

FDA Set to Decide on Morning-After Pill

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WASHINGTON - The government is considering whether to make morning-after birth control available without a prescription, and like most issues that involve sex and pregnancy, it has generated heated debate.

Fierce arguments have gone on inside and outside the Food and Drug Administration, which may decide as soon as this week whether drug stores can sell the emergency contraception known as Plan B without a prescription to women age 16 and older.

Each side accuses the other of manipulating science for political purpose.

Plan B supporters say the pill is a safe way to prevent thousands of unwanted pregnancies and the abortions that sometimes follow. Making the contraception available over the counter, they say, is crucial for women who might need the protection over a weekend or when it is difficult to obtain a prescription.

Plan B can prevent pregnancy for up to 72 hours after sex. The sooner the pill is taken, the more effective it is.

"Women's reproductive rights shouldn't hinge on someone else's schedule. We should have this at our fingertips. It should be next to condoms in drug stores," said Kelly Mangan, 22, president of the University of Florida's chapter of the National Organization for Women. She was arrested this month in a protest outside the FDA's headquarters in suburban Maryland.

Opponents worry that the drug encourages women - teenagers in particular - to have risky sex. If over-the-counter sales are permitted, older teenagers or adults might buy the pills for some of their younger friends or their sexual partners, critics say.

"It encourages risky sexual activity with the promise `just pop a pill in the morning and you don't need to worry about pregnancy,'" said Wendy Wright of Concerned Women of America, a conservative group that focuses on social issues.

"What we're concerned about is a number of young people who are not engaged in sexual activity who feel tremendous pressure, and this will only add to the pressure that is on them," Wright said.

Not contested, by either side, is that the drug is safe or effective. Some who work for the FDA believed that questions about people's sexual behavior

were overwhelming scientific ones, according to an internal agency memo written last year.

"Some staff have expressed the concern that this decision is based on non-medical implications of teen sexual behavior, or judgments about the propriety of this activity," said the memo by the FDA's acting drug chief, Dr. Steven Galson.

"These issues are beyond the scope of our drug approval process, and I have not considered them in this decision," wrote Galson, who last spring rejected the first application for Plan B's sale over the counter.

A study this month is providing evidence for both sides.

Researchers in San Francisco found that women who were given a supply of Plan B to keep at home were no more likely to have unprotected intercourse than women who had to go to a clinic or pharmacy for the contraceptive. Women with easy access were more likely to use Plan B, leading researchers to conclude that easy access could prevent unwanted pregnancies.

But the study, which only followed women for six months, found that the two groups had about the same pregnancy rate, undercutting the argument that Plan B prevents unwanted pregnancies and abortion.

Last May, the FDA rejected nonprescription sales of emergency contraception, against the overwhelming recommendation of the agency's own scientific advisers.

The FDA said it worried that there was not enough data about the pill's use by young teenagers. The agency promised to reconsider if the pill's manufacturer, Barr Laboratories of Pomona, N.Y., figured out how to sell over the counter only to those 16 and older.

In July, Barr again applied for approval. The company now proposes that drug stores check customers' ages to be certain that buyers are at least 16, an approach the FDA has not approved before. Younger teenagers could continue to get the drug with a doctor's prescription.

The morning-after pill is a higher dose of the contraceptive hormones found in the Pill. It prevents ovulation or fertilization, and can prevent a fertilized egg from implanting into the uterus.

Because medical experts do not consider a woman to be pregnant until after an egg implants into the uterus, the morning-after pill is not considered abortion, although some conservatives object to any interference with a fertilized egg.

If a woman already is pregnant, morning-after pills have no effect. But taken within 72 hours of unprotected intercourse, they can cut a woman's chances of pregnancy by up to 89 percent.

The decision to reject Barr's first application led critics to say that the FDA was bending to conservative politics.

"A treatment for any other condition, from hangnail to headache to heart disease, with a similar record of safety and efficacy would be approved quickly," three physicians on the FDA advisory committee wrote in an editorial published by the New England Journal of Medicine last April.

They said that requiring customers to prove their age or putting the drug behind the counter are steps "designed to intimidate women." The authors noted that the advisory committee rejected such moves.

"In this case, there is no medical dispute," they wrote. "Rather, the delay results from the concern of some groups ... that the availability of the drug may have a corrupting influence on sexual behavior. If easy access to the drug could have such an influence, it would seem that the battle had already been lost."