THINKING ETHICALLY ABOUT EMERGENCY CONTRACEPTION

Critical judgments require adequate and accurate information

BY RON HAMEL, Ph.D.

The controversy over the use of emergency contraception in Catholic hospitals for victims of sexual assault continues to be played out in various forums — in the literature, state legislatures, pharmacies, professional groups, state Catholic conferences, dioceses and Catholic hospitals themselves.

At its heart is whether medications used for emergency contraception have an abortifacient effect, that is, whether they prevent the implantation of a fertilized egg by altering the lining of the endometrium. On the belief that they do have such an effect, some either object to or prohibit their use in Catholic hospitals or agree to their use only in conjunction with testing for ovulation to ascertain whether the woman is at or around the time of ovulation (and, therefore, could become pregnant).[1] Obviously, for women who have been subjected to a sexual assault and who seek assistance at a Catholic hospital, much hinges on accurately understanding how these hormonal medications work.

Unfortunately, such understanding is not always in play. In many instances, critics base their moral judgments on prevailing beliefs or assumptions about mechanisms of action that may be based on drug manufacturer labeling, or on outdated scientific literature, or on mere supposition. Researchers have been virtually certain that the drugs prevent or disrupt ovulation, but they have generally been uncertain about other possible effects on sperm, cervical mucus, the process of fertilization and on the endometrium. Yet manufacturers and others typically list these specific effects as possible mechanisms of action.

One of the well-known truisms in ethics is that good moral judgments depend in part on good facts.

But are such beliefs and assumptions about emergency contraceptives accurate and adequate? This is a critical question, for women who have been sexually assaulted and for the Catholic hospitals that care for them.

One of the well-known truisms in ethics is that good moral judgments depend in part on good facts. Absent adequate and accurate information, there is an increased possibility of a faulty analysis and, therefore, of an erroneous judgment. In addition, the moral judgment itself might be seen to lack credibility either because its basis is unclear or because it seems to fly in the face of reputable data.

Take one example. In late February 2007, in a LifeSiteNews interview, Bishop Elio Sgreccia, the then-president of the Pontifical Academy for Life, reaffirmed the academy's 2000 statement that the "morning-after pill" is abortifacient and that physicians and Catholic hospitals are prohibited from administering it, even in cases of sexual assault.[2] Unfortunately, the 2000 statement employed the generic term "morning-after pill," which can refer to a variety of medications with different mechanisms of action, and the statement made no reference to scientific literature substantiating its claim that the pill is abortifacient. In addition, the comment in the 2007 interview seemed not to take account of recent scientific literature on how these medications work, particularly in the

case of levonorgestrel, also known as Plan B, the current standard treatment for women who have been sexually assaulted. Yet after the interview, despite the lack of evidence, some described both the bishop's comment and the Pontifical Academy's statement as "authoritative."

GOOD FACTS ARE NECESSARY FOR GOOD ETHICS

What, in fact, do we find if we look at the scientific literature on how Plan B, a progestin-only form of emergency contraception, works?

Over the past five years, CHA staff have collected, reviewed and summarized the great majority of articles on emergency contraceptive medications' mechanisms of action — both for combination drugs (such as Preven) and Plan B.[3] In addition, CHA obtained two independent analyses of the literature — one by an ob-gyn and the other by a pharmacist. The reviews concluded that virtually all of the evidence in the scientific literature indicates Plan B has little or no post-fertilization effect, that is, it has little or no effect on the endometrium that would make it inhospitable to implantation. Its mechanism of action is to disrupt ovulation.

In a thorough review of the scientific literature, Fr. Nicanor Pier Giorgio Austriaco, OP, Ph.D., a priest, theologian and scientist, wrote in the Winter 2007 issue of *The National Catholic Bioethics Quarterly*:

> Studies published in the past few months provide mounting evidence that levonorgestrel has little or no effect on post-fertilization events. In other words, given the limitations of scientific certitude, they suggest that Plan B, when administered once, is not an abortifacient. These human studies correlate well with earlier findings in rodents and monkeys that convincingly showed that the postcoital administration of levonorgestrel in amounts several times higher than typical doses given to women does not interfere with the post-fertilization processes required for mammalian embryo implantation. The evidence also addresses what until now has been a nagging, unanswerable question for pharmacologists: Why would levonorgestrel, a progesterone agonist that mimics the effect of progesterone, prevent implantation, when progesterone produced from the corpus luteum immediately after ovulation actually promotes implantation by converting the endometrium to deciduas? Answer: It does not.[4]

