Congress of the United States
Washington, DC 20515

September 22, 2005

Dr. Lester Crawford, Commissioner
Food and Drug Administration
Room 1471
Rockville, MD 20857

Dear Dr. Crawford:

We write as representatives of many New York women who are severely disappointed with the Food and Drug Administration's (FDA) continued delay tactics on Plan B(r), a concentrated dosage of ordinary birth control pills that, if taken within 72 hours of contraceptive failure or unprotected sex, can reduce a woman's risk of pregnancy by up to 89 percent. We are concerned that your agency's August 26th, 2005 decision to delay issuing a final ruling on Plan B(r) as an over-the-counter (OTC) medication is endangering the reputation of the FDA and having a direct and irreversible effect on the health and well-being of thousands of women. Americans have long relied on the FDA to make scientific, evidence-based decisions that are in the best interest of the American public and that will help improve our health. The decision to withhold Plan B(r) from OTC use and limit its access when it has been deemed safe and effective for this purpose is not in the best interest of the American public.

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While the FDA imposed 60-day comment period may appear brief and harmless, the reality is that this 60-day period is in addition an already extended process. As you may recall, on December 16, 2003 a joint panel of the FDA's Reproductive Health Drugs Advisory Committee and Non-prescription Drugs Advisory Committee voted 28-0 that Plan B(r) could be safely sold as an over-the-counter medication; it then voted 23-4 to recommend that the FDA approve the application to make Plan B(r) available over-the-counter for women of all ages. At the beginning of 2005, the FDA declined to issue a decision on the application by the pre-set deadline. A 60-day comment period in addition to the previous delays appears to be excessive.

Based on the evidence and the history of this process, it appears that politics and ideology has been allowed to influence sound science. The recent announcement by the Director of the Office of Women's Health, Susan Wood, who resigned in August citing concerns about Plan B(r), is evidence of this serious problem. Specifically, she noted that "scientific and clinical evidence" is effectively being "overruled." This is a dangerous path to tread.

The reasons for approving Plan B(r) for over-the-counter use remain the same. Millions of women have successfully used Plan B(r). Plan B(r) does not result in more frequent usage or more unprotected sex. However, Plan B(r) will result in fewer abortions and unintended pregnancies. Moreover, as determined by the expert panels, Plan B(r) meets the requirements to be available OTC as extensive evidence shows that Plan B(r) is safe and effective for OTC use.

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The data proves that this product should be made available for OTC use. Americans rely on the FDA to protect them from harm. They must also be able to rely on the FDA to protect them from partisan politics that could prevent them from accessing the best available care. We encourage you to act on this issue and make Plan B(r) available for OTC use.

Sincerely,

Joseph Crowley
Member of Congress

Carolyn B. Maloney
Member of Congress