Congress of the United States
Washington, DC 20515

October 7, 2005

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

RE: Docket No. 2005N-0345

Dear Acting Commissioner von Eschenbach:

As Members of the Bipartisan Congressional Pro-Choice Caucus, we are submitting the following remarks in response to your request for public comment on over-the-counter sales of Plan B.

First and foremost, we are very disappointed with then-Commissioner Crawford's announcement on August 26, 2005, to further delay the FDA's decision on over-the-counter sales of Plan B emergency contraception (EC). We believe this new delay does not truly reflect valid scientific or regulatory concerns.

In late 2003, the FDA's own expert Advisory Panel voted overwhelmingly in favor (23-4) of allowing over-the-counter sales of Barr Laboratories' Plan B. The Advisory Panel and FDA's professional and scientific staff concluded that EC meets standard criteria for over-the-counter use: low-toxicity; no potential for overdose or addiction; no teratogenicity (is not harmful to an existing pregnancy); no need for medical screening; self-identification of the need; uniform dosage; and no significant drug interactions. Yet, 20 months later, the FDA still refuses to accept a sensible, safe solution to preventing unintended pregnancies.

Other studies have also proven the effectiveness and safety of Plan B. A recent policy statement by the American Academy of Pediatrics highlights the fact that Plan B has no contraindications and points to a study featured in the *Journal of Obstetrics & Gynecology*,[1] which concludes that young women are able to use EC "effectively and safely without health care provider intervention." Experts estimate that wider access to EC would prevent 1.7 million unintended pregnancies and 800,000 abortions each year. By further delaying the FDA's decision to expand access to EC, you are seriously hindering efforts to reduce abortions across the U.S.

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[1] Raymond EG, Chen, PL, Dalebout SM. "Actual use" study of emergency contraceptive pills provided in a simulated over-the-counter manner. Obstet Gynecol. 2003; 102:17-23.

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Last May, the FDA rejected Barr Laboratories' first application for providing EC over-the-counter. The FDA cited the concern that easier access to EC might lead to promiscuity among women under the age of 16, despite numerous studies disproving this claim. The FDA stated that unless an age-based sales distinction was made, it would not approve Barr Laboratories' application. In order to address the FDA's concern, Barr Laboratories submitted a new application to the FDA to provide over-the-counter sales of EC to women 16 years and older. On August 26, 2005, more than one year later, the FDA released a statement expressing its sentiment that selling EC to two different age groups would present regulatory concerns. We find it contradictory and disconcerting that the FDA's concerns are a direct result of the agency's own recommendations last May.

We are displeased that the FDA continues to delay, postpone and create impediments to issuing a decision on an application that its own expert advisory committee endorsed nearly 20 months ago. Unfortunately, this important decision has been delayed too long and at the expense of women's reproductive health throughout the country. We, therefore, strongly urge the FDA to approve Barr Laboratories' application without further delay. Thank you for your immediate consideration.

Sincerely,

Lauren M Slaughter

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