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FDA considers putting Plan B in drugstore aisles

Morning-after pill could be made available to all without prescription

BY ROB STEIN

The federal government is grappling with the explosive question of whether to let anyone of any age buy the controversial morning-after pill Plan B directly off drugstore and supermarket shelves without a prescription.

The Food and Drug Administration has until Wednesday to respond to a request from the drug's manufacturer to make the pill as easy to get as toilet paper and toothpaste, a move pushed by some doctors, health advocates, family-planning activists, members of Congress and others to help women prevent unwanted pregnancies.

Opponents, however, say such a decision would expose girls and women to potential risks from taking high doses of a potent hormone, interfere with parents' ability to monitor their children and make it easier for men to prey on vulnerable minors.

The request follows a series of steps in recent years that have gradually made Plan B easier to obtain. If it is approved, the pill would move out from behind pharmacists' counters, eliminating the requirement that women produce a prescription or prove that they are at least 17 years old to get it without a doctor's order. Instead, Plan B would be available on store shelves, along with condoms, contraceptive sponges and spermicides.

"Hopefully, it will be right on the shelves between the condoms and the pregnancy tests," said Kirsten Moore of the Reproductive Health Technologies Project, a Washington-based advocacy group. "We think it's good news for women's health and long overdue."

Plan B consists of a synthetic form of progesterone; this hormone is found in many standard birth-control pills, but Plan B contains it at higher doses. Taken within 72 hours of unprotected sex, the pill has been shown to be 89 percent effective at safely preventing pregnancy.

The drug has long been controversial and was the focus of one of the biggest health disputes during the administration of President George W. Bush. Plan B works primarily by preventing an egg from being fertilized. Critics, however, focus on the chance that it may prevent a fertilized egg from implanting in the womb, an action they consider equivalent to an abortion. As a result, it has been the subject of intense debate and conflict. Some doctors refuse to write prescriptions for it, some pharmacists refuse to fill requests, and some hospitals refuse to provide it to patients.

"It's not a drug that prevents life — it's a drug that destroys life," said Jeanne Monahan of the Family Research Council, a conservative advocacy group. "If we define life as beginning at fertilization or conception, then this drug can be an abortifacient."

The debate over restrictions

The FDA approved Plan B in 1999, but only for women who first obtained a prescription from a doctor. With strong support from women's health groups and family-planning advocates, the drug's maker asked the FDA in 2003 to ease the rules to allow totally free sale without a prescription so women would not have to scramble — often in late-night or weekend panics after having sex without protection, having a condom break or being raped — to find a doctor to write a prescription and an open pharmacy to fill it.

"If you got into a Wal-Mart and the pharmacy is closed, you're out of luck," said Susan Wood of George Washington University, who resigned from the FDA a few years ago to protest the agency's delays in making Plan B available without a prescription. "By having it on the shelf, more women will become aware of the availability of emergency contraception and won't have to ask someone in an emergency situation about a very private and personal situation. Hopefully, that will help women when time is of the essence."

Conservative lawmakers and advocacy groups have opposed every request to relax the restrictions on Plan B. They question the drug's safety and whether young girls and women would use it properly without a doctor's supervision, and they argue that wider availability could encourage sexual activity and make it easier for men to have sex with underage girls by forcing them to take the drug to prevent any pregnancies that could result.

"When anybody can buy an emergency contraceptive like this over the counter, you open the door for all sorts of abuse, and especially so when it comes to child abuse and child exploitation," said Janice Crouse of Concerned Women of America, another advocacy group.

In addition, by removing the need to see a doctor, women and girls would miss an opportunity to receive diagnoses and treatment for sexually transmitted diseases, and parents would have less influence over their children's behavior, critics charge.

"Parents have to sign a permission slip for their children to go on a class trip or get their ears pierced," Crouse said. "When you are talking about selling something like this over the counter, you are opening up a can of worms when it comes to parental involvement in their children's lives."

But teen-pregnancy-prevention advocates back the change.

"I appreciate the discomfort some feel about making it easier for teens to get backup contraception," said Sarah Brown of the National Campaign to Prevent Teen and Unplanned Pregnancy. "The good news is that there is simply no evidence to suggest that making contraception available to teens encourages them to begin having sex, have sex at younger ages or have more sexual partners. Moreover, most of us would rather have sexually active teens use contraception than become pregnant."

Delay sparks criticism

The FDA delayed a decision on the original request to relax the need for a Plan B prescription for three years, despite endorsements of nonprescription sales by its outside advisers and internal reviewers. The delay spurred intense criticism during Bush's administration that the agency was allowing politics to influence the decision.

The agency eventually approved nonprescription sale of Plan B in August 2006, marking the first time a hormonal contraceptive was made broadly available in the United States without a prescription. Proponents, however, were disappointed that the drug was limited to women age 18 and older and sued the FDA.

Three years later, the agency allowed the sale of Plan B One-Step, a new version that works with one pill instead of the original two, to 17-year-olds without a prescription. But the decision came only after a federal judge ordered the FDA to make the change, ruling that the restrictions were imposed for "political and ideological" reasons.

In February, Teva Pharmaceutical Industries asked the agency to drop the remaining restriction, citing the results of two new studies. One involving 335 girls ages 12 to 17 showed that between 72 percent and 96 percent of them understood the proposed package label well enough to use the drug safely and effectively on their own. The second, involving about 300 girls ages 11 to 16, showed that they could use the product properly and safely, according to Teva.

"We have a tremendous amount of safety information regarding this particular product. It is classified as very, very safe," Teva's Amy Niemann said. "Hopefully, we'll get full approval. It would be an historic and important decision for women."

The lawsuit that spurred the FDA's relaxation of restrictions is pending. A hearing is scheduled for Dec. 13 on a motion to declare the agency in contempt of court for failing to review its decision to leave age restrictions in place.

Another morning-after pill, Next Choice, the generic version of the original two-pill Plan B that sells for about $35, is available only by prescription.

"We think it's important for both the original two-pill as well as the new one-pill One-Step to be available to all women of all ages," said Nancy Northrup of the Center for Reproductive Rights, which filed the suit. "It's especially important for younger women, for whom cost can be an important issue."

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