THE ALAN GUTTMACHER INSTITUTE
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Division of Documents Management (HFA – 305)
United States Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

To Whom It May Concern:

Thank you for the opportunity to comment on the Advisory Committee for Reproductive Health Drugs' consideration of the public health issues associated with switching Plan B, the FDA-approved emergency contraceptive, from prescription to over-the-counter (OTC) status. 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 Alan Guttmacher Institute (AGI) has developed and analyzed a great deal of information that provides insight into the importance of facilitating access to contraception in general and emergency contraception in particular.

Convenient access to a wide array of safe, effective and affordable contraceptives is critical to helping American couples achieve their overall desired family size and the optimal timing of their births. It is also critical to reducing this country's high rates of unintended pregnancy and abortion. Wider access to emergency contraception is one of the most promising avenues for lowering unintended pregnancy and reducing the need for abortion.

Nine out of 10 U.S. women at risk of unintended pregnancy are using a contraceptive method. But despite this widespread use of contraception, a substantial number of women experience unintended pregnancy. Some 45 of every 1,000 women aged 15-44 in the United States had an unintended pregnancy in 1994 (the latest year for which data are available). Approximately half of unintended pregnancies in the United States end in abortion. At current rates, about one in three American women will have had an abortion by the time she reaches age 45.

Because many people have difficulty using contraception correctly or consistently, especially over long periods of time, women at risk of unintended pregnancy using contraception account for roughly half of the three million unintended pregnancies per year. (The very small proportion of at-risk women who do not practice contraception account for a vastly disproportionate share of unintended pregnancies. Most of these women had used contraception before.)

A recent national survey by AGI of over 10,000 women having abortions (article attached) found that emergency contraception has already played an important role in reducing unintended pregnancy in the United States. According to the survey, only a small number of women used emergency contraception in 2000. Even so, AGI estimates that use of this method averted over 100,000 unintended pregnancies and 51,000 abortions in that one year; moreover, emergency contraceptives accounted for up to 43% of the decrease in total U.S. abortions during the period 1994-2000. Clearly then, providing a greater level of access to emergency contraception would reduce U.S. unintended pregnancy and abortion rates even further.

Making emergency contraception available OTC could play a major role in providing that greater level of access. We ask the Advisory Committee for Reproductive Health Drugs to give full and fair consideration to the question of OTC status. The panel should make a science-based recommendation, treating the pending application as it would any other proposed switch from prescription to OTC status. This application should not be held to a different standard simply because the product involved is a contraceptive method.

We call on the medical and public health communities to recognize that conversion to OTC status, by itself, will not guarantee the desired greater level of access to emergency contraception. The method must be made available—and genuinely accessible—to all women in the country, regardless of their age or place of residence. Its cost must be sufficiently nominal to guarantee access on the part of lower-income American women, who experience higher rates of unintended pregnancy and abortion than do their better-off sisters. Physicians must be educated about the method so as to be inclined, and equipped, to discuss it with their patients. Women, likewise, must be informed so as to be able to raise the subject with their physicians. Pharmacies must stock the method, and hospital emergency rooms must provide women who have been sexually assaulted with information about and access to it. Public education and advocacy campaigns are underway in several of the above areas, and they should continue. The panel should consider the need for these continued post-approval efforts in making its recommendation to the FDA.

We thank the committee for the opportunity to provide this testimony and would be happy to respond to any questions it may have.

Sincerely,

Sharon L. Camp, Ph.D.
President and CEO