. Müller, C. M. Lladós, and H. B. Croxatto, "Postcoital Treatment with Levonorgestrel Does not Disrupt Post-fertilization Events in the Rat," *Contraception* 67 (2003): 415-419.

<sup>64</sup> P. Corfman and S. Segal, "Biological Effects of Intrauterine Devices," *American Journal of Obstetrics & Gynecology* 100 (1968): 448-459. Also M. Ortiz et al., "Mechanisms of Action of Intrauterine Devices," *Obstetrical and Gynecological Survey* 51 (1996): S42-51.

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<sup>65</sup> The most recent magisterial reference to this issue is found in the instruction *Dignitas Personae*. Without naming a specific drug, with regard to “morning-after pills” it states:

Scientific studies indicate that the effect of inhibiting implantation is certainly present, even if this does not mean that such interceptives [the intrauterine device and the so-called morning-after pills] cause an abortion every time they are used, also because conception does not occur after every act of sexual intercourse. 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 abortion.

Congregation for the Doctrine of the Faith, Instruction *Dignitas Personae*: On Certain Bioethical Questions (September 8, 2008), n. 23, [http://www.usccb.org/comm/Dignitaspersonae/Dignitas\\_Personae.pdf](http://www.usccb.org/comm/Dignitaspersonae/Dignitas_Personae.pdf) (accessed April 4, 2011).

<sup>66</sup> Sulmasy, “Emergency Contraception,” 308-309.

<sup>67</sup> A. A. Kubba et al., “The Biochemistry,” 512-516.

## PART II

### MORAL EVALUATION

We will now undertake a moral evaluation of the issue at hand, framing it in the following terms: under what conditions, if any, would it be morally licit to provide sexual assault victims with EC (hormonal pregnancy prophylaxis), given what we know today of the mechanisms by which these hormonal drugs achieve their purpose? We undertake this analysis from within the natural moral law tradition and adhering fully to the Magisterium of the Catholic Church.<sup>65</sup>

We will articulate that analysis in the form of responses to the following specific questions: (1) Is it morally licit for a sexual assault victim to act with the intent to avoid conception? (2) Do statistical estimates of the likely incidence of actual chemical abortions occurring as a result of administering EC have a bearing on the moral evaluation of this issue? (3) How do possible ways of including or excluding the effects of EC in one’s intention bear on such a moral evaluation? (4) How does the imminent need to resist state mandates that jeopardize the free exercise of conscience in the practice of healthcare, especially in Catholic hospitals, bear on a moral evaluation? Finally, we will make a summary statement that crystallizes our current judgment on the liceity of providing sexual assault victims with hormonal pregnancy prophylaxis.

Prior to commencing our moral analysis based on these four specific considerations, we must acknowledge that the current sharp disagreements between Catholic moral theologians on the liceity of providing EC hinge on quite different interpretations of the currently available scientific data we explored in Part I.

First, we recognize that the scientific understanding of how EC works has changed considerably over the last 20-25 years.<sup>66</sup> Difficulties in understanding have been compounded by the fact that the earlier FDA approved (1998) product for EC use was a drug combining estrogen with progestin, modeled after the Yuzpe method of using high doses of standard birth control pills for this purpose. Plan B, approved in 1999, contains a single drug, the progestin LNG. Early studies of the Yuzpe method’s mode of action demonstrated its effect on the endometrium to be a negative impact on implantation.<sup>67</sup> Earlier studies of the actions of LNG also concluded that its primary effect was to change the endometrium and, therefore, prevent implantation. The idea that LNG worked largely by altering the endometrium was commonly accepted for many years. However, more recent studies, many of which we have already discussed in Part I, have demonstrated that the most common mode of action of LNG is to prevent ovulation. Therefore, over the years the understanding of LNG’s mode of action has changed within the medical and scientific community to reflect the research, moving from a belief that LNG worked by changing the endometrium to prevent implantation to an understanding that LNG acts primarily to prevent ovulation.

The current state of disagreement among Catholic moral theologians on this point can be explained as differences of opinion in prudential judgment in light of an evolving scientific understanding. Though such disagreements are not comfort-

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able, they require time, much collegial debate, prayer, and discernment for achieving consensus as to which prudential determination best approximates a sound moral approach. We hold, however, that the science indicates that EC can sometimes work by preventing implantation of a newly conceived embryo, and that there is no conclusive evidence to believe that it never does so. Some continue to argue that there is no credible evidence to date that EC ever prevents implantation; but, in light of current scientific data, we argue that moral prudence requires us to pursue a safer moral course: namely, in light of the reasonable danger that ovulation may have been initiated prior to the administration of Plan B, medical personnel are morally obligated to take reasonable measures in attempting to detect whether ovulation can be prevented in each given instance—or if it will instead act to block implantation.

A number of bioethicists have argued that such a possibility is statistically insignificant. Thus, they justify the administration of EC within sexual assault protocols at Catholic hospitals without first determining if it is possible for the drug to have the desired anovulatory effect in the patient being treated. In defense of this view, some offer various statistical assumptions and mathematical conjectures, using the Bayesian method, which is controversial when applied to particular cases.<sup>68</sup> In the subsequent section (2), this method of reasoning will be analyzed for its ability to provide the requisite moral certitude for the administration of EC to victims of sexual assault. We turn now to our moral evaluation.

### IS IT MORALLY LICIT FOR A RAPE VICTIM TO ACT WITH THE INTENT TO AVOID CONCEPTION?

We affirm that it is morally licit for a woman, while being sexually assaulted or having been sexually assaulted,<sup>69</sup> to take reasonable measures to avoid the conception of a child. The victim's intention to avoid conception is reasonable and morally licit inasmuch as it is a facet of her intention to repel the unjust aggressor who has forced intercourse upon her. By such actions as forcing the aggressor away from herself physically, perhaps even attempting to make him withdraw prior to ejaculation in her vagina, or subsequently treating herself with spermicides and taking an oral contraceptive, she licitly intends to avoid further penetration by the rapist, conception being the completion of that penetration forced upon her.<sup>70</sup>

In so doing, her action is, in principle, different in kind (is of a distinct moral species) than the action of a man or woman who, in the context of the marital act or in non-marital consensual sexual intercourse,<sup>71</sup> attempts to impede conception by chemical or other means. In other words, the sexual assault victim, in attempting to avoid conception, does not contracept as the moral tradition of the Church has come to understand the latter action.<sup>72</sup> Rather, the moral species of her action—even after the assault—is best characterized as defending herself from the aggressor and any

<sup>68</sup> Bayesian probability theory is a branch of mathematics that allows one to model uncertainty about the world and outcomes of interest to various agents by combining common-sense knowledge and observational evidence. The Bayesian method is applied validly when it is used to find correlations among events in general. See later discussion beginning on p. 14 of this paper and also Sulmasy, "Emergency Contraception," 305–331.

