

FDA to allow 'morning-after' pill for 17-year-olds

April 22 2009, By RICARDO ALONSO-ZALDIVAR , Associated Press Writer



FILE -- This undated image provided by Barr Pharmaceuticals Inc. Aug. 22, 2007 shows the packaging for the "Plan B" pill. The Food and Drug Administration said Wednesday it would accept, not appeal, a federal judge's order that lifts Bush administration restrictions limiting over-the-counter sales of "Plan B" to women 18 and older. (AP Photo/Barr Pharmaceuticals Inc., File)

(AP) -- Women's groups cheered the government's decision to allow 17-year-olds to buy the "morning-after" emergency contraceptive without a doctor's prescription, but conservatives denounced it as a blow to parental supervision of teens.

The [Food and Drug Administration](#) said Wednesday it would accept, not appeal, a federal judge's order that lifts Bush administration restrictions limiting over-the-counter sales of "Plan B" to women 18 and older. U.S.

District Judge Edward Korman ruled last month in a lawsuit filed in New York that President George W. Bush's appointees let politics, not science, drive their decision to restrict over-the-counter access.

Women's groups said the FDA's action was long overdue, since the agency's own medical reviewers had initially recommended that the contraceptive be made available without any age restrictions.

Korman ordered the FDA to let 17-year-olds get the birth control pills. He also directed the agency to evaluate clinical data to determine whether all age restrictions should be lifted.

The FDA's latest action does not mean that Plan B will be immediately available to 17-year-olds. The manufacturer must first submit a request.

"It's a good indication that the agency will move expeditiously to ensure its policy on Plan B is based solely on science," said Nancy Northup, president of the Center for Reproductive Rights, which filed the lawsuit.

Conservatives said politics drove the decision.

"Parents should be furious at the FDA's complete disregard of parental rights and the safety of minors," said Wendy Wright, president of Concerned Women for America.

Plan B is [emergency contraception](#) that contains a high dose of birth control drugs and will not interfere with an established pregnancy. It works by preventing ovulation or fertilization. In medical terms, pregnancy begins when a fertilized egg attaches itself to the wall of the uterus.

If taken within 72 hours of unprotected sex, it can reduce a woman's chances of pregnancy by as much as 89 percent.

Critics of the contraceptive say Plan B is the equivalent of an abortion pill because it can prevent a fertilized egg from attaching to the uterus. Recent research suggests that's possible but not likely.

The battle over access to Plan B has dragged on for the better part of a decade, through the terms of three FDA commissioners. Among many in the medical community, it came to symbolize the decline of science at the agency because top FDA managers refused to go along with the recommendations of scientific staff and outside advisers that the drug be made available with no age restrictions.

"The FDA got caught up in a saga, it got caught up in a drama," said Susan Wood, who served as the agency's top women's health official and resigned in 2005 over delays in issuing a decision. "This issue served as a clear example of the agency being taken off track, and it highlighted the problems FDA was facing in many other areas."

The treatment consists of two pills and sells for \$35 to \$60. Women must ask for Plan B at the pharmacy counter and show identification with their date of birth. The drug is made by a subsidiary of Teva Pharmaceutical Industries, an Israeli company. It does not prevent sexually transmitted infections, such as HIV/AIDS.

Supporters of broader access argued that Plan B is safe and effective in preventing unwanted [pregnancy](#) and could help reduce the number of abortions.

Opponents, including prominent conservatives, counter that it would encourage promiscuity and might even become a tool for criminals running prostitution rings, as well as for sexual predators.

Early in the Bush administration, more than 60 organizations petitioned the FDA to allow sales without a prescription. But according to court

documents, the issue quickly became politicized.

In 2003, a panel of outside advisers voted 23-4 to recommend over-the-counter sales without age restrictions. But top FDA officials told their subordinates that no approval could be issued at the time, and the decision would be made at a higher level. That's considered highly unusual, since the FDA usually has the last word on drug decisions.

In his ruling, Korman said that FDA staffers were told the White House had been involved in the decision on Plan B. The government said in court papers that politics played no role.

In 2005, the Center for Reproductive Rights and other organizations sued in federal court to force an FDA decision.

The following year, the FDA allowed Plan B to be sold without a prescription to adults. But the controversy raged on over access for teens.

On the Net:

FDA's Plan B page: <http://tinyurl.com/ch3ys6>

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Citation: FDA to allow 'morning-after' pill for 17-year-olds (2009, April 22) retrieved 20 April 2024 from <https://medicalxpress.com/news/2009-04-fda-morning-after-pill-year-olds.html>

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