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Division of Dockets Management  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Agency: FDA  
Docket Number 2005N-0345

Dear Acting Commissioner von Eschenbach:

As a pediatric and adolescent gynecologist, I am deeply concerned about the FDA's repeated delay on a decision regarding over-the-counter approval of Plan B emergency contraception. I urge you to approve Barr Laboratories' EC application immediately.

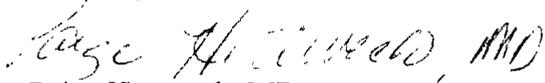
Currently, half of all pregnancies in the United States are unintended, of which about one-third end in abortion. Widespread availability of emergency contraception could prevent many of these unintended pregnancies and dramatically reduce the abortion rate in the United States.

In 1999, the FDA approved Plan B for the "prevention of pregnancy." In April 2003, Barr Pharmaceuticals filed an application with the FDA to make the drug available over the counter. The FDA's Advisory Panel voted 23 to 4 in favor of approving the application.

Since receiving the Barr Pharmaceutical's application, the FDA has at every opportunity delayed making a decision. HHS Secretary Leavitt, who oversees the FDA, assured the Senate that the FDA would make a decision by September 1, 2005. Instead, the FDA delayed its decision and initiated a 60-day public comment and rulemaking process with no timetable for making a decision.

Again, I urge you to approve the Plan B EC application today—providing women with safe and effective contraception that will both reduce pregnancies and abortions.

Sincerely,



Paige Hertweck, MD  
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