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October 10, 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 of Metropolitan New Jersey, Inc. to formally respond to the FDA's request for public comment on whether to initiate a rulemaking process regarding the issues the Agency claims are raised by the application to make the emergency contraception (EC) drug Plan B® available over the counter (OTC). A decision on the Plan B® OTC application is long overdue, and the attempt to hand this process over to rulemaking is simply another delay tactic. The FDA is seeking public comment on issues that are not legitimate concerns with respect to the Plan B® OTC application and are merely designed as a smokescreen to obscure the fact that politics is trumping science at the FDA. For these reasons, we recommend that a rulemaking not be initiated and instead strongly urge the FDA to approve Plan B® for over-the-counter use for women of all ages without further delay.

Despite the recommendations of the FDA's advisory committees, the support of major professional medical associations, overwhelming scientific evidence supporting the move, and, most recently, the FDA's conclusions that the available scientific data are sufficient to support safe use of Plan B® as an OTC product, the FDA has refused to make a decision on the Plan B® OTC application at every possible turn. These delay tactics are a major public health setback that put women's health and lives on the line. Americans deserve an independent FDA that will protect the public health and make decisions based on science and medicine, not politics. Every day that the FDA delays making a decision on increasing access to this second chance prevention medication, more women are put at risk of facing an unintended pregnancy.

Unintended pregnancy is a significant public health problem in the United States, and women deserve a chance to prevent it. Plan B® is a safe, effective, and easy to use

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contraceptive option that helps reduce the need for abortion. The Guttmacher Institute, widely respected for their reliable research and evenhanded approach, estimates that 51,000 abortions were prevented through the use of EC in 2000 alone. However, time is of the essence. The sooner EC is taken, the more effective it is. 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.

The simple fact is 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 demonstrate that Plan B® 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. Women in this country deserve the same unencumbered access to EC that women in 39 other countries around the world already enjoy. 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.

Despite the unequivocal support that over-the-counter access to EC has garnered, the FDA has decided to ignore the science and use delay tactics to avoid ruling on the application. In response to the manufacturer's original Plan B® OTC application, the FDA declared that the application was "not approvable," citing concerns about use in the under 16 population. These specious claims about teens and EC lack scientific merit. Study after study shows that EC is safe for 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

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restricting Plan B® for teenagers would compromise their health and well being by denying them a second chance to prevent an unintended pregnancy.

It is clear that the FDA's supposed concerns about use by the teen population are simply a delay tactic. Early last year, as a way to avoid making a decision, the FDA itself suggested to the manufacturer that it propose a way in which Plan B could be marketed as a prescription product for the under 16 population and over the counter for women 16 and over. Now, in a stunning development, and at this late stage, the Agency is seeking public comment on whether its own suggestion is even a viable legal option. If the FDA decides to institute a rulemaking, it could be years before it reaches a decision—or, more likely—comes up with another reason not to decide.

Instead of fulfilling its obligation to improve public health, the FDA, guided by misinformation and inflammatory rhetoric, has found ways to maneuver around the overwhelming consensus of an independent medical and scientific review process and obstruct increased access to a safe and effective medication. Providing further proof that politics is trumping science at the Agency, 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® OTC 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® for nonprescription sales in 2003, has also resigned due to the FDA's poor treatment of the Plan B® OTC application. In his resignation letter, he stated, "I can no longer associate myself with an organization that is capable of making such an important decision so flagrantly on the basis of political influence, rather than the scientific and clinical evidence" and added, "There wasn't any observable scientific or procedural reason for them to first decline and then further delay the decision."

In addition to the latest delay tactic, the FDA has subjected the Plan B® application to a different and higher level of scrutiny. A stronger microscope is being applied because the FDA has fallen prey to pressure from the minority fringe population who claim that EC terminates a pregnancy. However, the FDA approved Plan B® as a contraceptive for the purpose of *preventing* pregnancy. EC functions in the same way as ordinary birth control pills and can not interrupt an established pregnancy. Unfortunately, it seems

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that the FDA is treating Plan B® differently than other forms of contraception and differently than other OTC applications. Even the FDA's own staff finds the treatment of the Plan B® application to be unusual and unacceptable. There is no scientific explanation for why the FDA has subjected the Plan B® OTC application to a different and more rigorous standard than other drugs, only a political one.

Dr. John Jenkins, Director of the Office of New Drugs at the FDA, stated that "the data submitted by the sponsor in support of non-prescription use of Plan B® are fully consistent with the Agency's usual standards for meeting the criteria for determining that a product is appropriate for such use" and that the agency had not previously distinguished the safety and efficacy of birth control among different ages. We believe, as Dr. Jenkins does, that the "available data clearly support a conclusion that Plan B® meets the statutory and regulatory requirements for availability without a prescription for all age groups." Dr. Jenkins goes on to say that "such a conclusion is consistent with how the Agency has made determinations for other OTC products, including other forms of contraception available without a prescription." When the FDA's own leadership acknowledges that Plan B has been treated differently, it is time for the FDA to take a step back, assess the situation, and commit to moving towards restoring credibility and public trust.

As the new Acting Commissioner, you have the opportunity to set the FDA back on the right track by following the science. Science tells us that Plan B® should be made available to women of all ages without a prescription. Turning this process over to rulemaking has fully exposed the fact that what started off as scientific inquiry has only become a question of politics. The public wants a reason to be proud of the FDA. It is time for the FDA to stop playing politics with women's lives and return to the days where an obligation to protect the public health was taken seriously. The time has come to restore public confidence in the FDA and to approve the Plan B® OTC application so that women of all ages can have access to EC without delay.

Sincerely,

Jackie Cornell

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Planned Parenthood of Metropolitan New Jersey, Inc.

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