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October 27, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on Drug Approvals
Docket No. 2005N-0345

The Women's Law Project submits comments on circumstances under which a drug may be simultaneously marketed as both a prescription drug and an over-the-counter product, particularly in relation to Barr Labs' application for Plan B to be approved as an over-the-counter drug for women ages 16 and older. Our comments reflect years of experience working on issues related to women's contraceptive rights. We submit our comments to highlight just how critical making emergency contraception more readily and easily accessible is to ensuring the well-being of adult and adolescent women. Furthermore, considering that as much as 43 percent of the decrease in abortions between 1994 and 2000 can be attributed to the use of emergency contraception, increasing access to emergency contraception presents a significant opportunity to further reduce the number of unwanted pregnancies and abortions that occur each year in the United States.

The Women's Law Project is a non-profit public interest legal advocacy organization located in Philadelphia, Pennsylvania that seeks to advance the legal, social, and economic status of women through litigation, public policy advocacy, public education, and individual counseling. Since its founding in 1974, the Women's Law Project has worked to defend and ensure access to contraceptive and reproductive rights.

These comments explain: (1) why easy accessibility to emergency contraception is critical to ensuring the drug's effectiveness and, in turn, drastically lowering the number of unwanted pregnancies and abortions; (2) how emergency contraception satisfies the FDA's requirements for over-the-counter status because the drug is safe for self-medication, the condition the drug treats is easily diagnosable, and the drug regimen is effective when self-administered; (3) how studies have repeatedly shown that increasing access to emergency contraception does not lead to greater risk-taking behaviors; and (4) that engaging in further debate over FDA regulation and pragmatic considerations would only

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serve to substantially delay putting emergency contraception on the shelves of drugstores. Emergency contraception is, therefore, appropriate for immediate approval as an over-the-counter drug for all women, or in the alternative, for women ages 16 and older without the need for further regulation.

These comments are being submitted electronically, with a paper copy to follow. Thank you for your consideration of these comments.

Very truly yours,

Terry L. Fromson
Managing Attorney

David S. Cohen
Staff Attorney

COMMENTS ON DRUG APPROVALS

SUBMITTED BY

WOMEN'S LAW PROJECT

OCTOBER 27, 2005

I. The Critical Need for Quick Access to Emergency Contraception

The availability of over-the-counter emergency contraception is necessary to protect the needs of adult and adolescent women. Immediate access to emergency contraception is not only a matter of convenience, but is *critical to the drug's effectiveness*. If taken within 72 hours of unprotected intercourse, Plan B can reduce the risk of pregnancy by at least 75 percent. *See* Trussel J. et al., *Updated Estimates of the Effectiveness of the Yuzpe Regimen of Emergency Contraception*, 59 Contraception 147-51 (1999). Plan B is even more effective the sooner it is taken within this 72-hour window. For example, emergency contraception is seven times more successful if used within the first 24 hours of unprotected intercourse. *See* Alan Guttmacher Institute, *Emergency Contraception Has Tremendous Potential in the Fight to Reduce Unintended Pregnancy* (2005), *at* http://www.guttmacher.org/media/presskits/2005/05/06/ec.html.

Despite the clear need for women to take immediate action, there are currently many unnecessary barriers to obtaining the treatment in the necessary timeframe. With most states currently requiring a prescription for Plan B, a woman cannot receive treatment until she is able to contact a physician, obtain an appointment, receive the prescription, and then find a pharmacist to fill it—all before the 72-hour window lapses. This is further complicated by most clinics and doctors' offices being closed on weekends, evenings, and holidays—the time when unprotected sex most often occurs. These barriers may render prompt, effective use of this preventative therapy nearly impossible. However, pharmacies and drugstores are much more accessible, particularly with many having convenient locations, easy accessibility, and open hours on weekends, evenings, and holidays.

Unintended pregnancies remain an endemic problem in the United States, and increasing accessibility to emergency contraception presents a huge opportunity to decrease the number of unwanted pregnancies and abortions that occur each year. Forty-three million women of reproductive age, or seven in ten, are sexually active and do not want to become pregnant. *See* Alan Guttmacher Institute, *Facts in Brief: Contraceptive Use* 1 (2005), *available at* http://www.guttmacher.org/pubs/fb_contr_use.pdf. Nearly half of America's 6.3 million annual pregnancies are accidental, resulting in approximately 1.3 million abortions annually. *See* Alan Guttmacher Institute, *Facts in Brief: Induced Abortion in the United States* 1 (2005), *available at* http://www.agi-usa.org/pubs/fb_induced_abortion.pdf. "Most unintended pregnancies occur after an immediately apparent contraceptive failure—a condom breaks, oral contraceptive pills are missed, a spermicide tablet fails to melt—or after a couple fails to use any contraception at all. If emergency contraceptive pills were used in three-quarters of these situations, unintended pregnancies and consequent abortions could be reduced by as much as half." David A. Grimes et

al., *Emergency Contraception Over-The-Counter: The Medical and Legal Imperatives*, 98 Obstetrics & Gynecology 151 (2001), *available at* http://www.acog.org/from_home/publications/green_journal/2001/ong12791fla.htm. It is estimated that *1.7 million unintended pregnancies would be avoided* and that the *annual number of abortions could be cut by 800,000* if emergency contraception were widely available in the United States. Indeed, as much as 43 percent of the decrease in abortions between 1994 and 2000 can be attributed to the use of emergency contraception. *See* Rachel K. Jones et al., Alan Guttmacher Institute, *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 Persp. Sexual & Reprod. Health 300 (2002), *available at* http://www.guttmacher.org/pubs/journals/3429402.pdf.

