

# The Morning-After Pill: The Dangers of Over-the-Counter Availability

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**ABSTRACT:** In response to a request by Barr Laboratories to market their “emergency contraceptive” Plan B across the counter, the Food and Drug Administration (FDA) held a public hearing. Objections to the proposal included: (1) A considerable increase in tubal pregnancies following ingestion of Plan B was found in U.K., prompting a warning to physicians. Lack of medical supervision when providing this drug is the height of medical irresponsibility. (2) Following a highly publicized trial of dispensing the drug without a prescription but only counseling by pharmacists in five states, the rate of the most common sexually transmitted diseases increased by 20%. (3) The availability of a “fall back” pill will only increase sexual irresponsibility, especially by teens. (4) It will also provide an easy means to make sure that a perpetrator of sexual assault will not become liable for child support. (5) When taken during the fertile window of the cycle, the pill may act as an abortifacient rather than as a means to prevent conception. (6) The “fertile window” is six days long; its start and finish can be determined by teaching women to understand their cervical mucus patterns. Yet the manufacturers offer the drug for use at any time and charge the same amount for two pills that they charge for a month’s supply of oral contraceptives, although the pills could only have a possible application for one fourth of the cycle.

**T**HE FOOD AND DRUG Administration’s Center for Drug Evaluation and Research held a public meeting of its Advisory Committee for Reproductive Health Drugs and the Nonprescription Drugs Advisory Committee December 16, 2003 to discuss application of Women’s Capitol Corporation to change their Plan B (2 tablets each of 0.75 mg of levonorgestrel) from “prescription” to “over-the-counter” (OTC). I was one of many who

testified against the proposed change in status of Plan B. I consider it medically inadvisable for the following reasons.

(1) Levonorgestrel is a synthetic progesterone that has been shown to retard endometrial development in two of five women who received the drug in the early luteal phase, that is, after ovulation.<sup>1</sup> It has also been shown to slow the normal movements of the Fallopian tube. Thus, if a woman takes the pills as prescribed, after she has conceived, the embryo's passage in the tube may be slowed sufficiently to lead it to implant in the tube, resulting in a tubal ectopic pregnancy instead of proceeding to the uterine cavity, which may or may not be hospitable to implantation of the embryo. When the British discovered that 12 of 201 (5.9%) of the unintended pregnancies following ingestion of levonelle as a "morning-after" pill (levonorgestrel 0.75 mg, the same drug as in Plan B) were ectopic, the U.K. Committee on Safety in Medicines issued a warning to doctors, which was also picked up by New Zealand's public health system. To make a drug that has the potential of increasing the rate of ectopic pregnancy four-fold available without medical supervision is the height of medical irresponsibility.<sup>2</sup>

Young women who would obtain the drug over the counter would not receive any counseling. Most people do not bother to read labeling, and a girl in panic over a possible pregnancy would most probably not process the information correctly even if she did read it. Expelling uterine contents, even the size of a week-old embryo, may involve some cramps or pain and the warning that the presence of pain should alert the woman to seek medical attention may well not be taken seriously in a timely manner.

(2) The World Health Organization (WHO) study<sup>3</sup> found that when levonorgestrel 0.75 mg (Plan B) was used immediately after intercourse by 295 women who had infrequent intercourse and who essentially used the morning after pill as their only contraceptive, the [Pearl Index] failure rate was 6.8%. Not surprisingly, one-third of the participants discontinued the study before the end of the six months. Some 70% complained of bleeding problems, for they had disrupted their cycles, some by taking the morning-after pill more than once in a "cycle." Others mentioned nausea, breast tenderness, weakness,

dizziness, headache, abdominal bloating, loss of libido, depression, and vomiting.

Earlier in the FDA hearing, Dr. David Grimes of Family Health International stated that pregnancy is a great burden and health risk, gladly accepted by women who desire it, but one that should never be imposed on women who do not desire it. He was persuaded that the public can be expected to follow complicated instructions such as were proposed for the labeling of Plan B, which admonishes women to use “Plan A” (ordinary contraception) as their normal practice. Another physician, Dr. Vivian Dickerson, then Vice-President and now President of the American College of Obstetricians and Gynecologists, asserted that the availability of Plan B would not reduce utilization of ordinary contraceptives, citing a study that showed that consumption of Plan B was equal among contraceptors and non-contraceptors. No one asked why the contraceptors would need Plan B in the first place, unless the modality used was a condom that broke. Yet the study purported to be drawn from pill users. Had they “forgotten” to take their pill? And if so, why?