Several months later in the Autumn 2008 issue of the quarterly, responding to his critics, Fr. Austriaco offered an even more detailed argument in support of his conclusion.[5] If Plan B is abortifacient, the author observes, it can have this effect in three primary ways. The first is by increasing the rate of ectopic pregnancies. However, he notes that the "combined data from five clinical trials with nearly six thousand women showed that the rate of ectopic pregnancies in women who have used Plan B is 1.02 percent as compared to the

overall national ectopic pregnancy rate between 1.24 percent and 1.97 percent. In light of this finding, it is unlikely that Plan B increases the ectopic pregnancy rate ... ."[6]

The second way in which Plan B could be abortifacient is by preventing implantation of an embryo. Fr. Austriaco noted that there are three ways in which this could occur. One is by altering the lining of the endometrium, making it inhospitable to implantation. "[M]orphological and biochemical analyses of endometrial biopsies of women who had taken Plan B eight or nine days prior to the biopsy have revealed that the drug does not dramatically alter the structures of this tissue. This suggests that the drug does not compromise endometrial development."[7]

Another way in which the drug could make the endometrium inhospitable is by disrupting the function of the corpus luteum which releases

hormones that are necessary for the proper development of the endometrium, including making it receptive to an embryo. After reviewing the scientific literature, Fr. Austriaco concluded that "[T]ogether, these data suggest that the risk of a post-fertilization effect from this mode of action for any particular individual woman, if it is real, would be vanishingly small."[8]

The final manner in which Plan B could prevent implantation is by directly interfering with the implantation process itself. Fr. Austriaco replied: "[O]ne study that directly tested the ability of human embryos to implant on endometrial tissue exposed to LNG — though grossly immoral — does not support this mode of action for Plan B."[9] Two other recent studies confirm this conclusion.[10]

A third way in which Plan B could be abortifacient is by destroying an already implanted embryo. With regard to this possibility, Fr. Austriaco wrote: "[A] report from the FDA shows that Plan B does not increase the rate of pregnancy loss or the frequency of fetal abnormalities once a pregnancy has been established."[11]

Fr. Austriaco concluded his article: "[I] stand by my earlier conclusion: In light of the available scientific evidence and given the inherent limitations of the studies, it is unlikely that Plan B is an abortifacient."[12]

What about the manufacturer's label which claims that one of the drug's mechanisms of action is to prevent implantation of a fertilized egg?

What is meant by moral certitude? Moral certitude means that the agent has excluded all reasonable possibility of error.

Many appeal to the manufacturer's label in their arguments against the use of Plan B. In Fr. Austriaco's judgment, "labels mean nothing without the scientific data to back up their claims."[13]

MORAL CERTITUDE, NOT ABSOLUTE CERTITUDE

While the preponderance of scientific evidence strongly suggests that Plan B does not have an abortifacient effect, the evidence stops short of providing absolute certitude. But is absolute certitude needed?

In the Catholic moral tradition, what is required of an agent when he or she makes a moral judgment is that he or she have *moral* certitude about the correctness of the action. In the words of Thomas Slater, SJ, author of a manual of moral theology: "In order to act lawfully and rightly, I must have at least moral certainty of the imperfect kind that the proposed action is honest and right. This degree of certainty will be sufficient, for ordinarily no greater can be had, as we have just seen. It is also required for right action; for if I am not at least to this extent morally certain that my action is right, I am conscious that it may be wrong."[14]

What is meant by *moral* certitude? Moral certitude means that the agent has excluded all reasonable possibility of error. It stands between mere probability, where alternative opinions are equally plausible, and absolute certainty, where any theoretical possibility of error is not only excluded, but is impossible. Again, in the words of Fr. Slater:

> Certainty in general is a firm assent of the mind to something known, without the fear of mistake. In mathematics and in other branches of exact science we can often attain absolute certainty, which rests on the evident truth of the principles which are employed to arrive at it. ... In the science of morality we have frequently to be content with a lower degree of certainty than this; there is often some obscurity about the principles to be applied, and human acts are not the matter of necessary and unvarying law. We have to be content with what is called moral certainty. ... I may be conscious that mistake is possible but not probable, as when a man has been condemned on evidence which has satisfied a jury of intelligent men. In such cases if there can be no prudent doubt about the justice of the verdict I have moral certainty of an imperfect but real kind. ... Ordinarily greater certainty cannot be obtained in human affairs. ... If I have this imperfect moral certainty that my action is right, I am justified in acting ... ."[15]

How does moral certitude play out with regard to emergency contraception, and Plan B in particular? The first consideration deals with Plan B's mechanism of action. Is there sufficient moral certitude that Plan B is not abortifacient? In other

words, do the results of scientific research on how Plan B works rise to the level of moral certitude? Given the mounting evidence from the scientific literature that Plan B does not prevent implantation, there does seem to be moral certitude, of the imperfect kind, about the mechanism of action. It is, of course, theoretically possible that all of the studies that have been done could be mistaken, but this is not likely. Hence, if these scientific studies are correct, then Plan B is consistent with Directive 36 which states that a woman who has been sexually assaulted may be "treated with

