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

Via e-mail to: fdadockets@oc.fda.gov

Re: Petition to Sell Emergency Contraceptive "Plan B" Over-the-Counter, No. 2001P-0075

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To Whom It May Concern:

The ACLU urges the Food and Drug Administration ("FDA") to reconsider its recent decision denying Barr Laboratory's application to allow the emergency contraceptive, Plan B, to be sold over-the-counter, without a doctor's prescription. Easier access to Plan B would help prevent unintended pregnancies, reduce abortions, and promote women's reproductive health and rights. Because the FDA's decision permits politics to trump science and the public health, it should be reversed.

**Two FDA Advisory Committees, FDA Officials,
and Major Medical Groups Supported this Petition.**

In December, two FDA advisory committees of medical experts voted overwhelmingly (23-4) in favor of granting Barr's petition. In reaching this conclusion, the joint advisory panel considered extensive scientific and social science evidence indicating that the drug is safe and effective and that over-the-counter access to it would serve the public health. The panel also considered a study that showed that easy access to emergency contraception does not cause adolescents to have more unprotected sex or to stop using contraception. See Melanie Gold, Testimony at the Meeting of the FDA Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs 155-57 (Dec. 16, 2003), available at www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf. Indeed, the FDA panel unanimously agreed both that Plan B was safe for use in a non-prescription setting and that there was no evidence that over-the-counter availability leads people to substitute emergency contraception for regular use of other contraceptive methods. *Id.* at 354-64.

Moreover, FDA staff in the Center for Drug Evaluation and Research also recommended Plan B be approved for over-the-counter use. For a director to reject the decision of his staff and the advisory committee is virtually unprecedented. See Gardiner Harris, *Morning-After-Pill Ruling Defies Norm*, N.Y. TIMES, May 8, 2004, at A13. Indeed, recent memoranda from the FDA staff shows the extent of disagreement with the agency's final decision: One senior FDA employee described the reasoning used to justify denying immediate approval for Plan B as "speculative and

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unbalanced.” Marc Kaufman, *Staff Scientists Reject FDA’s Plan B Reasoning*, WASH. POST, June 18, 2004, at A02.

Major medical groups also supported making Plan B more readily accessible to women to who need it, including the American College of Obstetricians and Gynecologists, the American Medical Association, and the American Public Health Association. In the face of such strong recommendations, the FDA’s rejection can only be seen as ideologically motivated and unrooted in science.

Over-the-Counter Availability Ensures Access to Emergency Contraception for the Many Women Who Need It.

Nearly half of all pregnancies in the United States are unintended. See Stanley K. Henshaw, *Unintended Pregnancy in the United States*, 30 Fam. Plan. Persp. 24, 26 (1998). For the women who face a potential unintended pregnancy, widespread and timely access to emergency contraception is critical.

Emergency contraception must be taken within 72 to 120 hours after unprotected intercourse, but most experts agree that it is more effective the sooner it is taken. See Charlotte Ellertson et al., *Extending the Time Limit for Starting the Yuzpe Regimen of Emergency Contraception to 120 Hours*, 101 Obstet. Gynecol. 1168, 1168 (2003). This narrow window makes ready access to emergency contraception critical. The current requirement that emergency contraception only be dispensed with a doctor’s prescription acts as significant barrier to obtaining this safe and effective method of birth control. For women who cannot afford a doctor’s appointment, whose doctor’s office is closed during the critical period, who cannot obtain an appointment within the short window, or whose pharmacist does not stock emergency contraception, the prescription requirement serves as a major impediment to obtaining the drug within the necessary time frame.

Denied access to emergency contraception, some women will face a choice of either continuing an unwanted pregnancy or having an abortion. See Rachel K. Jones et al., *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 Persp. on Sex & Reprod. Health 294, 300 (2002) (estimating 51,000 abortions were prevented in 2000 alone because of emergency contraceptive use). Emergency contraception prevents pregnancy, but does not disrupt an existing pregnancy. Moreover, emergency contraception is safe: despite the millions of women who have used emergency contraception, there are no serious side effects or contraindications that would endanger women’s health. World Health Organization, *Emergency Contraception: A Guide for Service Delivery* (1998).

Access to Emergency Contraception Is Particularly Critical for Sexual Assault Survivors.

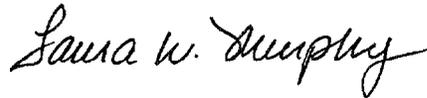
Over-the-counter access to emergency contraception is especially important for sexual assault survivors. Every year, approximately 25,000 pregnancies occur because of sexual assault. See Felicia Stewart et al., *Prevention of Pregnancy Resulting from Rape: A Neglected Preventive Health Measure*, 19 Am. J. Preventive Med. 228, 228 (2000). Emergency contraception could prevent approximately 22,000 of these pregnancies. *Id.* at 229. Yet in many areas, more than half of hospital emergency rooms fail to provide emergency contraception to sexual assault patients routinely. See Ashlesha Patel et al., *Shouldn’t All Victims of Sexual Assault Be Offered Emergency Contraception?*, 99 Obstet. Gynecol. 29S (Supp. 2002); Clara Bell Duvall Reproductive Freedom Project of the ACLU of Pennsylvania, *Fact Sheet: Emergency Contraception*

Services for Rape Victims in Pennsylvania Hospitals (2001), at <http://www.aclupa.org/duvall/pubs/ecinpa.html>; National Abortion Rights Action League Wisconsin, *Revictimization: Access to Emergency Contraception in Wisconsin Emergency Rooms Denied* (2002). The prescription requirement serves as a major barrier to access to emergency contraception for sexual assault survivors in these areas. If a woman is denied access to emergency contraception in the emergency room to which she is initially brought, she must then somehow track down another doctor, answer more personal and painful questions, and find a pharmacy to fill her prescription, all within 72 to 120 hours of the assault. Ready availability of emergency contraception without a doctor's prescription would mean that at least one injury from the assault, the possibility of pregnancy, could be quickly and safely alleviated.

Approving over-the-counter access to Plan B will promote public health, prevent unintended pregnancies, and reduce abortions. Given the strong support for the petition expressed by the FDA's independent committee of experts, FDA staff, and major medical groups, we urge you to reconsider your decision denying the request for over-the-counter status for Plan B emergency contraception.

AMERICAN CIVIL
LIBERTIES UNION

Sincerely,



Laura W. Murphy
Director



Gregory T. Nojeim
Associate Director and Chief Legislative Counsel