On the one hand, many people, especially teens, take the course of least resistance, especially if they have been persuaded by advertising that planning for contraception is unnecessary when Plan B is readily available. Teens especially are apt to use the drug more than once per cycle, regardless of warnings. And when side-effects occur, they will more than likely turn away from the drug that has caused them. Plan B has been available in Washington State since 1998. The abortion statistics there did not change between 1998 and 2001.<sup>4</sup>

On the other hand, there may be far deeper psychological reasons for not using contraception. For a mature person, that may be based on the understanding of the indissoluble unity between the unitive and procreative aspects of marital intercourse. For a teenager who is still trying to understand her gender identity, including her now-present capability of becoming a mother, the suppression of this aspect of herself goes counter to the integrative thrust of the developing personality, which values both sexuality and fertility. Perhaps, in a panic, such a girl would want to make sure that her

actions would not have a permanent impact on her life, as she most likely is not yet ready to parent a baby. But helping her to deny reality is not going to help her to grow up. Far better to reach her prior to the point of crisis, help her accept her fertility, and work through the “decision tree” that she must work through before choosing to become sexually active.

(3) Recent increases of some 20% in sexually transmitted diseases, especially chlamydia and gonorrhea, reported by the CDC for 15-24 years old females<sup>5</sup> parallel the high profile advertising campaign for the “morning-after pills.” This rise in sexual irresponsibility may result from the belief that pregnancy can easily be avoided by timely ingestion of the morning-after pill. Adolescents seldom “plan” sexual intercourse. Women aged 15-25 years of age are the main group targeted as “consumers” of Plan B, for they are most likely to omit female contraception. At the same time, given the ease of “avoiding” pregnancy, fewer males will take the trouble to use condoms. Some sexually transmitted diseases are incurable, others are lethal. The human and financial costs of these illnesses will dwarf the “gains” of the trumpeted 50% reduction of abortions confidently predicted by purveyors of Plan B.

(4) Plan B is alleged to act either by delaying ovulation or preventing implantation of the embryo if conception has already occurred. There are many studies and many reviews of studies that investigate the effect of levonorgestrel on the endometrium; some purport to show no adverse effect if given after ovulation; some show changes in the progesterone receptors that may interfere with nidation. Many women have ethical objections against aborting an embryo at any stage of development. They have a right to make an informed decision in this matter.

(5) Dr. Ben-Maimon (President of Barr Laboratories, the main presenter of the request for change to OTC status of Plan B) acknowledged that there are only 6 days in the woman’s cycle when conception is possible (the five days of mucus and the day after peak, well known to Natural Family Planners.) So, offering the drug for *any* “unprotected act” coital act during the cycle means that the drug will not have been necessary 75% of the time. To promote a

medication priced at thirty dollars for use at any time during the cycle, when it could only be of any use for just six days, borders on fraudulent advertising. Rather than keep women in ignorance, the public relations campaign planned to market Plan B could be used to educate women about their fertility. Barr Labs is not likely to agree to this, since it would reduce their income by at least 75%, and have an impact on the entire contraceptive industry as well as on one-third to one-half of the practice of general gynecologists. Yet any woman can recognize when mucus begins. She needs to learn its significance. Why not teach women to recognize their fertility pattern so that they will know when conception is possible?

(6) It is also obvious that the existence of an easily available “morning after pill” may be welcomed by any man who has coerced a woman to have intercourse. Add two pills and there is no fear of being sued for child support. This pill will only make it easier to turn women into sexual objects as well as sources of profit for the manufacturer.

For all these reasons I strongly urged the Food and Drug Administration to deny the application to make Plan B available OTC.

#### NOTES

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1. L. Marions, L. Hultenby, I. Lindell, X. Sun, N. Stabi, K. Genzell-Danielson, “Emergency Contraception with Mifepristone and Levonorgestrel: Mechanisms of Action,” *Obstetrical Gynecology* 100 (2002): 65-71.

2. See [http://www.doh.gov.uk/cmo/cmo\\_35.htm](http://www.doh.gov.uk/cmo/cmo_35.htm) and <http://www.medsafe.govt.nz/Profs/PUarticles/ectopic.htm>.

3. “Efficacy and Side Effects of Immediate Postcoital Levonorgestrel Used Repeatedly for Contraception.” UN Development Programme/United Nations Population Fund/World Health Organization/World Bank Special Programme of Research, Development and Training in Human Reproduction, Task Force on Post-Ovulatory Methods of Fertility Regulation. *Contraception* 61/5 (May 2000): 303-08.

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4. See [http://www.doh.wa.gov/ehsphi/chs/chs-data/abortion/download/Intro\\_tb1\\_2001.xls](http://www.doh.wa.gov/ehsphi/chs/chs-data/abortion/download/Intro_tb1_2001.xls).

5. Table 1. Cases of sexually transmitted diseases reported by state health departments and rates per 100,000 civilian population: United States, 1941-2002. (<http://www.Cdc.gov/std/stats/tables/table1.htm>).