<sup>69</sup> For a complete discussion of the moral meaning and content of the term "sexual assault," see Germain Grisez, *Difficult Moral Questions: The Way of the Lord Jesus*, v. 3 (Quincy IL: Franciscan Press, 1997), 86–94.

<sup>70</sup> The rape victim surely intends, in repelling the vestiges of her attacker which remain in her body, to avoid a possible conception. She is not merely choosing to prevent ovulation; she wants to prevent becoming with child; she intends to avoid conception. The moral licitness of her choice depends on what further qualifying facets of her situation may inform her intention. The morally licit choice is to avoid conception as the completion of the aggressor's penetration in her body. Lacking that further qualification, we note that it is entirely possible for the victim to formulate what is, in essence, a contraceptive choice—namely, to avoid conception as the beginning of a new life in her fallopian tube—as is essentially the nature of the choice made in contraception in the context of consensual intercourse. Admittedly, this is a fine moral distinction. The latter intention is "contra life" and, in the opinion of many Catholic moralists, is at the very least a constitutive element of the intrinsically immoral act called contraception.

This distinction would apply especially to women who present in the ER and give evidence of an impoverished or deficient degree of moral experience and reasoning, and who normally use contraceptives (perhaps even Plan B) as part and parcel of their sex lives. It will often be the case that experience has conditioned such a woman to deal with her own sexual issues with a contraceptive mentality, and that such a predisposition could easily influence her way of dealing with the tragedy of her sexual assault. Consequently, a reasonable effort should be made by the attending nurse or physician to help the victim—by means of adequate observations and motivations—to form an intention to avoid conception, not as avoiding a new potential life, but as thwarting the completion of the rapist's aggression. Furthermore, the nurse or attending physician should provide adequate moral observations directed at helping the patient refrain from setting her will on the potential post-fertilization effect of Plan B (as described on the medical label itself), lest she at least come to conditionally intend Plan B to be effective under all of its possible mechanisms of action. Once reasonable attempts have been made, attending medical personnel are not morally required to obtain assurances that their motivations have been embraced by the victim before administering Plan B to the victim (assuming such administration is otherwise licit for that specific patient).

<sup>71</sup> Whether use of contraceptives in the case of fornicators constitutes the same intrinsically disordered act which Catholic morality calls contraception (as defined in the encyclical *Humanae Vitae* as occurring in the context of marital intercourse and is prohibited by an absolute moral norm) is still disputed among moral theologians

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faithful to the Church's Magisterium. If it does constitute an intrinsically evil act, it is disputed as to whether this is because the fornicating couple formulates a "contra life will"—and only that, since they putatively could not be harming the goods of marriage or setting asunder the dual meaning of conjugal intercourse as articulated in *HV*, 14—or whether the fornicating couple also harms these latter meanings since intercourse in and of itself already embodies the very conjugal dimensions of union and procreation which fully unfold in marriage. The authors hold that the meaning of contraception, as described in the context of *HV*,<sup>14</sup> can certainly be extended to describe actions between non-married couples engaging in consensual sexual intercourse which "either before, at the moment of, or after sexual intercourse, [are] specifically intended to prevent procreation—whether as an end or as a means."

<sup>72</sup> For a comprehensive treatment of Catholic moral teaching on the act of contraception (and extensive bibliographical references), see Germain Grisez, *Living a Christian Life: The Way of the Lord Jesus*, v. 2 (Quincy IL: Franciscan Press, 1993), 506-519; E. Christian Brugger and Thomas Berg, "Abortion and Contraception in Catholic Moral Teaching: A Reply to Recent Objections," *Josephinum Journal of Theology*, 15, no. 2 (August 2008): 335-354.

<sup>73</sup> Some have suggested that the engendered embryo could be considered the unjust aggressor. This is completely inconsistent with an understanding of the concept of an unjust aggressor who engages in a deliberate evil act of the will, creating two victims: the assaulted woman and the engendered embryo.

<sup>74</sup> Grisez, *Difficult Moral Questions*, 297.

<sup>75</sup> "A woman sins gravely by expelling the seminal fluid or preventing its entry into the uterus. It is not sinful to do so if she has been the victim of rape or deception provided she does so before conception, since in this instance the semen is equivalent to an unjust aggressor" (Heribert Jone and Urban Adelman, *Moral Theology* (Westminster, MD: The Newman Bookshop, 1951), 541, cited in Sulmasy, "Emergency Contraception," 326, note 1); "Furthermore, if a woman is attacked, she may subsequently use a douche to prevent conception from occurring. But she should not do something that even probably would produce an abortion, in the event that conception has taken place" (Francis J. Connell, *Outlines of Moral Theology* (Milwaukee: Bruce, 1958), 171, cited in Sulmasy, "Emergency Contraception," 326, note 1); "A woman who is sexually assaulted has the right to defend herself against this unjust aggression before, during and after the assault. Any semen that might have been deposited in the reproductive tract of the survivor by the attacker is one of the lingering effects of the assault and can be considered part of the aggression. The woman has the right to defend herself against this effect and the possibility that it will lead to fertilization. It has been long recognized in the Catholic moral tradition that if it is morally justifiable for a woman to take measures to prevent a sexual attack, then it is justifiable for her to prevent any continuation of the same attack" (Peter Cataldo and Albert Moraczewski, "Pregnancy Prevention After Sexual Assault," in *Catholic Health Care Ethics: A Manual for Ethics Committees*, ed. Peter Cataldo and Albert Moraczewski

remaining vestiges of the aggressor's presence, most especially from what remains of the attacker in the form of his semen deposited in her vagina.<sup>73</sup> As Germain Grisez explains, "inhibiting ovulation, sperm capacitation, or fertilization in a woman who has been raped is morally similar to pushing the rapist away so that he ejaculates outside her vagina rather than within it."<sup>74</sup> Indeed, such a moral analysis has been affirmed for decades as the most reasonable manner of articulating the moral object in question among Catholic moral theologians faithful to the Church's Magisterium.<sup>75</sup>

