

Congress of the United States
Washington, DC 20515

September 8, 2005

Lester M. Crawford, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RECEIVED
U.S. HOUSE OF REPRESENTATIVES
SEP 20 PM 1:43

Dear Commissioner Crawford:

As co-chairs of the bipartisan Congressional Pro-Choice Caucus, we are disappointed with your announcement last Friday to further delay the FDA's decision on over-the-counter sales of Plan B emergency contraception (EC).

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.

In late 2003, the FDA's own expert Advisory Panel voted overwhelmingly in favor (23-4) of over-the-counter sales of Barr Laboratories' Plan B. The Advisory Panel 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.

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 more promiscuity among women under the age of 16, despite numerous studies disproving this claim. The FDA stated that unless an age-based sales distinction were made, it would not approve Barr Laboratories' application. In order to address the FDA's concern, Barr Laboratories did exactly that: it 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 concern that selling EC to two different age groups would present regulatory challenges. We find it contradictory and disconcerting that the FDA's concerns are a direct result of the agency's own recommendations last May.

Furthermore, the FDA's claim that this is an unprecedented regulatory requirement is inaccurate. It is simply false to argue that the FDA lacks the capability to administer regulations on the use of a drug that are contingent upon a person's age – this is the type of regulatory regime that was

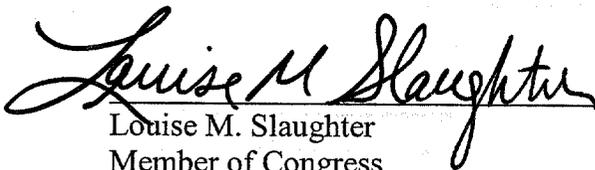
2005-6210

implemented for over-the-counter sales of nicotine gum in 1996. Just as it did before, we are confident that the FDA can navigate itself through this type of regulatory challenge.

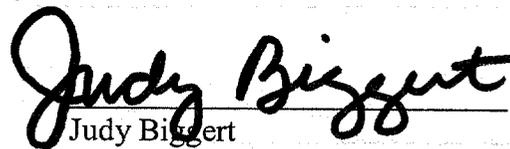
The FDA also indicated in the August 26th statement that its drug center, the Center for Drug Evaluation and Research or CDER, "has concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product, but only for women who are 17 years of age and older." However, the statement did not indicate *how* or on what basis CDER came to that conclusion.

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, every time a decision on Barr Laboratories' application is delayed, it is done at the expense of the reproductive health of women throughout the country. We, therefore, strongly urge the FDA to approve Barr Laboratories' application without further delay. We also respectfully request that you indicate when the FDA will make a final decision on Plan B following the 60 day public comment period. Thank you for your immediate consideration.

Sincerely,



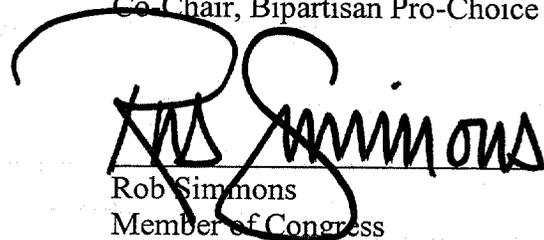
Louise M. Slaughter
Member of Congress
Co-Chair, Bipartisan Pro-Choice Caucus



Judy Biggert
Member of Congress
Co-Chair, Bipartisan Pro-Choice Caucus



Diana DeGette
Member of Congress
Co-Chair, Bipartisan Pro-Choice Caucus



Rob Simmons
Member of Congress
Co-Chair, Bipartisan Pro-Choice Caucus