

## Emergency Contraception: Out of Sight, Out of Mind?

by Vivian M. Dickerson, MD

*“It is amazing that medications such as aspirin are available to anyone of any age, but Plan B—with an infinitely better safety profile—is not.”*

Hormonal contraception has been available by prescription for more than 50 years. For much of that time, physicians have been aware that providing a concentrated dose of the standard birth control pill within 72 hours after unprotected intercourse decreases risk of pregnancy. By 1999, the US Food and Drug Administration (FDA) had

approved 2 prepackaged forms of such emergency contraception (EC): Preven (levonorgestrel/ethinyl estradiol) and Plan B (levonorgestrel). Both were approved for provision by prescription only, but due to the greater number of side effects (namely nausea and vomiting) and lower efficacy of the former, Plan B is currently the EC of choice for most patients and physicians. And, in December 2003 two FDA advisory committees overwhelmingly approved Plan B for over-the-counter access. However, as of this writing Plan B still is not available over-the-counter, and many physicians and patients are asking why.

What do we know? First, the Alan Guttmacher Institute has shown that more than 51 000 induced abortions can be prevented every year by using EC. They also estimate that the rate of unintended pregnancies and elective abortions could be reduced by 50% if EC were more readily available to women.<sup>1</sup> Almost half of women aged 15 through 44 years in the United States have experienced at least 1 unplanned pregnancy in their lifetimes.<sup>2</sup> Accidents happen to everyone; most unintended pregnancies occur after a contraceptive failure such as missed pills or broken condoms, or failure to use a contraceptive method. Second, lack of medical insurance for many women, as well as limitations based on physician availability, impair access to EC. Third, EC has been used safely and effectively over-the-counter in France, Norway, the United Kingdom, and other European coun-

tries with no reports of adverse events. Lastly, in order to meet FDA requirements for over-the-counter status in the United States, a medication must be nontoxic and safe for self-medication, effective in a uniform dose, used for a self-diagnosable condition, nonteratogenic, without potential for overdose, and without important drug interactions.

How does Plan B measure up? First, no serious adverse events have been reported with the use of the progestin-only Plan B.<sup>3,4</sup> Data show that while Plan B is most effective when used within 24 to 72 hours following intercourse, it may be effective for up to 1 week. Further, although it is recommended to take 1 tablet and repeat in 12 hours, data show that effectiveness is similar if both tablets are taken at the same time. Couples do not need a physician to tell them when unprotected sex has occurred or when a method of birth control has failed. There is no teratogenicity associated with Plan B; indeed, even for women who have become pregnant while taking combined oral contraceptives or medroxyprogesterone acetate injectable suspension, termination is not recommended. Finally, the labeling was extensively studied by the FDA advisory committees and found to be appropriate and understandable to women of all ages.<sup>5</sup>

So, we are left asking, what happened?

In May 2004, against the advice of its own committees and in what appeared to be a response at least in part to political pressures from Congress, the acting director of the FDA announced that Plan B would not be approved for over-the-counter status and that further data were needed on use in women younger than age 16. This was unusual, not only because the FDA chose not to listen to its own experts, but because rationale for delaying access was not supported by the data in both label comprehension and actual use studies.<sup>3,5</sup> Teenagers had been found to be just as successful as their older counterparts in all areas. What is really going on? Is there good reason to support restriction of Plan B to physician prescription only?

The first argument, presented vociferously at the FDA hearings in December 2003, was that over-the-counter availability of Plan B would increase the risk of sexually transmitted diseases by encouraging unprotected intercourse. European data and US studies since that time have unequivocally shown that this simply is not the case.<sup>6</sup> A second argument was that women might not realize they are appropriate candidates for this medication. Clearly, this underestimates the knowledge of women and is specious in

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that these same women would still have to understand and recognize their need for EC in order to seek a prescription from their physicians. But, entertaining this idea, it should also be remembered that use “just in case” is not a health threat. There are no known contraindications to the use of Plan B with the exception of pregnancy, since the drug is no longer effective during pregnancy; however, use during pregnancy does not have potential to cause birth defects.<sup>7</sup> A third argument by opponents is that EC would be overused, misused, and thereby dangerous to the hormonal “balance” of adolescents. Since adolescents have been successfully and safely taking prescribed combination oral contraceptives for years, this argument has no scientific basis. In addition, the price of a single packet of Plan B would make it prohibitive for women to use it as their primary contraceptive method. Finally, opponents argue that Plan B is an abortifacient and should not be available at all.

Plan B does not interrupt an implanted pregnancy and, if taken after implantation, is not associated with adverse outcomes. However, while the FDA defines pregnancy as commencing with implantation, others believe it starts with fertilization. There are rare instances (just as with the intrauterine device) in which the use of levonorgestrel after fertilization could—although with less efficacy—prevent implantation. This is not the primary method of action and indeed occurs rarely. However, when informed about this possible mode of action, particularly if the pill is used after the 72-hour window, some women may choose not to use EC on this basis. Availability over-the-counter vs availability by prescription only has no bearing on this method of action. In addition, no complications, such as severe bleeding, have been associated with late use. Again, it is to be emphasized that Plan B does not interrupt an implanted pregnancy.

Given these data, it is amazing that medications such as aspirin are available to anyone of any age, but Plan B—with an infinitely better safety profile—is not. Experience in states such as Washington that have provision by a pharmacist also has yielded good safety and increased accessibility and use data, which should not be ignored.<sup>8</sup> The prescription requirement for EC in the United States is an unnecessary impediment to contraception, pregnancy prevention, and abortion prevention. It hurts women’s health and directly contributes to the fact that the United States has the

highest rate of teenage pregnancy in the industrialized world. The American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the American Medical Association, Planned Parenthood, and the Campaign to Prevent Teen Pregnancy all support over-the-counter status for Plan B. Science supports both safety and efficacy. US law—specifically the Durham-Humphrey Amendment of 1951—demands over-the-counter status. Safety and efficacy data make over-the-counter emergency contraception a public health mandate.

So, what happened at the FDA? The logical person can only come to the conclusion articulated by Dr David Grimes in his August 2004 editorial in *Obstetrics and Gynecology*: “politics trumps science at the US Food and Drug Administration.” One thing is sure—if we keep EC out of sight behind the counter and available only by a doctor’s prescription, it will not be accessed as frequently as needed and will not be available to numerous couples throughout the country. The time has come to take EC out of the closet and put it on display at a drug store near you!

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