In this case, the distinction between these two moral species of action—contraception and self-defense against the sexual aggressor—rests on whether the woman engages in intercourse willingly (i.e., with consent) or not. Here, the presence or absence of consent to the act is an essential circumstance determining the moral intelligibility of the object of choice in what are otherwise, on the level of their physical descriptions, similar physical acts (granted, of course, the physically distinct aspects of consensual sexual intercourse vs. forced sexual intercourse). The absence of consent in a sexual assault morally renders the prevention of fertilization, after the assault, an act of self-defense rather than a contraceptive act.

## DO STATISTICAL ESTIMATES OF THE LIKELY INCIDENCE OF ACTUAL CHEMICAL ABORTIONS OCCURRING AS A RESULT OF ADMINISTERING EC HAVE A BEARING ON THE MORAL EVALUATION OF THIS ISSUE?<sup>76</sup>

Statistical probability theory is a branch of mathematics that allows one to model uncertainty about the world and the outcomes of interest to various agents by combining common-sense knowledge and observational evidence. Some ethicists argue that the probability of an unintended abortifacient effect from emergency contraceptives when administered in the pregnancy-test-only protocol is very low, that the inaccuracy of ovulation testing means that an unintended abortifacient effect could still occur after the testing, and that it is questionable whether emergency contraceptives function as an abortifacient at all.<sup>77</sup>

Statistical probability arguments must start with accurate definitions and recent data on the frequency of pregnancy occurring after sexual assault, not data from 1979 (as were used by one advocate for a pregnancy-test-only protocol, who claimed the frequency was 1%<sup>78</sup>). As stated from the outset, we define sexual assault as "unwanted sexual intercourse."<sup>79</sup> More recent information on pregnancy resulting from sexual assault on women over 18 years of age indicates a rate of 5%.<sup>80</sup> Insofar as these studies were confined to women 18 years old and older, the actual pregnancy rate may be higher. Data indicate that about 44% of sexual assault victims are under age 18 and that 80% are under age 30.<sup>81</sup> The peak of female fertility occurs before age 30.<sup>82</sup> Therefore, the statistical probability that EC may be abortive must begin with this latter statistic of 5%, not the unfounded 1%, which is not merely exaggerated, but false.



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Furthermore, false assumptions can be made concerning the number of women who, at the time of a sexual assault, are already pregnant, assumptions resulting in inaccurate determinations of the statistical probability of an abortifacient effect from administering EC. One proponent of a statistical probability approach states, "I assume, based on background prevalence rates for U.S. women of child-bearing age, that 1 percent already will have a positive pregnancy test from intercourse prior to the rape," and then inaccurately deducts this rate from a 1979 resulting pregnancy rate of 1%, yielding a 0.99% pregnancy rate.<sup>83</sup> However, the rate of 1% for women who become pregnant because of sexual assault does not include women who are pregnant because of prior consensual sex. The pregnancy test in the emergency room already excludes them from these statistics.

Furthermore, women who arrive at an emergency room are less likely, statistically, to be a cross-section of those of child-bearing age. As referenced earlier, 80% of victims are under the age of 30. The result is that the pre-existing pregnancy rate among these women is likely to be smaller than 1%. The sad fact is that in the United States, sexual activity and contraceptive use begin in the teenage years, with 35.6% of all ninth- to twelfth-grade girls reporting being currently sexually active, 54.9% indicating use of a condom during their last sexual intercourse, and 18.7% reporting use of oral contraceptives.<sup>84</sup> Of teens 15 to 19 years old who have had sex, 98% report using at least one method of birth control.<sup>85</sup>

In addition, more than 98% of sexually active women in the United States have used at least one contraceptive method.<sup>86</sup> This would render them less likely to be pregnant from a prior act of intercourse. However, the condom was found to be the third-leading method of contraception in the United States, used by about nine million women and their partners.<sup>87</sup> Such victim-protective methods are unlikely to be used by a rapist; thus, while the incidence of a prior pregnancy is greatly overestimated using the statistical probability method mentioned above, the probability that a woman will become pregnant from a sexual assault is greater than has been estimated by that same method. Specifically, among women 19 to 26 years of age (the age group at which fertility is greatest and the incidence of being sexually assaulted is high), the probability of pregnancy resulting from unprotected intercourse, if occurring on a day relative to ovulation, may be as high as 50%.<sup>88</sup> Hence, the chance increases that a greater number of women who will become pregnant from sexual assault will present at the hospital.

Proponents of statistical probability arguments also attempt to predict fertility periods without engaging in medical testing to determine such periods. Such inaccurate methodology assumes that 11% of the women who seek EC at a Catholic hospital will be in their fertile period (which is deemed by one proponent of statistical probability to be a 3-day window).<sup>89</sup> Sperm, while having a standard viability of 72 hours, may remain potent for 5 days.<sup>90</sup> Thus, it is possible that a woman who is sexually assaulted 5 days prior to the 3-day window of greatest day-specific fertility potential in the middle

(National Catholic Bioethics Center, 2001) 11). See also Thomas J. O'Donnell, *Medicine and Christian Morality*, 3rd ed. (New York: Alba House, 1996), 195-196; Germain Grisez, *The Way of the Lord Jesus, Vol. 2, Living a Christian Life* (Quincy IL: Franciscan Press, 1993), 512; Edward J. Bayer, *Rape Within Marriage: A Moral Analysis Delayed* (Lanham, MD: University Press of America, 1985); John T. Noonan, *Contraception: A History of Its Treatment by the Catholic Theologians and Canonists* (New York: The New American Library, 1965), 440-442.

