

FDA rethinks its delays on sale of morning-after pill: Decision may be in a matter of weeks

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After a three-year fight, the Bush administration signaled that it may be ready to reverse course and approve over-the-counter sales of an emergency contraceptive pill despite strong opposition from the religious right.

The Food and Drug Administration notified Barr Pharmaceuticals that it wanted a meeting early this month to discuss the “rigorous” steps the company would have to take to sell its morning-after pill without a prescription.

Barr has been seeking approval to sell its Plan B contraceptive to those 16 and older but has faced vocal opposition from antiabortion groups and conservative lawmakers and repeated roadblocks from the FDA.

Now the agency says a final decision could be reached “in a matter of weeks” if Barr meets conditions necessary to ensure that the pill does not fall into the hands of “young girls who can’t safely use it” without the supervision of a doctor. The FDA insists on a minimum age of 18.

“Obviously we are pleased,” said Barr spokesperson Carol Cox. “We think this is a positive development.”

Plan B, which has been sold by prescription in the United States since 1999, contains higher doses of the hormones used in regular birth control pills. The emergency contraceptive is considered effective in preventing implantation up to 72 hours after sexual relations, but it works best if taken in the first 24 hours.

Family planning, abortion rights and physician groups say easier access to the pill could greatly reduce unintended pregnancies, and they have accused the Bush administration of politically interfering with a science-based decision. The administration has promoted abstinence, with its conservative allies adamantly

opposed to creating easier access to the emergency contraception.

The announcement on July 31 came the day before Andrew von Eschenbach, President Bush's nominee to lead the FDA, appeared at his Senate confirmation hearing. On August 1, Senate Democrats grilled von Eschenbach, the acting FDA commissioner since last September, on why approval of over-the-counter sales of Plan B has been thwarted despite positive recommendations by the agency's scientific advisers and professional staff.

Two Democrats, Senators Hillary Clinton of New York and Patty Murray of Washington, vowed to continue to hold on to von Eschenbach's confirmation until a final decision is made on Plan B. At the hearing, Clinton urged von Eschenbach to end the "politicizing" of the FDA. "This is a slippery, dangerous slope we are on, doctor, and we are looking to you to make a decision," she said, according to the Associated Press. Von Eschenbach, in turn, said he would make decisions based "not on a political ideology, but on a medical ideology."

Wendy Long, head of Concerned Women for America, a conservative Christian advocacy group, expressed dismay over the FDA announcement. She warned that over-the-counter sales could lead to greater promiscuity, an increase in sexually transmitted diseases, and the likelihood that adolescent girls will gain access to the pill.

"You could have a 19-year-old man buy it and hand it to a 13-year-old girl," Long said. "Any restriction on who can buy it without a prescription will be meaningless."

Nancy Keenan, president of NARAL Pro-Choice America, said Plan B could prevent unintended pregnancies and reduce the need for abortion.

"We are cautiously optimistic that, after more than three years of delays, sound science could prevail," said Keenan. "We are eager to see the FDA put women's health before ideology and approve the application of the morning-after pill." -

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