

Oct 7 2005 - Rep. Slaughter, Other Members Come Out Swinging for Plan B

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Bipartisan Congressional Coalition Appeals to FDA in

Support of Over-the-Counter Sales of Emergency Contraception

Washington, DC - Rep. Louise M. Slaughter (D-Fairport), Ranking Member of the House Rules Committee and Co-Chair of the Bipartisan Congressional Pro-Choice Caucus, today released a letter signed by a bipartisan coalition of 62 Members of Congress to the Food and Drug Administration in support of over-the-counter sales of Plan B emergency contraception.

"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," the letter circulated by Rep. Slaughter begins.

The FDA's own expert Advisory Panel voted overwhelmingly in favor (23-4) of allowing over-the-counter sales of Plan B. The Advisory Panel and FDA's professional and scientific staff concluded that EC meets standard criteria for over-the-counter use. Yet, 20 months later, the FDA still refuses to accept a sensible, safe solution to preventing unintended pregnancies. The FDA's repeated refusal to approve Plan B for over-the-counter sales resulted in the resignation of Dr. Susan Wood, head of the FDA's Office of Women's Health, who confirmed that politics was trumping science.

"EC could safely and drastically reduce the number of unintended pregnancies and abortions in the United States," said Rep. Slaughter, "but unfortunately, barriers to information and access hinder this preventative contraceptive method from reaching its full potential." She concluded, "We can and we must do more to protect women's reproductive health by increasing knowledge of emergency contraception and expanding access to this critical preventative solution. However, the FDA has turned its back on this responsibility and is now, jeopardizing its own scientific integrity by playing politics with women's lives."

In July, Rep. Slaughter also introduced H. R. 3326, the Emergency Contraception Education Act, which now has 80 co-sponsors. If passed the legislation would direct the Secretary of Health and Human Services to develop and disseminate information on EC to health care providers, including recommendations on the use of EC in appropriate cases, and how to obtain copies of information developed by HHS for distribution to patients. The Secretary will also be required to develop and disseminate information on EC to the American public.

LETTER TO THE FDA:

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, 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.

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,

/s

Louise M. Slaughter, Member of Congress

Judy Biggert, Member of Congress

Diana L. DeGette, Member of Congress

Robert R. Simmons, Member of Congress

Rosa DeLauro, Member of Congress

Sherwood L. Boehlert, Member of Congress

Tom Lantos, Member of Congress

Nancy L. Johnson, Member of Congress

Nita M. Lowey, Member of Congress

Mark S. Kirk, Member of Congress

Henry A. Waxman, Member of Congress

Christopher Shays, Member of Congress

Neil Abercrombie, Member of Congress

Thomas H. Allen, Member of Congress

Joe Baca, Member of Congress

Tammy Baldwin, Member of Congress

Earl Blumenauer, Member of Congress

Sherrod Brown, Member of Congress

Lois Capps, Member of Congress

Michael E. Capuano, Member of Congress

Russ Carnahan, Member of Congress

Julia Carson, Member of Congress

Joseph Crowley, Member of Congress

Elijah Cummings, Member of Congress

Susan Davis, Member of Congress

Peter DeFazio, Member of Congress

William Delahunt, Member of Congress

Lloyd Doggett, Member of Congress

Anna Eshoo, Member of Congress

Sam Farr, Member of Congress

Raúl M. Grijalva, Member of Congress

Luis V. Gutierrez, , Member of Congress

Jane Harman, Member of Congress

Maurice Hinchey, Member of Congress

Jesse Jackson, Jr. , Member of Congress

Rick Larsen, Member of Congress

Barbara Lee, Member of Congress

Sheila Jackson Lee, Member of Congress

Sander Levin, Member of Congress

John Lewis, Member of Congress

Zoe Lofgren, Member of Congress

Carolyn Maloney, Member of Congress

Betty McCollum, Member of Congress

Jim McDermott, Member of Congress

James P. McGovern, Member of Congress

Gwen Moore, Member of Congress

Jerrold Nadler, Member of Congress

John W. Olver, Member of Congress

Steven R. Rothman, Member of Congress

Lucille Roybal-Allard, Member of Congress

Martin Olav Sabo, Member of Congress

Linda T. Sánchez, Member of Congress

Bernard Sanders, Member of Congress

Jan Schakowsky, Member of Congress

Adam Schiff, Member of Congress

Debbie Wasserman Schultz, Member of Congress

Adam Smith, Member of Congress

Hilda L. Solis, Member of Congress

Pete Stark, Member of Congress

Chris Van Hollen, Member of Congress

Diane E. Watson, Member of Congress

Lynn Woolsey, Member of Congress