

December 17, 2003

Dr. Linda C. Guidice, Chair, Reproductive Health Drugs Advisory Committee
Dr. Louis R. Cantilena, Jr., Chair, Nonprescription Drugs Advisory Committee
Division of Dockets Managements (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket number 01P-0075-“Switch Status of Emergency Contraceptive from Rx to OTC”

Dear Drs. Guidice and Cantilena:

We are writing in support of the proposed switch of Plan B[®] from prescription to over-the-counter status because this change in status will greatly benefit victims of sexual assault.

Each year, an estimated 600,000 or more American women are raped,¹ with approximately 25,000 of those rapes resulting in pregnancy. As many as 22,000 of these pregnancies could be prevented by timely administration of emergency contraception.²

Emergency contraception is most effective when taken within 12 hours of unprotected intercourse, with effectiveness decreasing as time passes³ and an outside limit of effectiveness now calculated at five days following intercourse.⁴ The sooner the medication is administered to a sexual assault victim, the greater the odds that pregnancy can be prevented.

Given these time constraints, over-the-counter availability of emergency contraception at local pharmacies is crucial for those rape victims who do not receive treatment at hospital emergency departments. While we have worked to ensure the availability of emergency contraception for rape victims at hospitals, we also recognize that many rape victims – a majority, according to a 1992-2000 U.S. Department of Justice report -- do not seek care at hospitals. For these women, over-the-counter availability of emergency contraception is extremely important in ensuring their timely access to the means to prevent pregnancy from rape.

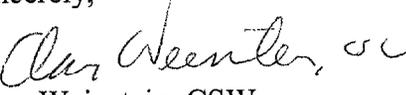
Over-the-counter access to emergency contraception would mean that a rape victim would be spared the additional trauma of having to visit a doctor or clinic immediately after the assault in order to obtain a prescription for the medication. A friend or relative could simply go to the drug store and obtain the medication for her quickly.

On behalf of the thousands of rape victims a year who will face the potential horror of becoming pregnant from a sexual assault, we urge the FDA to make Plan B[®] available widely and easily through a switch to over-the-counter status.

01P-0075

C 326

Sincerely,


Amy Weinstein, CSW
SAVI Clinical Coordinator

¹ Kilpatrick DG, Edmunds CN, Seymour AK. Rape in America: A report to the nation. National Victim Center, 1992.

² Stewart FH, Trussell J. Prevention of pregnancy resulting from rape: A neglected health measure. *Am J Prev Med.* 2000;19(4).

³ Piaggio G, von Hertzen H, Grimes DA, Van Look PFA. Timing of emergency contraception with levonorgestrel or the Yuzpe regimen: Task Force on Postovulatory Methods of Fertility Regulation. *Lancet.* 1999;353(9154):721.

⁴ Seeking Ways to Improve Emergency Contraception: An expanded time limit and a one-dose regimen are among options under study. *Network.* 2001;21(1).