

October 28, 2005

Acting Commissioner Andrew C. von Eschenbach  
Food and Drug Administration  
Division of Dockets Management  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. 2005N-0345 / RIN 0910-AF72**

To Acting Commissioner von Eschenbach:

I am writing on behalf of Planned Parenthood Affiliates of Washington state to formally respond to the FDA's request for public comment on whether to initiate a rulemaking process regarding making the emergency contraception (EC) drug Plan B<sup>®</sup> available over-the-counter.

Planned Parenthood Affiliates of Washington (PPAOW) represents the five Planned Parenthood Affiliates of Washington state. PPAOW protects and advances reproductive health and rights in Washington. Collectively, the five Affiliates provide clinical and education services at 40 Planned Parenthood clinics in 18 counties across the state. In 2004, Planned Parenthood clinics in Washington served 229,957 clients.

PPAOW believes that there have already been unjustified delays in making the EC drug Plan B<sup>®</sup> available over-the-counter and to hand this process over to rulemaking is simply another delay that negatively impacts the health and safety of women. Planned Parenthood providers in Washington State unanimously agree that Plan B<sup>®</sup> should be available over-the-counter for the following reasons: 1) according the FDA's own scientific experts, Plan B<sup>®</sup> has met every stringent safety criteria for over-the-counter contraception; 2) data shows that safe and effective contraception, including emergency contraception, improves women's and children's lives by allowing women to plan and space pregnancies; 3) the FDA should be an independent body which can rise above political pressure and act solely according to scientific evidence. For these reasons, we recommend that a rulemaking not be initiated and instead strongly urge the FDA to approve Plan B<sup>®</sup> for over-the-counter use for women of all ages without further delay.

Washington State is uniquely qualified to offer comment about expanded access to EC. Since 1998, women in Washington have been able to obtain EC from pharmacists without a prescription from a doctor. Pharmacists, under collaborative practice agreements with physicians, are able to offer women EC when they walk into their pharmacy. Washington was the first state in the nation to directly distribute EC in pharmacies. There was, and is today, tremendous support from the medical and public health communities for pharmacists to administer this safe and effective contraceptive option.

Don Downing, Clinical Associate Professor in the Department of Pharmacy at the University of Washington and EC protocol trainer says the following about access to EC in our state: “Beginning in 1998, pharmacists in Washington State not only continued filling emergency contraception medications but began prescribing them under protocol to thousands of women who came directly to them for assistance. It is estimated that currently over 2000 women per month use the convenient hours of operation and locations of hundreds of pharmacies in our state to access emergency contraception in order to help prevent unintended pregnancies. I believe that this convenient access to emergency contraception information and medication provided by pharmacists on weekends, evenings, and holidays has contributed to the continuing decline in unintended pregnancies in Washington State.”

There is no question that EC has been found to be safe and effective for over-the-counter use. Even the experts on the FDA’s own advisory committees agreed, by a unanimous vote of 28-0, that the data demonstrates Plan B<sup>®</sup> is safe for use in the non-prescription setting. Requiring any woman to obtain a prescription for EC is not only medically unjustified, but presents a significant barrier in gaining access to this time-sensitive medication. More than 70 of our nation’s leading medical and public health organizations – including the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the Society for Adolescent Medicine, and the American Public Health Association – support unrestricted over-the-counter access to EC and agree that doing so would improve public health.

Study after study shows that EC is safe for all women – including younger women - and that they use it responsibly. Access to EC does not increase or encourage sexual activity among teens; in fact, teens provided with advance provision of EC report increased condom use, fewer pregnancies, and no increase in sexually transmitted infections. Moreover, an overwhelming majority of the experts on the FDA’s advisory committees agreed that restricting Plan B<sup>®</sup> for teenagers would compromise their health and well being by denying them a second chance to prevent an unintended pregnancy.

Unintended pregnancy is a significant public health problem in the United States and in Washington. According to the Guttmacher Institute, half of the six million pregnancies in the United States are unintended and among teenagers the proportion is eight out of ten. The United States has among the highest rates of unintended pregnancy of all industrialized nations. In Washington State, the Department of Health estimates that in 1999-2001, (the most recent data), 52.8% of our 79,500 pregnancies were unintended. The health, social and economic costs associated with unintended pregnancy have been clearly demonstrated and

include less access to pre-natal care, poorer birth outcomes, and increased need for abortion. When women have children from an unintended pregnancy, it can result in fewer educational and economic opportunities for those mothers, and fewer resources to care for unplanned children.

Plan B<sup>®</sup> is a safe, effective, and easy to use contraceptive option that helps reduce the incidence of unintended pregnancy. The Guttmacher Institute estimates that 51,000 abortions were prevented through the use of EC in 2000 alone. If taken within 72 hours of unprotected sex, EC can reduce the risk of pregnancy by as much as 89 percent, and efficacy is greatest if the drug is taken within 24 hours. Studies show that increasing access to EC could prevent as many as half of the 3 million unintended pregnancies in the U.S. each year, including as many as 700,000 that now end in abortion. EC is an essential component of comprehensive health care and millions of women, including those who have experienced contraceptive failure, those who have had unprotected intercourse, and those who have been sexually assaulted stand ready to benefit from increased access to this back-up method of birth control.

A portion of the FDA's mission statement reads as follows:

*The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.*

Approving the Plan B<sup>®</sup> over-the-counter application, considering the wealth of supportive scientific data and the known public health benefits, is completely in line with the mission of the FDA. There is no reasonable explanation to delay expanded access to a safe, effective and affordable drug that will improve the lives and health of millions of Americans. As you know, Dr. Susan Wood, Assistant Commissioner for Women's Health and Director of the Office of Women's Health at the FDA, recently resigned due to the handling of the Plan B<sup>®</sup> over-the-counter application. In her statement of resignation, she stated, "I have spent the last 15 years working to ensure that science informs good health policy decisions. I can no longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled." Similarly, Dr. Frank Davidoff, who was a member of the advisory panel when it voted to recommend approval of Plan B<sup>®</sup> for nonprescription sales in 2003, has also resigned due to the treatment of the Plan B<sup>®</sup> application. In his resignation letter, he stated, "There wasn't any observable scientific or procedural reason for them to first decline and then further delay the decision."

As the new Acting Commissioner, Planned Parenthood Affiliates of Washington hopes that you restore American's faith in the FDA. Americans expect the Agency to act as an independent body and make decisions according to science and medical expertise alone. Science tells us that Plan B<sup>®</sup> should be made available to women of all ages without a prescription. It is time for the FDA to return to the days where an obligation to protect the public health was the primary driver of decision making. The time has come to restore

public confidence in the FDA and to approve the Plan B<sup>®</sup> over-the-counter application so that women of all ages can have access to EC without delay.

Sincerely,

Elaine Rose  
Executive Director  
Planned Parenthood Affiliates of Washington