II. Emergency Contraception Has Been Proven Safe as an Over-the-Counter Treatment

The scientific and medical community has joined in an unparalleled consensus over the safety and merits of nonprescription status. More than 70 organizations—including the American Medical Association and the American College of Obstetrics and Gynecologists—joined to support the over-the-counter application with written or oral testimony. *See* Reproductive Health Technologies Project, *The Case for Plan B Over the Counter: Solid Science, Common Sense, Common Ground* 2 (2005), *at* http://www.rhtp.org/news/media/documents/Factsheet-ThecaseforOTCPlanBAug05.doc. In December 2003, the FDA Drug Evaluation and Research Advisory Panel, after reviewing more than 50,000 pages of clinical data, *overwhelmingly recommended over-the-counter approval* of Plan B by a 23-to-4 vote. *See id.*

Indeed, emergency contraception has all the characteristics of a nonprescription drug. According to Dr. David Grimes, vice president of biomedical affairs at Family Health International and professor at the University of North Carolina at Chapel Hill School of Medicine, "[e]mergency contraception poses no serious risks. It is nontoxic; there is no danger from overdose or potential for addiction; and dosage is the same for all women." Heather Boonstra, *Emergency Contraception: Steps Being Taken to Improve Access*, Guttmacher Rep. on Pub. Pol'y 10, 12 (Dec. 2002), *available at* http://www.guttmacher.org/pubs/tgr/05/5/gr050510.pdf. The American Medical Association has announced that its decision to support the change to over-the-counter status is based, in part, on the fact that "Plan B treats a condition that patients can diagnose themselves and is safe and effective when used without direct physician supervision; [t]he drug's label adequately explains potential adverse effects and conditions of use; Plan B is simple to use, non-addictive, and has no known health hazards . . . side effects are minor and temporary . . . ." *See* J. James Rohack, Chairman, Board of Trustees of the American Medical Association, Report on Increasing Access to Emergency Contraception (2004), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/465/bot2i04.rtf.

Moreover, a study published in *Obstetrics & Gynecology* of more than 660 women showed that the regimen is easy to follow without the supervision of a physician and that most women could understand key information necessary for safe and effective use. Of the women studied (a group that included minors, minority women, and women of low literacy), the vast majority (85%) understood crucial messages about indications for use, contraindications, instructions, possible side effects and management of serious complications, and almost all

women (97%) understood that the pill should be taken within 72 hours or as soon as possible after unprotected intercourse in order to prevent pregnancy. Elizabeth G. Raymond et al., 100 Obstetrics & Gynecology 342 (2002).

These findings show that emergency contraception is exactly the type of medication that is appropriate as an over-the-counter drug. Under the FDA's own regulations, the agency is required to switch a drug to over-the-counter status if the prescription limitation is unnecessary. 21 CFR § 310.200(b) (1999). This occurs when: (1) the drug is safe for self-medication, (2) the drug is effective when self-administered, (3) the condition to be treated is self-diagnosable, and (4) the drug's labeling is tailored to self-administration and not misbranded. *See id.*; 21 CFR § 330.10(a)(4) (1999). Since both the FDA's expert panel and the entire medical community have concluded that Plan B fulfills all these requirements, the FDA should, by its own regulations, be required to switch emergency contraception to over-the-counter status without further delay.

III. Increasing Access to Emergency Contraception Does *Not* Lead to Use of the Drug as a Primary Birth Control Method or Greater Risk-Taking Behaviors

While critics of providing emergency contraception over-the-counter indicate their concern that easy accessibility will encourage its use as a primary birth control method and lead to higher risks of sexually transmitted infections, both common sense and numerous studies indicate otherwise. One such study found that women who were given emergency contraception pills to take home used other birth control methods no differently than the control group of women who were not given the pills. While those women who had the drugs were more likely to use them once, they were not more likely to use them repeatedly. Anna Glasier & David Baird, *The Effects of Self-Administering Emergency Contraception*, 339 New Eng. J. Med. 1 (1998).

