

FDA Ordered to Rethink Age Restriction for Plan B

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Judge Says Politics Influenced Policy on the Contraceptive

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A federal judge ordered the Food and Drug Administration yesterday to reconsider its 2006 decision to deny girls younger than 18 access to the morning-after pill Plan B without a prescription.

U.S. District Judge Edward R. Korman in New York instructed the agency to make Plan B available to 17-year-olds within 30 days and to review whether to make the emergency contraceptive available to all ages without a doctor's order.

In his 52-page decision, Korman repeatedly criticized the FDA's handling of the issue, agreeing with allegations in a lawsuit that the decision was "arbitrary and capricious" and influenced by "political and ideological" considerations imposed by the Bush administration.

"These political considerations, delays and implausible justifications for decision-making are not the only evidence of a lack of good faith and reasoned agency decision-making," he wrote. "Indeed, the record is clear that the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug from prescription to non-prescription use."

FDA lawyers are reviewing the decision, said Rita Chappelle, an agency spokeswoman, who declined to comment further.

Critics of the FDA's decision hailed the ruling.

"We're very excited," said Suzanne Novak, a senior staff lawyer for the Center for Reproductive Rights, which filed the lawsuit. "The message is clear: The FDA has to put science first and leave politics at the door."

Opponents of Plan B condemned the judge's order.

"This ruling puts politics above women's health, and intrudes into parents' ability to protect their minor daughters," said Wendy Wright of the group Concerned Women for America. She also questioned the drug's effectiveness.

"Making the morning-after pill easy to get has not resulted in fewer pregnancies or abortions, as advocates promised it would," Wright said. "Pregnancy counselors report more young women relying on it as a regular form of birth control -- even though the drug has not been tested to discover what happens when it is used multiple times."

Plan B consists of higher doses of a hormone found in many standard birth-control pills. Taken within 72 hours of unprotected sex, it has been shown to be highly effective at preventing pregnancy.

With strong support from women's health groups and family planning advocates, Barr Pharmaceuticals, which makes Plan B, asked the FDA in 2003 to allow the drug to be sold without a prescription so women would not have to obtain a doctor's order to get it.

Conservative Congress members and advocacy groups opposed the request. They questioned the drug's safety and argued that wider availability could encourage sexual activity and make it easier for men to have sex with underage girls. They also maintain that Plan B can cause the equivalent of an abortion.

The FDA delayed its decision for three years despite endorsements of nonprescription sales by its outside advisers and internal reviewers, leading to intense criticism that the agency was allowing politics to influence the decision.

When the agency eventually approved nonprescription sale in August 2006, proponents were disappointed that the drug was limited to women age 18 and older. The FDA said that there was too little safety data to approve the drug for teenagers younger than 18 and that pharmacists would be unable to enforce the age cutoff. The requirement also meant that women must show proof of their age when buying the drug, which made it more difficult for some women, such as illegal immigrants.

In his ruling, Korman detailed repeated interference by "political actors" in the agency's handling of Plan B, including the long delay in approving the drug and the ultimate decision to act only after some senators tried to apply pressure by blocking confirmation of acting FDA commissioners. The agency's justification for its final decision "lacks all credibility," Korman said.

"The court has vindicated our claim that the Bush administration's FDA was playing political games with women's health," said Nancy Northup, president of the Center for Reproductive Rights. "The judge's opinion makes clear that the FDA should have put medical science first and left politics at the lab door."

Susan F. Wood of George Washington University, who resigned from the FDA because of the agency's delays, noted that several officials involved in the decision are either still at the agency or in other key government positions, including Janet Woodcock, who heads the FDA's drug approval office, and Steven Galson, now acting surgeon general and assistant secretary of health. But Wood and others said they are confident that the new leadership at the agency will make Plan B widely available after reviewing the case.

"I think FDA is now in a position where it can make a fair decision because of the change in leadership and the commitment by everyone involved to make science-based decisions," Wood said. "This is a chance for the agency to demonstrate it is back on track."

President Obama recently announced plans to name former New York City health commissioner Margaret A. Hamburg as FDA commissioner and Baltimore Health Commissioner Joshua M. Sharfstein as her deputy. He also issued an order he said was designed to insulate scientific decisions throughout the government from political influence.

Plan B remains the focus of intense debate, particularly over whether pharmacists who oppose its use on moral grounds should be required to sell it.

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