



EMERSON COLLEGE

Center for Health & Wellness

120 BOYLSTON STREET
BOSTON, MA 02116-4624
(617) 824-8666 phone
(617) 824-7897 fax
email: healthservices@emerson.edu
www: www.emerson.edu/health_center.htm

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

Re: Docket number 2001P-0075 in the *Federal Register* 25 November 2003 (Volume 68, Number 227)

Dear Sir/Madam:

This letter is being written to urge you to approve the emergency contraceptive (EC) pill, Plan B[®], for over-the-counter sales. We are College health nurse practitioners who respond daily to students concerned regarding the possibility of an unplanned pregnancy and the impact that it would have on their academic goals. Our health center is not available 24/7 and is open for clinical visits only during the academic year. This creates gaps in access to timely use of the ECP and is viewed as a barrier.

Our clinical experience (over 37 combined years in practice) with use of Plan B as a safe and effective emergency contraceptive is supported not only in our practice experience with Plan B, but also with the Yuzpe regimen of combined OCP use for this purpose prior to the advent of ECP's such as Preven & Plan B. Numerous studies (cited below) also support Plan B as a safe and effective ECP. We believe that the decision to deny the original application for over-the-counter status of Plan B[®] completely disregarded evidence-based medicine and went against the interest of public health.

The rate of unintended pregnancy in the U.S. is higher than in most other industrialized nations and has serious consequences for women, children, and society at large. Children born as the result of an unwanted pregnancy are at greater risk of being born at low birth weight, dying in their first year of life or being abused.ⁱ There are also significant costs associated with unplanned pregnancy that states incur for prenatal care, deliveries, and abortions for women on Medicaid and other public funding.

But much of this could be avoided. Emergency contraception is safe and effective. More widespread use of EC could prevent 1.7 million unintended pregnancies and 800,000 abortions each year.ⁱⁱ It is 89% effectiveⁱⁱⁱ and very easy to use. Plan B[®] is safer than many products currently available over-the-counter. However, for maximum effectiveness, women should take EC as soon as possible after unprotected intercourse. Many women have difficulty making an appointment with a health care provider within the 72-hour window, especially women who live in rural areas or who don't have a primary care provider. Making Plan B[®] available over-the-counter would greatly increase the chances of women having access to it when they need it.

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Studies show that improved access to EC does not increase the incidence of unprotected sex or encourage repeat use of EC, but it does decrease the incidence of unintended pregnancy.^{iv,v} Plan B[®] should not be held to different standards than other drugs because of political considerations. The FDA's own advisory committees recommended that EC is suitable for over-the-counter use.

We urge you to approve Plan B[®] for over-the-counter sale. In order to restore America's faith in the objectivity of the FDA and to work in the interest of public health, it is essential that the FDA make Plan B[®] available as an over-the-counter product.

Sincerely,



Jane Powers, R.N.C.S., M.S.N. Director Center for Health & Wellness



Kathleen Fitzgerald, FNP-C, M.S.N. Family Nurse Practitioner

ⁱ Brown SS, Eisenberg L. The Best Intentions: Unintended Pregnancy and the Well-being of Children and Families. Washington DC: National Academy Press, 1995.

ⁱⁱ Trussel J. Emergency Contraception Pills: A Simple Proposal to Reduce Unintended Pregnancies. *Family Planning Perspectives*. 1992;24:269-273.

ⁱⁱⁱ Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998;352:428-433.

^{iv} Glasier A, Baird D. The effects of self-administering emergency contraception. *N Engl J Med* 1998;339:1-4.

^v Jackson RA, Schwarz EB, Freedman L, Darney P. Advance supply of emergency contraception: Effect on use and usual contraception – A randomized trial. *Obstet Gynecol* 2003;102(1):8-16.