Moreover, there is no evidence showing that access to emergency contraception encourages risky sexual behavior or leads women to forgo more reliable birth control methods. Rather, a recent study of 2,117 young women, ages 15 to 24, demonstrated that providing women with access to Plan B did *not* lead them to engage in more risky sexual behavior and did not negate the ability of women to act responsibly. *See* Tina R. Raine et al., *Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs*, 293 JAMA 54 (2005). The study concluded that "[g]iven that there is clear evidence that neither pharmacy access nor advance provision compromises contraceptive or sexual behavior, it seems unreasonable to restrict access to EC to clinics." *Id.* Another study of adolescent women, ages 15 to 20, further substantiates these findings: the group of women who were educated about and given emergency contraception pills were twice as likely to use the pills than the education-only group; they took the pills an average of 10 hours sooner; and they were more likely to report condom use at six months. Melanie Gold et al., *The Effects of Advance Provision of Emergency Contraception on Adolescent Women's Sexual and Contraceptive Behaviors*, 17 J. Pediatric & Adolescent Gynecology 87 (2004). In addition, a British study of 14-15 year olds found that a teacher-led lesson on emergency contraception did not result in any difference in the proportion of students who were virgins. Rather, the study concluded that the "intervention significantly improved the proportion of boys and girls knowing the correct time limits for both types of emergency contraception. The intervention did not change the pupils' sexual activity or use of

emergency contraception." Anna Graham et al., *Improving Teenagers' Knowledge of Emergency Contraception: Cluster Randomised Controlled Trial of a Teacher Led Intervention*, 324 British Medical Journal 1179 (2002), *available at* http://bmj.bmjjournals.com/cgi/reprint/324/7347/1179.

These studies clearly bolster the arguments in favor of making emergency contraception more accessible. According to Felicia Stewart, co-director of the Center for Reproductive Health Research & Policy at the University of California in Berkeley, "[p]articipants in studies who have their own supply overwhelmingly choose to use 'plan ahead' methods regularly and keep postcoital contraception for emergencies—because they know that when used correctly and consistently these regular methods offer better pregnancy protection." Heather Boonstra, *Emergency Contraception*, *supra*, at 13. Common sense clearly argues against frequent use of the method: not only is emergency contraception more expensive than other routinely-used birth control, but it is also less effective and more physically taxing to use. *See* Jane E. Boggess, *Viewpoint: How Can Pharmacies Increase Access to Emergency Contraception?*, 34 Perspectives on Sexual & Reprod. Health 162, 165 (2002).

IV. Further FDA Regulation and Pragmatic Considerations Will Only Unnecessarily Delay the Approval Process of Emergency Contraception

There is no need to initiate a rulemaking to codify the FDA's interpretation of section 503(b) regarding when a drug may be marketed both as prescription and as an over-the-counter product. Any determination that the FDA must initiate a rulemaking would only serve to unnecessarily delay the approval process for emergency contraction as an over-the-counter drug. According to the FDA's own public statement, "[t]he FDA's drug center, the Center for Drug Evaluation and Research or CDER, completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the *safe use of Plan B as an over the counter product*, but only for women who are 17 years of age and older." Statement by Lester M. Crawford, Commissioner, Food and Drug Administration, FDA Takes Action on Plan B (Aug. 26, 2005) (emphasis added), *available at* http://www.fda.gov/bbs/topics/news/2005/NEW01223.html.

Both limiting OTC sales to women ages 16 and older and selling the drug in the same packaging poses no pragmatic difficulties. Pharmacies and drug stores routinely check identification for the purchase of nicotine patches, nicotine gum, or tobacco products and refuse to sell to anyone who is under age 18. Likewise, pharmacies can easily screen over-the-counter purchasers of emergency contraception to ensure that the women attempting to purchase Plan B are of the requisite age. Despite having a dual system of marketing, identical packaging may easily be used without causing complications. As noted above, the dosage would be the same in both formats, and the current prescription labeling more than adequately explains the potential adverse effects and conditions of use. Indeed, the overwhelming majority of studied users understood key messages and instructions about the drug from its current packaging. This study demonstrates that the current prescription labeling is more than sufficient to be used for over-the-counter sales.

Since there are obvious solutions to both these pragmatic considerations, further debate is completely unnecessary and only serves to further delay getting the product out on the shelves. Women have a right to convenient access to this safe and effective contraceptive measure. Any decision not to approve emergency contraception as an over-the-counter drug would be contrary to the FDA's own regulations and would fly in the face of the determinations of the FDA expert panel and the medical community. The current prescription requirement is not only unnecessary but is also harmful to women's health because it impedes access to this important contraception.

Plan B should be made available over-the-counter to women of all ages. Not only has the medical and scientific community found that Plan B is safe for over-the-counter use for all women, but the claim that easier access to young women will result in riskier sexual behavior is unsubstantiated. While the alternative currently being considered—approving emergency contraception for women ages 16 and older—is far from ideal, the proposal is still a practical step toward ensuring women's well-being. Therefore, the Women's Law Project requests that the FDA approve Plan B as an over-the-counter drug, at least for women ages 16 and older, without any further delay.