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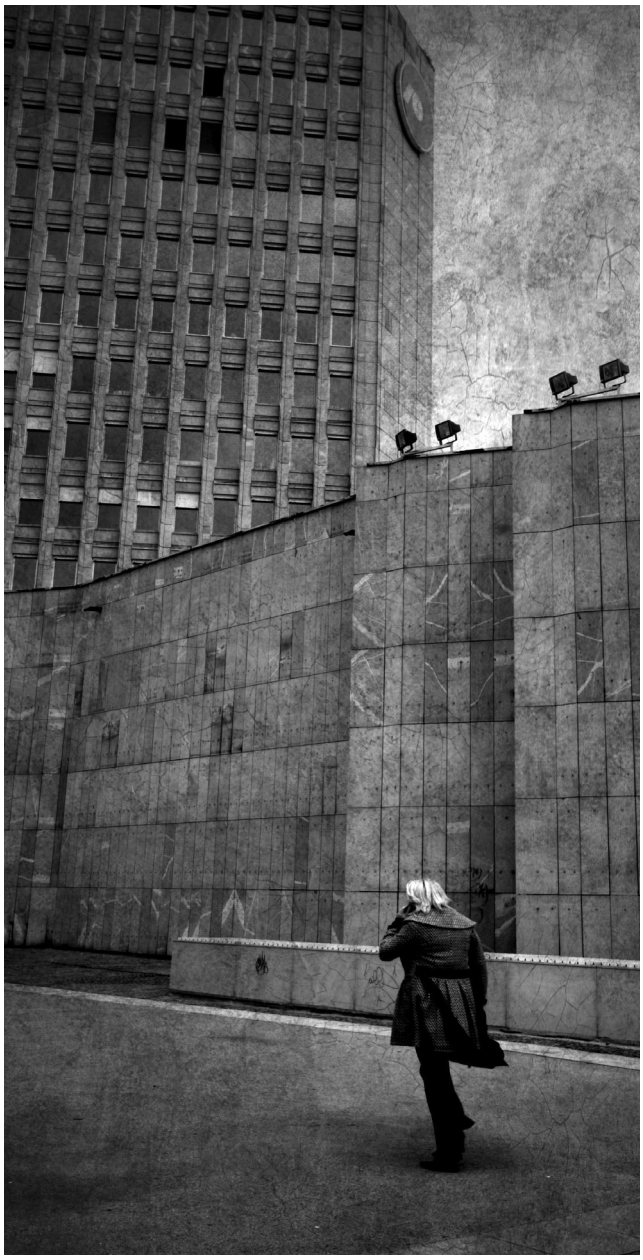
medications that would prevent ovulation, sperm capacitation, or fertilization."[16] Thus its use would not be prohibited by what follows in Directive 36: "It is not permissible, however, to initiate or to recommend treatments that have as their purpose or direct effect the removal, destruction, or interference with the implantation of a fertilized ovum."[17] Targeting implantation is not the purpose or direct effect of Plan B. Rather, its purpose and direct effect is to interfere with ovulation.

Second, is there moral certitude that a fertilized ovum will not be destroyed? Some argue that in order for moral certitude to be present, the woman who has been sexually assaulted must undergo an ovulation test to ensure that she is not at or around the time of ovulation such that she could become pregnant from the rape. For example, one advocate of ovulation testing says: "[C]atholic hospitals must have moral certitude that the possibility of an abortion is excluded. The ovulation test provides this certainty. ... Therefore, moral certitude can be achieved only through the administration of the [luteinizing hormone] test. To administer emergency contraception when there is insufficient information as to its effect on the specific patient in question is not only morally illicit but medically unsound."[18]

Given what has been said about Plan B's mechanism of action, such testing is not required to achieve moral certitude. Furthermore, moral certitude in these situations is strengthened by the



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fact that the incidence of a pregnancy after rape is between <1 percent and 5 percent. Typically the estimate is put at about 3 percent.[19] Given the scientific evidence regarding Plan B's mechanism of action and the high probability that there is no fertilized egg present subsequent to the sexual assault, the requisite moral certitude exists that a fertilized ovum would not be destroyed by the administration of Plan B.

Finally, it is generally maintained in textbooks of moral theology that when human life is involved, one should always take the safer course. This is sometimes illustrated by the example of the hunter in the woods who sees movement behind bushes. Is the hunter free to shoot, believing that the movement results from a deer? The response in the manuals is no, because the movement could be caused by another hunter. Unless the hunter can resolve his doubt, the hunter must take the safer course and not shoot. This example might suggest that Catholic hospitals must not use emergency contraceptive medications at all in the belief that they might have an abortifacient effect — or, at least, that hospital personnel do as much as they can to reduce the possibility there might be an egg present that could be or might have been fertilized. They would do this by testing for ovulation.

