

Morning-After Pill Study Contradicts Claim by Foes Easy Access Did Not Lead to Riskier Behavior

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Providing women with easy access to the emergency contraceptive Plan B did not lead them to engage in more risky sexual behavior, a study of more than 2,000 California women has concluded.

The study did find that women given a supply to keep at home were more than 1 1/2 times as likely to use the drug after unprotected sex as those who had to pick it up at a clinic or pharmacy. The findings led the study authors to conclude that easy access to Plan B, also called the morning-after pill, could reduce the number of unwanted pregnancies while posing no apparent risk to women.

The study contradicts a key claim made by opponents of easier access to Plan B at a time when the Food and Drug Administration is preparing to decide on a second application to allow non-prescription sales of the drug.

In an indication of the strong feelings on both sides, advocates of Plan B are planning a sit-in at FDA headquarters in Bethesda on Friday. Some protesters have called for civil disobedience if the FDA official who rejected the first Plan B application, Steven Galson of the Center for Drug Evaluation and Research, refuses to meet with them.

The FDA turned down the initial application last May, saying there was not enough information on how easy access would affect the sexual behavior of young teenagers.

"Our findings were that women don't change their sexual behavior when the drug is easily available, but rather that they're more likely to use it if access is easier," said lead author Tina R. Raine of the Center for Reproductive Health Research and Policy at the University of California at San Francisco.

The study looked at the experiences of 2,117 San Francisco-area women ages 15 to 24 who were randomly put into one of three groups -- one was given the drug to take home, the second could pick it up without a prescription at a clinic, and the third could get it without a prescription at a pharmacy.

The study found that about the same percentage of each group had unprotected sex over a six-month period, that incidence of sexually transmitted disease was equal, and that about the same percentage became pregnant.

Nonetheless, about 37 percent of women in the group given Plan B to take home used it at least once during the six months, compared with 21 percent in the clinic-access group and 24 percent in the pharmacy-access group.

The FDA's initial decision to reject non-prescription sales touched off sharp criticism - from the FDA's staff and members of its expert advisory panel, among others -- that the agency was bowing to political pressure from social conservatives. In a letter to President Bush, 49 members of Congress asked that the application be rejected.

The medical profession does not consider emergency contraception to be an abortion pill such as RU-486, or Mifeprex, because Plan B works by preventing a pregnancy rather than ending one. But some critics of Plan B consider it an abortifacient.

The new study, being published today in the Journal of the American Medical Association, supports the position taken by much of the FDA review staff and 23 of 27 members of the FDA advisory panel that the drug could be safely and properly used without a prescription.

After the FDA rejected its initial application, the maker of Plan B, Barr Pharmaceuticals Inc., submitted a modified application to address the concerns about teenage users. The company's new application would make the drug available over the counter for women older than 16, and by prescription only for those who are younger.

Barr spokeswoman Carol A. Cox said that the company still believes the drug can be safely sold on open shelves, but that it would accept a compromise to place Plan B behind the counter. That would require a pharmacy employee to retrieve the drug and would make enforcement of an age restriction easier.

Plan B consists of the synthetic progestin levonorgestrel and is most effective when used within 24 hours of an unprotected sexual encounter. While the FDA has approved it only for prescription use, six states have passed laws that allow pharmacists to dispense the drug without a prescription after a discussion with the woman.

The University of California study was initiated in part to see whether getting the drug from a pharmacy would be more acceptable to women than getting it from a clinic, and Raine said the results appear to show it was not. The study was funded by grants from private foundations that invested in the Women's Capital Corporation, which initially developed the drug. Raine said neither the foundations nor Barr Pharmaceuticals, which supplied the drugs for the women, had any influence over the study.

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