**76** Excerpts with permission from The National Catholic Bioethics Center, Marie T. Hilliard, "Moral Certitude and Emergency Contraception," in *Catholic Health Care Ethics: A Manual for Practitioners*, 2nd ed., edited by Edward J. Furton et al. (Philadelphia: NCBC, 2009), 153-162.

**77** Sulmasy, "Emergency Contraception," 305-331.

**78** *Ibid.*, 310-311, citing John R. Evrard and E. M. Gold, "Epidemiology and Management of Sexual Assault Victims," *Obstetrics and Gynecology* 53, no. 3 (March 1979): 381-387.

**79** See footnote 1; Stewart and Trussell, November 2000, 228-229.

**80** 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, no. 2 (August 1996): 320-324; and Rape, Abuse, and Incest National Network (RAINN), "Statistics," <http://www.rainn.org/statistics/> (accessed April 4, 2011).

**81** RAINN, "Statistics."

**82** *ADAM Medical Encyclopedia* (Atlanta, GA: ADAM, 2005), s.v. "Infertility," updated February 5, 2008, <http://www.nlm.nih.gov/medlineplus/ency/article/001191.htm>.

**83** Sulmasy, "Emergency Contraception," 311.

**84** Danice K. Eaton et al., "Youth Risk Behavior Surveillance—United States, 2007," *Morbidity and Mortality Weekly Report* 57, no. SS-4 (June 6, 2008): 99, 101.

**85** J. C. Abma et al., "Teenagers in the United States: Sexual Activity, Contraceptive Use, and Childbearing, 2002," *National Center for Health Statistics, Vital and Health Statistics* 23, no. 24 (December 2004): 1-48.

**86** William D. Mosher et al., "Use of Contraception and Use of Family Planning Services in the United States: 1982-2002," National Center for Health Statistics, *Advanced Data from Vital and Health Statistics* 350 (December 10, 2004), <http://www.cdc.gov/nchs/data/ad/ad350.pdf>.

**87** *Ibid.*

**88** D.B. Dunson, B. Colombo, and D.D. Baird, "Changes with Age in the Level and Duration of Fertility in the Menstrual Cycle," *Human Reproduction* 17, no. 5 (May 2002): 1399-1403.

**89** Sulmasy, "Emergency Contraception," 311.

**90** Allen J. Wilcox, Clarice R. Weinberg, and Donna 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, no. 23 (Dec 7, 1995): 1517-1521.

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<sup>91</sup> Mikolajczyk and Stanford, "Levonorgestrel Emergency Contraception," 565–571.

<sup>92</sup> The ERDs have a twofold purpose: "first, to reaffirm the ethical standards of behavior in health care that flow from the Church's teaching about the dignity of the human person; second, to provide authoritative guidance on certain moral issues that face Catholic health care today." U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (Washington, D.C.: USCCB, 2009), 1-2.

of her cycle will become pregnant. Furthermore, the ovum can live for 24 hours, presenting a window of possibly 9 days (extending to 32 percent for potential fertility) for conception to occur, instead of the 11% sometimes assumed.

Statistical probability using Bayesian methodology must rely on published research, not on defective data and unfounded assumptions. Misuse of the method perpetuates a chain of erroneous reasoning, and each of the errors in this chain is built upon the previous errors, so that a miscalculation at the beginning is compounded as the error progresses and is joined to those made in later assumptions.

Even if all the data and assumptions are factually supported, the key question is whether mere statistical probability provides sufficient evidence to support the proposition that EC will not have an abortive effect in this specific victim. The Bayesian method is applied validly when used to find correlations among events in general, as in the study by Mikolajczyk and Stanford, which indicates that EC has a post-fertilization effect.<sup>91</sup> The difficulty is that mere statistical frequency, as delineated by the Bayesian method, will not justify this conclusion for a specific victim being treated.

Advocates of the statistical probability method of developing a sexual assault protocol would have the healthcare provider justified in believing that EC will not have an abortive effect in this victim on the basis of the statistical frequency of sexually assaulted women who need treatment, are fertile, and yet have a negative pregnancy test result (which, as noted earlier, indicates nothing about whether or not the pregnancy is from the sexual assault). However, such a generalization does not indicate any linkage of cause and effect concerning a possible pregnancy in the present case. In order to move from premise to conclusion, one needs justification for the intervening premise: on the basis of relevant medical data, not statistical generalizations, EC will not act as an abortifacient in this victim.

### **HOW DO POSSIBLE WAYS OF INCLUDING OR EXCLUDING THE EFFECTS OF EC IN ONE'S INTENTION BEAR ON SUCH A MORAL EVALUATION?**

As a point of departure for a response to our third question, we begin with Directive 36 of the Ethical and Religious Directives for Catholic Health Care Services (ERDs) adopted by the bishops of the United States, as it is the most commonly referred to source of moral guidance on the issue of EC within Catholic healthcare in the United States:<sup>92</sup>

Compassionate and understanding care should be given to a person who is the victim of sexual assault. Healthcare 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>93</sup>

It is well known among Catholic moralists, however, that while ERD 36 requires “appropriate testing” to verify whether or not “conception” has occurred, application of Directive 36 remains problematic because no existing test can detect conception and the presence of a newly formed embryo prior to implantation.

Consequently, some moralists hold that, given the current state of medical technology, the only relevant moral requirement in light of ERD 36 is to verify that the sexual assault victim is not pregnant with an already implanted embryo. However, complying with the letter of the law, when it violates the intent of the law, still violates moral law. Thus, other moralists hold that the moral requirement extends much further—namely, that in administering EC in the case of sexual assault, practitioner and patient must attain to moral certitude that the licit administration of LNG, consistent with ERD 36, can be achieved. There are three differing fundamental positions on the moral liceity of administering LNG after a sexual assault which we summarize here:<sup>94</sup>

#### *Pregnancy-Test-Only Approach*

This protocol considers only the results from the administration of a pregnancy test to the sexual assault victim to determine whether or not administration of EC is morally licit. If the pregnancy test is negative, LNG is administered. If the test is positive, and the patient is pregnant, EC is not administered. Such a test in the emergency room context following sexual assault cannot detect the pregnancy resulting from rape, because pregnancy is undetectable for 5-12 days after conception. Rather, the pregnancy test simply indicates whether or not there is a pre-existing pregnancy, in which case EC would be pointless. Proponents of the pregnancy test approach bolster their argument, in part, by a consideration of the arguably low—and by some statistical calculations, near negligible—likelihood that actual chemical abortions could occur, as cited earlier.<sup>95</sup> Critics of this approach note that a pregnancy test fails to detect an embryo prior to implantation and that, therefore, if LNG is administered when a living human embryo is present in the patient, it may destroy that embryo as an abortifacient.