In the situation under consideration, if there were a likelihood that a fertilized egg were present and if there were a likelihood that Plan B has an abortifacient effect, then the example and the obligation to take the safer course would be applicable. However, neither of these conditions is the case, because there is virtually no evidence that Plan B is abortifacient and, in cases of sexual assault, there is a very high probability that there is no fertilized egg present.[20] Hence, there does not seem to be an obligation to take the safer course. If one were obliged to take the safer course in these situations, in order to be consistent, one would also have to take the safer course in many of life's other activities (e.g., driving one's car, flying in a plane) as well as in the practice of medicine generally (e.g., agreeing to a surgery with a 25 percent risk of dying, undergoing chemotherapy that could have a lethal effect).

The administration of emergency contraception to women who have been sexually assaulted is a matter of utmost seriousness since it touches on human life. It is also a matter of utmost seriousness because it touches on the well-being of women who have been subjected to one of the most heinous of crimes. Any decision about whether or not to permit the dispensing of emergency contraceptive medications in Catholic hospitals and about the protocols for their administration has profound consequences.

Those who make such decisions, whether bishops, hospital executives, emergency room physicians, nurses or others, have a grave moral obligation to take seriously one of the first rules in making good ethical judgments, namely, to obtain adequate and accurate information about the matter at hand. To do any less is not only to shortchange the moral process, but also to risk significant harm to others. And once the best possible information is obtained, those making the decisions need to keep in mind that the use of emergency contraception for women who have been sexually assaulted is a matter about which moral certitude is sufficient. Given what is currently known about Plan B from scientific research, Catholic hospitals can respond with sensitivity, compassion and assistance to women who have been raped and are in need of care, while being confident that they are also remaining true to Catholicism's fundamental commitment to respect for human life.

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NOTES

1. If ovulation testing determines that the woman is at or around the time of ovulation, generally emergency contraception would not be administered out of concern that a possible abortifacient effect of the medication could result in the loss of an embryo.
2. Pontifical Academy for Life, "Statement on the So-Called 'Morning-After Pill,'" (October 31, 2000), http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20001031_pillola-giorno-dopo_en.html
3. For information about the mechanism of action of emergency contraceptive medications generally: www.chausa.org/ECmedicationsReview; for information about Plan B's mechanism of action: www.chausa.org/LevonorgestrelReview.
4. Nicanor Pier Giorgio Austriaco, "Is Plan B Abortifacient? A Critical Look at the Scientific Evidence," *The National Catholic Bioethics Quarterly* 7, no. 4 (Winter 2007): 707.
5. Nicanor Pier Georgio Austriaco, "Colloquy: More on Plan B — Fr. Austriaco Replies," *The National Catholic Bioethics Quarterly* 8, no. 3 (Winter 2008): 421-25.

6. Austriaco, 422.
7. Austriaco.
8. Austriaco, 423.
9. Austriaco.
10. Chun-Xia Meng et al., "Effect of Levonorgestrel and Mifepristone on Endometrial Receptivity Markers in a Three-Dimensional Human Endometrial Cell Culture Model," *Fertility and Sterility* 91, no. 1 (2009): 256-64; Natalia Novikova et al., "Effectiveness of Levonorgestrel Emergency Contraception Given Before or After Ovulation: A Pilot Study," *Contraception* 75, no. 2 (2007): 112-18. The immoral, but important study to which Austriaco refers is 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, no. 11 (2007): 3031-37.
11. Austriaco.
12. Austriaco, 424.
13. Austriaco, "Is Plan B Abortifacient?", 707.
14. Thomas Slater, SJ, *A Manual of Moral Theology*, (New York: Benziger Brothers, 1925), 1:31.
15. Slater, 1:31-32.
16. United States Conference of Catholic Bishops, *The Ethical and Religious Directives for Catholic Health Care Services*, (Washington, D.C.: USCCB, 2001), Directive 36.
17. United States Conference of Catholic Bishops.
18. Marie Hilliard, "Dignitas Personae and Emergency Contraception," *Ethics and Medics* 34, no. 2 (February 2009): 4.
19. Melisa M. Holmes, et al., "Rape-Related Pregnancy: Estimates and Descriptive Characteristics from a National Sample of Women," *American Journal of Obstetrics and Gynecology* 175 (August 1996): 320.
20. Gerald McShane, et al., "Pregnancy Prevention after Sexual Assault," in Peter Cataldo and Albert Moraczewski, eds., *Catholic Health Care Ethics: A Manual for Ethics Committees*, (Boston: The National Catholic Bioethics Center, 2001), 11, 16-17.

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