



THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg
Mayor

Thomas R. Frieden, M.D., M.P.H.
Commissioner

nyc.gov/health

October 31, 2005

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

RE: Docket No. 2005N-0345
RIN # 0910-AF72

Dear Acting Commissioner von Eschenbach:

We are deeply concerned by the Food and Drug Administration's recent decision to further delay over-the-counter status for Plan B emergency contraception. This decision will delay prompt access to a safe and effective method to prevent unintended pregnancy. Every day that the FDA delays is another day that women across the nation are more likely to have unintended pregnancies due to rape, contraception failure, or any incident of unprotected sex.

We do not believe the FDA should initiate rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug and Cosmetic Act. Therefore, we answer 'no' to questions 1A, 1B, and 1C of the Agency Request for Information. Scientific evidence, well documented in peer reviewed journals, and provided to the FDA by Plan B's manufacturer, demonstrates that emergency contraception meets the FDA criteria for over-the-counter use, and the FDA advisory committee voted 23 to 4 to approve over-the-counter status for emergency contraception without any age restriction. Since there is no evidence-based rationale for limiting over-the-counter status to a particular subpopulation, this comment does not address the enforcement and marketing issues raised in Questions 2A, 2B, 3A and 3B.

Each year in New York City, there are approximately 130,000 unintended pregnancies; more than 90,000 of these result in abortion. Unintended pregnancy increases the likelihood of infant mortality, developmental delay, domestic violence, homelessness, child abuse and poverty. These negative outcomes are the most pronounced for teenagers. Preventing unintended pregnancies would reduce these negative health and social effects and would prevent thousands of abortions.

Because emergency contraception pills are most effective when taken as soon as possible after unprotected sex, easy over-the-counter access is critical. I am distressed that the FDA has erected yet another regulatory barrier, and one without scientific basis, to a straightforward

proposal by the manufacturer of Plan B, especially since the FDA knew many months ago that the manufacturer had proposed an age differential as a way to move forward with over-the-counter approval. FDA decisions should be solely based on medical fact and reason, and no evidence has been produced to support the need for an age restriction for OTC emergency contraception. The FDA exists to protect public health by making scientific, evidence-based decisions on drug safety; no other agenda should interfere with its decision-making process.

Several countries have already made emergency contraception pills available without a prescription. In Great Britain, where emergency contraception pills have been available without a prescription since 2001, results of a recent study showed that easier availability has *not* led to more unprotected sex. Likewise, in the U.S., studies have shown no negative behavioral or health ramifications to making emergency contraception more readily available to adolescents. There is no increase in unprotected sex or reduction in condom use; no increase in the likelihood of missing a pill, switching birth control methods or not using a condom; no difference in the amount of unprotected sex or the number of sexual partners. Recently, the American Academy of Pediatrics (AAP) issued a position paper on emergency contraception, supporting increased availability of emergency contraction, including over-the-counter access for teens. AAP states, "An increase in awareness and availability of emergency contraception to teens does not change reported rates of sexual activity or increase the frequency of unprotected intercourse among adolescents."¹

In conclusion, the questions posed in the FDA Request for Information should not be considered in deciding whether to approve Plan B as an over-the-counter medication. I urge the FDA to recognize the strength of evidence demonstrating that emergency contraception pills are safe and effective for all women and adolescents of reproductive age and rapidly approve over-the-counter status for Plan B emergency contraception pills without any age restrictions.

Sincerely,

A handwritten signature in cursive script that reads "Thomas R. Frieden".

Thomas R. Frieden, M.D., M.P.H.
Commissioner

¹ American Academy of Pediatrics Policy Statement on Emergency Contraception, Pediatrics 2005; 116:1038-1047.