

August 26 2005 - FDA Plays Politics, Delays Approval on ...

FDA Plays Politics, Delays Approval on
Over-the-Counter Sale of Emergency Contraception

Washington, DC - Rep. Louise M. Slaughter (D-NY), Co-Chair of the Bi-Partisan Congressional Pro-Choice Caucus, made the following statement regarding the FDA's decision to delay the acceptance of Emergency Contraception sales over-the-counter. The announcement was made late Friday afternoon in a clear attempt to slip under the radar of the media.

"I am once again deeply disappointed that FDA has disregarded the recommendation of its expert Advisory Panel and instead has allowed politics to trump science," said Rep. Slaughter. "To further delay acceptance of this application that enjoys broad support in the medical and scientific communities, is completely and wholly unacceptable. The scientific facts irrefutably show that EC is a safe, effective way for women to prevent unintended pregnancies," she continued.

"This decision has seriously hindered the advancement of women's reproductive health. In a callous display of politics, the FDA has once again missed the opportunity to significantly reduce the number of unwanted pregnancies and abortions in America," Rep. Slaughter concluded.

Background

In December 2003, FDA's expert Advisory Panel voted overwhelmingly (23-4) in support of Barr Laboratories' application. The Advisory Panel claimed that EC was safe and effective at reducing unwanted pregnancies. Despite

significant support, the FDA decided in May 2004 to reject the application. The FDA argued that Barr Laboratories failed to demonstrate that women under 16 years would not become more promiscuous if EC was more readily available.

Following FDA's decision, Barr Laboratories submitted a new application that would allow women over 16 years of age to obtain EC over-the-counter, but women younger than 16 would still need a prescription. The FDA had said it would make a decision on Barr Laboratories new application in January 2005. That date came and went. Senators Murray and Clinton put a hold on Crawford's nomination to lead the FDA until FDA agreed to make a decision on Barr Laboratories. They lifted their hold in July when the Bush Administration committed to FDA making a decision before September 1st.

Timeline of events:

- § 7/18/05 - The Senate in a vote of 78 to 16 confirmed Crawford's nomination to head FDA. Senators Murray and Clinton agreed to lift their hold after the Administration said they would make a decision on Plan B by September.

- § 7/8/05 - A new study published in the July 8 issue of British Medical Journal Online First confirms previous findings that women use emergency contraception (EC) responsibly. The study, which tracked the use of EC in Britain since it became available without a prescription in 2001, revealed that over-the-counter status does not decrease the use of regular contraceptive methods.

- § 6/15/05 - The Senate HELP Committee approved the nomination of Crawford to be head of FDA. The nomination was approved by voice vote. Senators Murray and Clinton have put a hold on the nomination because of Crawford's failure to make a decision on Barr Laboratories' application for over-the-counter sales of EC.

- § 5/25/05 - Rep. Slaughter led a letter asking for the Inspector General at HHS to conduct an investigation into whether Dr. Hager's minority opinion unduly influenced FDA's decision, in May 2004, to reject Barr Laboratories' application to

distribute EC over-the-counter. Fifty-four Members signed onto the letter.

- § 5/12/05 - An article from the Washington Post appeared on Thursday about a "minority opinion" solicited by the FDA on emergency contraception. According to the article, after the Advisory Panel voted in December 2003, to overwhelmingly support Barr Laboratories' application to sell EC over the counter, the FDA asked one of the dissenting panelists, Dr. W. David Hager, to draft a minority opinion outlining why FDA should reject the application. FDA denies this.

- § 1/5/05 - The Journal of the American Medical Association published a study showing that ready access to EC increases its use, but does not make women more likely to engage in sexual risk taking behaviors or acquire STDs.

- § 5/04 - Rep. Slaughter signed onto a letter led by Rep. Waxman asking the GAO to investigate FDA's review of Barr Laboratories' application.

- § 5/04 - Despite the Advisory Panel's overwhelming support, the FDA's rejected Barr Laboratories' application claiming that there were concerns that with greater access to EC, women under 16 years of age would be more promiscuous.

- § 1/04 - Rep. Slaughter signed onto a letter to then FDA Commissioner McClellan in support of making EC available over the counter.

- § 12/03 - FDA's Advisory Panel voted overwhelmingly in favor (23-4) of over-the-counter sales of Barr Laboratories' Plan B emergency contraceptive. The FDA's Advisory Panel concluded that emergency contraception 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 important drug

interactions.

Statistics and Facts:

- § Emergency contraception is a concentrated form of the daily birth control pills taken by nearly 12 million women in the U.S.

- § It does not cause abortion, but instead stops the release of an egg from the ovary. EC will not harm an established pregnancy.

- § EC is a safe and effective means of preventing pregnancy -- it has low-toxicity and no potential for overdose or addiction; it is not harmful to an existing pregnancy; and because there are no important drug interactions, there is no need for medical screening allowing for self-identification of the need.

- § If taken within 72 hours after unprotected sex or contraceptive failure, EC can reduce the risk of pregnancy by as much as 89 percent. But because of the narrow window of effectiveness, timely access to EC is critical.

- § The Alan Guttmacher Institute has documented its effectiveness -- estimating that increased use of EC accounted for up to 43 percent of the total decline in abortion rates between 1994 and 2000.

- § In addition, EC is often the only contraceptive option for the 300,000 women who are raped each year.

- § Unfortunately, many women do not know about EC and many face insurmountable barriers in accessing this important product. A recent study in the Annals of Emergency Medicine found that less than 17 percent of hospitals dispense emergency contraception at the woman's request, without restrictions. Yet, scientific data suggest that increased timely access to EC could significantly reduce our nation's still staggering rates of unintended pregnancy and decrease the number of abortions performed in our nation by hundreds of thousands.

- § The American Medical Association and the American College of Obstetricians and Gynecologists have supported more widespread availability of EC.

- § Studies have shown that effectively preventing unwanted pregnancies is the best way to reduce abortion rates. Therefore, easier access to emergency contraception would significantly reduce the number of unwanted pregnancies and abortions.