



October 20, 2005

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Fax: 301-827-6870

Re: Docket No. 2005N-0345

To Whom It May Concern:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) September 2005 advance notice of proposed rulemaking. Through its work as an independent, not-for-profit organization focusing on reproductive health research, policy analysis and public education in the United States and internationally, the Guttmacher Institute has developed and analyzed a great deal of information on various methods of birth control and implications of their use for women's health.

We are very disappointed with the FDA's decision to delay, once again, making a final determination on whether to allow over-the-counter (OTC) sales of the emergency contraceptive Plan B. Although we agree with most experts that the agency, in fact, has the authority to approve an active ingredient as both a prescription-only and an OTC product, such a plan is unnecessary and unwarranted in the case of Plan B. We recommend that a rulemaking not be initiated and, instead, strongly urge the FDA to approve Plan B for OTC use for women of all ages without further delay.

Plan B has been available by prescription in the United States since 1999, and in 2003, the product's manufacturer applied for OTC status. Two FDA expert advisory panels, convened together in December of that year, voted overwhelmingly in favor of the switch. The 28-member joint body unanimously deemed the drug safe for OTC sales. Nonetheless, the FDA failed to approve the application in May 2004, citing concerns that OTC availability of Plan B might increase sexual activity, and therefore the risk of sexually transmitted infections, among young teens. The agency's "not approvable" letter explicitly encouraged the manufacturer to submit a revised application to permit OTC sales to most women but maintain prescription-only status for those under age 16.

It would be unprecedented for the FDA to establish an age restriction for a contraceptive product. It is the long-standing policy of the Division of Reproductive and Urologic Drug Products to make no distinction between postpubescent adolescents and adult women with respect to the safety of contraceptive products. Plan B consists of the same active ingredient found in ordinary birth control pills, which

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2005N-0345

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have been safely used by adolescents for many years. Serious side effects of Plan B are rare, and no deaths have been attributed to use of the product.

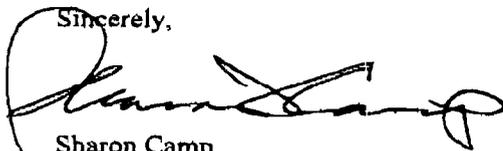
Moreover, there is no evidence to support the position that ready access to Plan B would put adolescents at greater risk of exposure to sexually transmitted infections. To the contrary, studies involving thousands of young women from Scotland to San Francisco have found that women given easier access to emergency contraceptives are no more likely to engage in unprotected sex or to use regular contraceptives less consistently than are women who were advised to obtain emergency contraceptives by prescription should they need it.¹

Those results contributed to the near-unanimity among FDA scientists and the scientific community that Plan B ought to move from prescription-only status to OTC. The American Academy of Pediatrics, the American College of Obstetricians and Gynecologists and the Society of Adolescent Medicine all support making Plan B available OTC and oppose age-based restrictions.

The benefits of making emergency contraception widely available are compelling. A hypothetical scenario calculated in the late 1980s projected that if emergency contraceptives were widely available in the United States, 1.7 million unintended pregnancies could be avoided each year, and the annual number of abortions could be cut by 800,000.² Indeed, there is evidence that emergency contraceptive use already has played a significant role in reducing the U.S. abortion rate. The Guttmacher Institute estimates that emergency contraceptives accounted for up to 43% of the decrease in total abortions between 1994 and 2000.³

OTC access to emergency contraception is a common sense approach to reducing the rates of unintended pregnancy and abortion in the United States. We urge you to abandon the dual status concept for Plan B and to make Plan B available OTC without an age restriction.

Sincerely,



Sharon Camp
President and CEO

¹ Raine T, et al., Emergency contraception: advance provision in a young, high-risk clinic population, *Obstetrics & Gynecology*, 2000, 96:1-7; Belzer M, et al., Advanced supply of emergency contraception for adolescent mothers increased utilization without reducing condom or primary contraception use, *Journal of Adolescent Health*, 2003, 32(2):122-123; Gold M, et al., The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors, *Journal of Pediatric and Adolescent Gynecology*, 2004, 17(2):87-96; Raymond EG, Chen P and Dalebout SM, "Actual use" study of emergency contraceptive pills provided in a simulated over-the-counter manner, *Obstetrics & Gynecology*, 2003, 102(1):17-23.

² Trussell J, et al., Emergency contraceptive pills: a simple proposal to reduce unintended pregnancies. *Family Planning Perspectives*, 1992, 24(6):269-273.

³ Jones RK, Darroch JE and Henshaw SK, Contraceptive use among U.S. women having abortions in 2000-2001, *Perspectives on Sexual and Reproductive Health*, 2002, 34(6):294-303.

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