#### *Pregnancy-Plus-Ovulation Testing Approach*

This protocol, in addition to testing for a prior pregnancy, in its simplest form considers the results from an “ovulation” test to determine whether or not ovulation is imminent. Such tests measure the level of luteinizing hormone (LH) in the urine

<sup>93</sup> *Ibid.*, number 36.

<sup>94</sup> All protocols include as an initial step the taking of a good history, as well as obtaining a thorough physical examination. The protocols described in this section are not intended to address the patient who is post-menopausal, has had a hysterectomy or has been otherwise surgically sterilized, or is pregnant. LNG treatment in such cases is clearly not appropriate.

<sup>95</sup> Sulmasy, “Emergency Contraception,” 305-331.

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<sup>96</sup> Ovulation tests that measure LH in the urine are commonly available, simple to administer, non-invasive, and inexpensive.

<sup>97</sup> Joseph J. Piccioni, "Rape and the Peoria Protocol," *Ethics & Medics* 22, no. 9 (September 1997): 1-2.

<sup>98</sup> Although an assault during the post-ovulatory phase would not coincide with the presence of an ovum, and therefore risk of pregnancy would be next to zero, LNG could be offered for the emotional benefit of the patient.

<sup>99</sup> "A resolution in favor of prohibiting all 'emergency contraception' in Catholic hospitals," passed at the Catholic Medical Association General Assembly, October 2003. The CMA has not made any additional formal statement since the resolution was adopted. It is possible that the CMA may elaborate on the organization's position in light of more recent scientific and legislative developments.

or the blood.<sup>96</sup> If the ovulation/LH test is positive, showing a surge in LH, then this indicates that ovulation is imminent. When ovulation is imminent, LNG would not be administered based on the understanding that (a) LNG is not effective at preventing ovulation once the LH surge has begun; (b) it is possible that LNG has a post-ovulatory effect that could prevent implantation of a newly conceived embryo if conception does take place. If the ovulation/LH test is negative for the sexual assault victim, then LNG would be administered.

A problem with the simple form of the "ovulation approach," in which an ovulation test measures the LH in the urine, is that such tests might miss the LH surge in a woman's urine. This means that even if the ovulation test is "negative," it is nonetheless possible that ovulation is imminent, despite the fact that the LH surge is not apparent in the urine at the time the test is taken. In response to this possibility, St. Francis Medical Center in Peoria, Illinois, has adopted a protocol that attempts to evaluate more accurately whether or not ovulation is imminent.<sup>97</sup> Known as the "Peoria Protocol," it requires not only the ovulation/LH test, but also a measurement of the serum progesterone level. Accordingly, if the LH test is negative, but the serum progesterone level is elevated to within a certain range (between 1.5 and 5.9 ng/mL) and the menstrual history indicates that the patient does not expect her next menses to begin within the next seven days, the patient is likely in her peri-ovulatory phase or her early post-ovulatory phase. In such cases, even if the ovulation/LH test alone is negative, the other factors indicate that ovulation is imminent or has very recently taken place and that LNG would not, therefore, be effective in preventing ovulation. Thus, LNG would not be administered. If the LH test is negative and if the progesterone and menstrual history indicate that the patient is in the pre- or late post-ovulatory phases of her cycle, LNG is administered.<sup>98</sup>

*EC Is Never a Morally Licit Approach*

The perspective that emergency contraceptives cannot be ethically administered through Catholic institutions is based on the fact that emergency contraceptives have uncertain modes of action, including the possibility that they may be abortifacient. One example of this perspective is the 2003 Catholic Medical Association (CMA) resolution stating that "as 'emergency contraception' has the potential to prevent implantation whether given in the pre-ovulatory, ovulatory, or post-ovulatory phase... it cannot be ethically employed by a Catholic physician or administered in a Catholic Hospital in cases of rape."<sup>99</sup>

*Conclusions Related to the Three Approaches*

The proponents of the Pregnancy-Test-Only Approach base their position on the mixed findings in the literature about the effects of LNG on the endometrium. Then they use statistical formulas, often based on conjecture more than on solid data, to determine the statistical probability of an abortifacient effect in the overall population of sexual assault victims. Even if the data used supported the validity of such

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statistical estimates, we find this approach unsound. While it may be true that the resolution of some moral questions can be achieved by attention to statistical probabilities, in our opinion, the question at hand is not one such instance. Statistical or probability reasoning is a tenuous approach at best to articulating a moral evaluation of this issue, notwithstanding very real considerations of the necessary degree of uncertainty in medical judgments. The relevant issue, as we will argue, is always going to be—at what stage is this particular sexual assault victim in her cycle here and now when she presents in the Emergency Room? And, given her situation, can EC have its only documented effect that is timely enough to prevent fertilization of an ovum—namely, its anovulatory effect?

Moral certitude concerning this fact for the specific victim presenting in the emergency room requires the Pregnancy-Plus-Ovulation-Testing Approach. Whether or not the statistically predicted abortifacient effect is infrequent is irrelevant to a proper analysis of this moral question.<sup>100</sup>

*Moral certitude concerning this fact for the specific victim presenting in the emergency room requires the Pregnancy-Plus-Ovulation-Testing Approach.*

The resolution of question 3 hinges on whether the potential abortifacient effect is to be understood as a “direct effect” (that is, included in the intention of those who receive and administer EC), or as no more than a foreseeable but unintended “side effect” (that is, excluded from what is directly intended by those involved). This leads to a question many ethicists have raised on the issue of EC: does the principle of double effect (PDE) apply in this moral analysis?<sup>101</sup>

To be sure, proponents of both the Pregnancy-Test-Only Approach and the Pregnancy-Plus-Ovulation-Testing Approach must equally appeal to the PDE since neither protocol can provide absolute assurance that no chemical abortion will occur. So the prospect that a chemical abortion will occur must be understood as a possible consequence. This also opens up the possibility that in at least some scenarios, this potential outcome is understood in moral reasoning as foreseeable, but not as an intended side effect.

