

Feminist Women's Health Center

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March 31, 2004

Lester Crawford, Acting Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 1093
Rockville, MD 20857

RE: Over-the-Counter status of Emergency Contraception (EC)

Dear Commissioner Crawford:

Feminist Women's Health Center urges the Food and Drug Administration to change the status of emergency contraception pills (EC) such as "Plan B" to over-the-counter because.

- EC meets FDA requirements for OTC drug status: it is safe, effective, and simple to use and is not associated with any serious or harmful side effects, which would require medical supervision. Consumers can easily diagnose the condition EC treats: contraceptive failure or failure to use contraception during intercourse. Medical experts agree there is no medical need for EC to be limited by the requirement of a prescription.
- The sooner a woman takes EC after unprotected sex, the more effective the pills are. Plan B® prevents 95% of expected pregnancies when taken in the first 24 hours after unprotected intercourse. However the efficacy declines when treatment is delayed. It is most practical for women to have direct access to EC through pharmacies that are commonly open 24 hours a day and are much more easily accessible than doctors' offices and clinics. Time is a critical factor in assessing the value of changing EC's status to OTC.
- Leading medical organizations including the American Medical Association (AMA) and the American College of Obstetricians and Gynecologists (ACOG) endorse the proposal to make EC available over-the-counter.
- Here in Washington State, women have been accessing Emergency Contraception "behind-the-counter" since 1998. Pharmacists, who have established a collaborative therapy agreement with physicians, can provide the pills directly to women in need. This pilot program initiated by the Program for Appropriate Technology in Health in collaboration with four other state groups: Washington State Pharmacy Association, University of Washington Department of Pharmacy, Washington State Board of Pharmacy and DDB Seattle, has been highly successful. In the first 16 months of this project alone, nearly 12,000 prescriptions were provided, preventing an estimated 700 unintended pregnancies.
- According to a survey conducted by the Alan Guttmacher Institute: increased use of EC probably reduced abortions by 51,000 in 2000.

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- At our clinic we have assisted hundreds of women in obtaining EC pills with general success. However it is still not as widely available as it would be if it were OTC.

Changing the status of emergency contraception to over-the-counter would dramatically increase availability of this important means of preventing unintended pregnancy for all women, most particularly for low-income women and women in rural areas, like the women we serve at our clinics. Since EC is very safe, we strongly support putting control of EC into the hands of individual women, so they can more effectively use this tool for preventing pregnancy.

Women deserve better access to EC as part of their ability to care for themselves and their families. It is known to be safe and effective, in fact much safer than many other medications that already have OTC status. Don't let anti-woman politics affect your decision. Look to medicine not politics for answers.

Feminist Women's Health Center provides reproductive health care, including abortion and birth control, to over 10,000 women annually in Washington State. We appreciate your attention to this important public health issue.

Sincerely,



Beverly Whipple
Executive Director
Feminist Women's Health Center of WA