Disagreements remain, however, on how PDE is applicable, and on the manner in which the EC issue constitutes a double-effect scenario. Interpretations hinge on the extent to which we believe that the abortifacient effect is likely to occur in any given instance in which a victim of assault presents in the emergency room. Some ethicists hold that the abortifacient effect is so remote (so improbable) that a PDE analysis would yield the apodictic conclusion that a physician may always proceed with administering EC, reasonably tolerating the presumptively low (across-the-board) probability that EC would ever have an abortifacient effect in any patient whatsoever. Advocates of this approach base their PDE analysis on Bayesian assumptions. Once

**100** It is striking how proponents of statistical probability go to lengths to explain why an apodictic approach to resolving this issue becomes necessarily dysfunctional given the reality of the medical environment, but will later offer an equally apodictic moral solution based on recourse to the principle of double effect. See Sulmasy, “Emergency Contraception,” 307-317.

**101** The criteria to be satisfied for meeting the Principle of Double Effect are as follows: (1) The action one is undertaking must be good or at least morally neutral considered in itself. (2) There are at least two anticipated outcomes, at least one of which is a good effect, which is intended, and at least one other, which constitutes a moral evil, but is unintended. (3) The evil effect does not cause the good effect (the good effect is not a direct result of the evil effect). (4) There is a proportionately grave reason for tolerating the evil effect. (5) There is no less detrimental alternative.

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<sup>102</sup> Durand et al., "Late Follicular Phase," 451-457.

<sup>103</sup> This would be similar to a situation in which there is the intent to alleviate suffering through the administration of pain control medication (object), while anticipating the possibility of respiratory depression. The administration of the pain control medication may not always control the pain, even while suppressing respirations. (Excerpts with permission from The National Catholic Bioethics Center, from Marie Hilliard, "Dignitas Personae on Caring for Victims of Sexual Assault: A Commentary On *Dignitas Personae*, Part Two, n. 23," <http://www.ncbcenter.org/NetCommunity/Page.aspx?pid=1009> (accessed April 3, 2011).

the statistical likelihood of an abortion is resolved as an academic question, Catholic physicians would then, in this view, be free to proceed without further hesitation or prudential judgment in each individual case.

We disagree with such an approach.

We hold, on the contrary, that the likelihood of the abortifacient effect must be determined in each given case. Only then can the attending physician make the requisite application of the PDE and judge whether the likelihood of an abortifacient effect in this specific case here and now may be reasonably tolerated and, therefore, excluded from his intention when administering EC. Furthermore, even if a priori the abortifacient effect is excluded from one's intention in administering EC, intention alone is not determinative of the moral liceity of an action. Especially in the case of EC, a significant circumstance—namely, appropriate testing—must be addressed in rendering an adequate moral judgment on the administration of EC in any given case.

Unlike the proponents of the EC Is Never Morally Licit Approach, we agree that the PDE can be invoked, if all of the criteria for its application are met. This is particularly true in the case of a victim presenting with a negative LH test and with a history supporting the likelihood that the victim is not peri-ovulatory, even if there is the possibility that she might ovulate despite the administration of LNG. If the object and intent are to prevent ovulation and if circumstances to achieve the object and intent are documented, then the PDE can be invoked in the administration of LNG to a sexual assault victim.

Having applied an ovulation test, and having obtained the necessary menstrual history, the attending physician will have done everything reasonably possible to ascertain whether ovulation has been initiated. In that case, the physician is now—and only now—in a position to meaningfully preclude the abortifacient effect from his intention in providing EC.

However, some researchers have indicated that if LNG is administered in the late follicular peri-ovulatory phases, even before the LH surge is evident, there can also be a foreseeable but unintended post-fertilization effect.<sup>102</sup> If ovulation occurs, there could be the unintended engendering of an embryo who does not implant. Therefore, some would argue for a serum progesterone test, which would determine the pre- or post-ovulation day more accurately. However, equipment for such testing is not readily available in many emergency rooms. Furthermore, if undetected ovulation does occur, despite the administration of EC in the presence of a negative LH test result, the conditions for the moral administration of EC under the principle of double effect (PDE) would have been met. Any minimal potential for harm would be an unintended consequence of the legitimate desire to suppress ovulation.<sup>103</sup>

In sum, the key is to have as much medical certainty as possible whether conception

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is imminent or has occurred in the particular patient in question. A positive ovulation test gives evidence that ovulation has occurred or will occur within the next 24 hours, and that conception could take place.<sup>104</sup> Once ovulation has been stimulated by the luteinizing hormone (LH), EC alone cannot prevent ovulation from occurring.<sup>105</sup> With the recent Instruction from the Congregation for the Doctrine of the Faith,<sup>106</sup> and given that EC may function as an abortifacient if fertilization has occurred, Catholic hospitals must have moral certitude that the possibility of an abortion is excluded. The ovulation test provides this certainty. Concerning the supposed inaccuracy of the test, the urine LH test has demonstrated a positive predictive value of 0.97.<sup>107</sup>

Evidence (discussed at length in Part I of this paper) supports that EC alone is unable to prevent ovulation once the LH surge stimulates ovulation, and current research indicates that the impact of EC on sperm capacitation is not fast enough to prevent fertilization.<sup>108</sup> Thus, the only reason for which EC can licitly be given is to prevent ovulation. Therefore, moral certitude can be achieved only through administering the LH test. To administer EC when there is insufficient information concerning its effect on the specific patient in question is not only morally illicit but also medically unsound.<sup>109</sup>

*...given that EC may function as an abortifacient if fertilization has occurred, Catholic hospitals must have moral certitude that the possibility of an abortion is excluded.*

**HOW DOES THE IMMINENT NEED TO RESIST STATE MANDATES THAT JEOPARDIZE THE FREE EXERCISE OF CONSCIENCE IN THE PRACTICE OF HEALTHCARE, ESPECIALLY IN CATHOLIC HOSPITALS, BEAR ON A MORAL EVALUATION?**

There is much more at stake here than winning an argument on which protocol achieves the moral certitude that Directive 36 of the ERD requires. The debate has developed in response to legislative mandates on Catholic healthcare that attempt to dictate hospital policies in violation of the tenets of the Catholic Church. It would be fair to conjecture that a mind-set of accommodation to secular mandates has generated a willingness to settle for statistical probability over moral certitude in developing sexual assault protocols. But in making these accommodations, Catholic ministries are allowing ongoing erosion of their religious liberty. By capitulating to such mandates, Catholic healthcare is paying tribute to secular law over the particular law of the Church contained in the ERDs.

In the debate over whether Catholic healthcare facilities should be obliged under the law to provide EC to victims of sexual assault, it should be noted that Catholic healthcare is fully prepared to do just that. Catholic hospitals had compassionate

<sup>104</sup> See Elaena Quattrocchi and Irene Hove, "Ovulation and Pregnancy: Home Testing Products," *U.S. Pharmacist* 23, no. 9 (September 1998).

<sup>105</sup> Natalia Novikova et al., "Effectiveness of Levonorgestrel," 112-118.

<sup>106</sup> See footnote 65.

<sup>107</sup> E. Guermandi et al., "Reliability of Ovulation Tests in Infertile Women," *Obstetrics & Gynecology* 97, no. 1 (January 2001): 95.

<sup>108</sup> Novikova et al., "Effectiveness of Levonorgestrel," 112-118.

<sup>109</sup> Excerpts with permission from The National Catholic Bioethics Center, from Marie Hilliard, "Dignitas Personae and Emergency Contraception," *Ethics & Medics* 34, no. 2 (Feb 2009): 3-4.

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**110** See "Protocol for Sexual Assault: Anovulatory Hormonal Treatment Component: Saint Francis Medical Center." Reprinted with permission in *Catholic Health Care Ethics: A Manual for Practitioners*, ed. Edward J. Furton, Peter J. Cataldo, and Albert S. Moraczewski (Philadelphia, PA: The National Catholic Bioethics Center, 2nd ed., 2009), 131-133.

**111** Ulipristal acetate is an emergency contraceptive available by prescription which can be used to prevent pregnancy up to 120 hours (5 days) after unprotected intercourse or contraceptive failure. Thus, the potential impact on the endometrium, preventing implantation of a conceived embryo is even greater than for LNG. See [http://www.hra-pharma.com/downloads/ellaOne\\_english.pdf](http://www.hra-pharma.com/downloads/ellaOne_english.pdf) (accessed April 4, 2011).

**112** J.R. Reel, Sheri Hild-Petito, and Richard P. Blye, "Antiovarian and Postcoital Antifertility Activity of the Antiprogestin CDB-2914 When Administered as Single, Multiple, or Continuous Doses to Rats," *Contraception* 58 (1998): 129-136, p. 129 (abstract).

**113** Catherine A. VandeVoort et al., "Effects of Progesterone Receptor Blockers on Human Granulosa-Luteal Cell Culture Secretion of Progesterone, Estradiol, and Relaxin," *Biology of Reproduction* 62 (2000): 200-205, 200.

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

**114** *Ibid.*, 824.

**115** D. S. F. Settlage et al., "Sperm Transport," 655.

**116** Donald Coustan et al., *Human Reproduction*, 22.

**117** See ACOG Committee on Terminology, *Obstetric-Gynecologic Terminology, with Section on Neonatology and Glossary of Congenital Anomalies*, ed. Edward Hughes (Philadelphia: F.A. Davis, 1972).

and medically sound sexual assault protocols in place before many of their secular counterparts because of an awareness of the potential for two victims from the sexual assault: the woman and the child who may be conceived by the act of unjust aggression. Such protocols are replete with compassionate care, including psychological and spiritual support. Immediate involvement of forensic medical experts and law enforcement personnel is provided, as well as social, psychological, and spiritual services. A thorough health history and physical examination is obtained. Laboratory data is gathered, including baseline testing for sexually transmitted diseases. The history, physical examination, and laboratory data are analyzed to determine what can be done to avoid conception and sexually transmitted diseases, as well as to determine how to address the psychological trauma to the victim effectively. Medications are administered to address these issues, and if it can be determined that conception can be prevented by the administration of EC, it is administered. Follow-up care is provided in all the aforementioned areas of support.<sup>110</sup>

The fact that Catholic healthcare institutions have already capitulated to such secular legal mandates reveals a willingness to compromise religious liberty in the delivery of healthcare. Furthermore, what will be Catholic healthcare's response now that the FDA has approved administration of ulipristal acetate,<sup>111</sup> which can be administered effectively up until five days after the sexual assault? Ulipristal acetate may prevent ovulation, but it is clearly an abortifacient. Its chemical structure is similar to that of mifepristone (RU486), blocking natural progesterone receptors in three critical areas: at the endometrial glands, destroying receptivity to embryo implantation;<sup>112</sup> at the corpus luteum, destroying its capacity to produce progesterone, necessary for initial support of the implanted embryo;<sup>113</sup> and at the endometrial stromal tissues, destroying these tissues that are necessary for the survival of the embryo.<sup>114</sup> Unlike LNG, which must be given within three days post sexual assault, ulipristal acetate can be effective up to five days after the assault. Since sperm can reach the fallopian tubes, the place in which conception occurs, within five minutes,<sup>115</sup> and since sperm capacitation occurs within five hours of ejaculation within the vagina,<sup>116</sup> the use of ulipristal acetate clearly would violate the ERDs since it would act as an abortifacient.

With these properties and now that ulipristal acetate has received FDA approval, it is obvious that it will become the drug of choice for EC. State mandated protocols include drugs that prevent "conception." The medical definition of "conception" has been changed to reflect a political, not a biological, reality: conception is now viewed as implantation, not fertilization.<sup>117</sup> In the face of such mandates, how will Catholic healthcare justify the administration of ulipristal acetate when a victim arrives at the emergency room four days after the assault? The legal quandary within which Catholic healthcare has placed itself by not asserting its religious liberty and its independence of medical judgment in the face of EC mandates will be unavoidable.

Such a capitulation bodes ill for the future of Catholic healthcare. The path of least resistance always poses a temptation, especially when the media takes an active



interest in such controversial issues as sexual assault protocols in Catholic hospitals. There are ongoing efforts in the political arena, at the federal level and in various states in this country, to use the force of law to compel Catholic healthcare facilities to violate the ERDs. The list of legal mandates affecting Catholic ministries continues to grow, from the proposed federal Freedom of Choice Act, which will require Catholic healthcare facilities to provide abortions, to the requirement that Catholic Charities be an agent for the adoption of children by same-sex couples. These efforts are a pernicious trespass on the religious liberty of Catholics and on the right of every individual to follow the moral teachings of his or her own religious tradition. Catholic healthcare, having attempted to accommodate secular legal mandates, and given the recent efforts to reverse protections briefly afforded by the “conscience rule” of the U.S. Department of Health and Human Services in December 2008, now finds itself at a crossroads. Indeed, for Catholic healthcare professionals the pressure seems to be reaching a breaking point. The struggle to maintain conscience protections in healthcare now looms as one of the next great conflicts in the battle for a culture of life.

*The struggle to maintain conscience protections in healthcare now looms as one of the next great conflicts in the battle for a culture of life.*

Consequently, there is no more room for legal accommodation, as threats to religious freedom and Catholic identity have reached alarming new heights. We cannot allow legislative and judicial efforts to override sound medical and moral decisions in Catholic healthcare.

The prospect that some individuals might encounter a potential temporary limitation on their access to abortion, sterilization, or contraception is an altogether acceptable and reasonable consequence that our society should quite readily be capable of accommodating. In contrast, the outright denial of free exercise of conscience or religion of healthcare providers, in violation of the protections intended by the First Amendment of the US Constitution, undermines the very practice of medicine as we know it. In the scenario where conscience rights are not protected, healthcare workers have no recourse; violation of their conscience is not a temporary limitation, but a shocking desecration of their most deeply held beliefs and moral convictions, and of the very virtue of justice on which our democracy stands.

Furthermore, we would do well to recall the dangers of treating the healthcare system like a fast-food enterprise: it is certainly not the case that patrons of the former should expect the same kind of service-on-demand as patrons of the latter. Medical services have always been and always must be provided to individuals through the necessary medium of prudential medical judgment. The conscience of the healthcare provider is of a piece with that ability to make sound medical judgments.

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As it stands, however, Catholic institutions are not being asked merely to provide emergency contraceptives; they are being forced to accept all the potential effects of these drugs, including their potential to act as abortifacients. It is to such unjust and unconstitutional coercion that Catholic healthcare must say “no.”

*A Summary of Our Moral Argument*

In Part II, we have attempted to articulate the conditions under which it would be morally licit to provide sexual assault victims with emergency contraceptives, given what we know today of the effects of levonorgestrel (LNG, trade name Plan B). Because the available body of scientific evidence indicates that LNG can at times work by preventing implantation of a newly conceived human embryo, and indicates no conclusive evidence that LNG never acts in that manner, we hold that the possibility of a chemical abortion will be present when Plan B is administered too close to the time of ovulation. Consequently, we hold that, in addition to a pregnancy test, victims of sexual assault who present in the emergency rooms of Catholic hospitals should be administered a urine-based ovulation test as a reasonable attempt to determine whether the victim has already ovulated or is close to ovulation as judged by the presence of a luteinizing hormone (LH) surge in the blood. Such testing is easy and inexpensive, and does not submit the patient to an unreasonable burden. Only on the basis of a negative ovulation test (in addition to information regarding the patient’s own menstrual cycle, based on a thorough history and physical examination, as is appropriate for any victim of a sexual assault) can a healthcare professional licitly provide the patient with Plan B.

Where reasonably feasible, administration of a serum progesterone test, which would determine the pre- or post-ovulation day more accurately, could also be administered, but is not essential for arriving at the requisite degree of moral certitude needed for a licit administration of Plan B. We argue that if undetected ovulation does occur, despite the administration of Plan B in the presence of a negative LH test result, the conditions for the licit administration of Plan B under the principle of double effect (PDE) would have been met.

In the course of arriving at this conclusion, we first affirm the moral licitness of a sexual assault victim’s intention to avoid conception. We go on to explore specifically how the PDE is applicable to the issue of emergency contraceptives. To that end, we reject the opinion of some moral theologians that the mere statistical improbability that Plan B will ever bring about a chemical abortion suffices as an across-the-board guarantee of moral certitude in administering Plan B in all cases of sexual assault without benefit of an ovulation test.

On the contrary, we hold that moral reasoning from such probability fails to provide grounds for the requisite moral certitude that Plan B will not have an abortive effect in the specific victim who presents in the emergency room. It is on the basis of

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relevant medical data, not statistical generalizations, that a physician must determine whether Plan B will or will not act as an abortifacient in any one specific victim of sexual assault. Only then can the attending physician make the requisite application of the PDE and judge whether the likelihood of an abortifacient effect in each specific patient may be reasonably tolerated and, therefore, excluded from his intention when administering Plan B.

Finally, we argue against passive compliance with governmentally imposed protocols which require Catholic healthcare professionals to provide Plan B to patients of sexual assault without benefit of an ovulation test. As threats to religious freedom and Catholic identity have reached alarming new heights, we cannot allow such legislative and judicial efforts to supersede the exercise of conscience and the free and independent determination of sound medical and moral decisions in Catholic healthcare institutions.

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## CONCLUSION

Concern that provision of emergency contraceptives might occasion the chemical abortion of nascent human life is not only legitimate, but also a genuine expression of the solidarity and stewardship we owe to the most vulnerable members of our society. Catholic moral theologians currently disagree on how that legitimate concern should bear on the formulation of EC protocols in Catholic hospitals. We maintain that, in addition to a pregnancy test, victims of sexual assault should be administered an ovulation test which detects the presence of an LH surge. We sincerely hope that the present study will contribute to the continued substantive discussion of this issue among Catholic moralists. We further trust that it will serve to foster a more cautious approach within the Catholic healthcare establishment to unreasonable incursions by the state that strike at our principled institutional autonomy and identity, and at the very exercise of conscience in Catholic healthcare.

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