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F.D.A. Approves Broader Access to Next-Day Pill

By [GARDINER HARRIS](#)

WASHINGTON, Aug. 24 — The [Food and Drug Administration](#) on Thursday approved over-the-counter sales of the morning-after contraceptive pill to women 18 and older, resolving one of the most contentious issues in the agency's 100-year history.

Nationwide over-the-counter sales of the drug, Plan B, are expected to start by the end of the year. It will be sold in pharmacies and health clinics only, and buyers must show proof of age. Anyone under age 18 will still need a prescription. Men may also buy Plan B for a partner.

The prescription drug now sells for \$25 to \$40 per two-pill dose, but the manufacturer, Barr Pharmaceuticals of Woodcliff Park, N.J., said the price could change.

The agency's decision, which took three years and spanned the terms of three F.D.A. commissioners, did little to dampen what has become a central part of the nation's debate on [abortion](#). Abortion rights advocates argue that the wide availability of Plan B may reduce abortions; abortion opponents assert that Plan B will cause them.

Abortion rights advocates hailed the F.D.A.'s decision on Thursday, although many bemoaned the age restriction.

"We are pleased that a common sense, common ground agenda for reducing unintended [pregnancy](#) and the need for abortion finally won out," said Kirsten Moore, president of the Reproductive Health Technologies Project in Washington.

Abortion opponents threatened political retribution, however, and were displeased when President Bush backed the agency's decision.

"Let there be no mistake about it," said the Rev. Thomas J. Euteneuer, president of Human Life International, an anti-abortion group based in Virginia. "Today's decision lies at the feet of President Bush and has created a lasting rift with the Catholic faithful who comprise a large part of his support base."

In a briefing on Monday, Mr. Bush was asked whether he supported the intention by Andrew C. von Eschenbach, acting commissioner of the F.D.A., to approve over-the-counter sales of Plan B.

"I support Andy's decision," he replied, a rare moment when a president addressed an

application pending before the drug agency.

Barr Pharmaceuticals said that sales of Plan B would barely register on its balance sheet and that it had no plans to advertise the drug on television or radio. [BusinessDay, Page C1.]

Dr. von Eschenbach wrote that he had decided that 18 was the appropriate cut-off age because pharmacies already used it for restricted nicotine and cold medicines sales.

“This approach builds on well-established state and private-sector infrastructures to restrict certain products to consumers 18 and older,” Dr. von Eschenbach wrote in a memorandum.

His predecessor, Dr. Lester M. Crawford, said last year that science supported giving over-the-counter access of the drug to women at 17, but that he could not figure out how to ensure that such an age restriction was enforced.

The agency has now decided that it will rely on Barr to enforce the rules. The company’s chairman, Bruce Downey, said in an interview that the company would depend on pharmacists to abide by the restrictions.

Barr will not sell the pills to gasoline stations or convenience stores, and it will conduct surveys to measure adherence, Mr. Downey said.

The drug agency decided that younger women would benefit by seeing a doctor before having access to Plan B. It also determined that Barr had failed to prove that young women would understand how to use the drug as well as older women.

The F.D.A.’s approval was widely expected and led to a flood of prepared press releases from Capitol Hill offices, advocacy and medical groups.

“This long overdue decision is a victory for women’s health and for the American people who have been waiting for years for the F.D.A. to act,” Senators [Hillary Rodham Clinton](#), Democrat of New York, and Patty Murray, Democrat of Washington, said in a statement.

Senator Tom Coburn, Republican of Oklahoma and a family practice doctor, denounced the decision, saying, “Exposing women to the high-dose [hormones](#) in Plan B without the guidance of a physician will put them at risk.”

Studies suggest that both the anti-abortion groups and abortion rights advocates are wrong in their predictions of the pill’s effect on the number of abortions performed each year and on the rate of [sexually transmitted diseases](#). Couples in the United States have so much unprotected sex — half of all pregnancies are unplanned — that even if the pills were passed out like aspirin, they would be unlikely to cause a major change in abortion and disease rates.

“Emergency contraceptives don’t work if, like condoms, they’re left in the drawer,” said Dr. James Trussell, director of the Office of Population Research at [Princeton University](#). “And

studies show that even if women have the pills on hand, the drawer is where they remain.”

Still, Dr. Tina Raine, associate professor of obstetrics and gynecology at the [University of California](#), San Francisco, said that over-the-counter access to Plan B would help some women avoid becoming pregnant.

“Unintended pregnancy rates have been dropping over the last decade,” Dr. Raine said. “Lots of things have contributed to that, and this will, too.”

Plan B’s effect on the F.D.A. and its image may well overshadow its public health impact.

The agency has regulatory authority over a quarter of the United States economy. Despite this huge portfolio, three commissioners devoted countless hours to considering whether to switch Plan B, a small-selling, decades-old medicine, to over-the-counter status.

“I cannot recall any other issue in my 45 years of watching F.D.A. that has garnered this much attention at all levels of government,” said Peter Barton Hutt, a former general counsel for the agency who now teaches drug law at [Harvard](#).

The director of the Office of Women’s Health at the drug agency resigned last year to protest what she said was the abortion politics behind the delay in approving Plan B. An investigation by the Government Accountability Office concluded that top agency officials had decided to reject the initial Plan B application months before a scientific review was complete.

Sworn depositions taken by lawyers from the Center for Reproductive Rights, a legal advocacy organization, show that some of the agency’s staff members were convinced that no amount of scientific evidence would have persuaded the F.D.A.’s political appointees to approve the application.

Dr. John Jenkins, director of the Office of New Drugs at the agency, said in a deposition that his boss, Dr. Steven Galson, told him “that he felt he didn’t have a choice” but to reject the application, according to transcripts provided to The New York Times.

“And he characterized that in a sense that he wasn’t sure that he would be allowed to remain as center director if he didn’t agree with the action,” Dr. Jenkins said. Dr. Galson is director of the Center for Drug Evaluation and Research at the F.D.A.

Dr. Florence Houn, director of the office that evaluated the Plan B application, said that she was told by Dr. Janet Woodcock, a deputy commissioner at the agency, that a rejection was necessary “to appease the administration’s constituents, and then later this could be approved,” according to the transcripts.

Drs. Galson and Woodcock said in their own depositions and public statements that scientific considerations drove their decisions. In an interview, Dr. Galson refused to address the

apparent inconsistencies.

“I’m extremely happy to put this phase of the decision-making process behind me and to move on to other priorities,” Dr. Galson said.

But the issue may not go away.

Barr will study Plan B’s use in young adolescents in hopes of getting the agency’s age restrictions lifted, Mr. Downey said.

“In my mind,” he said, “if we go back and have an adequate study that includes the younger group, the basis for any age restriction goes away.”

Last year, Senators Clinton and Murray placed a legislative hold on Dr. Crawford’s nomination as commissioner to pressure the agency to make a decision on Plan B. They lifted their hold after Health and Human Services Secretary [Michael O. Leavitt](#) promised a decision by Sept. 1 of that year. Dr. Crawford was then confirmed, but the agency announced yet another delay in a decision on Plan B.

When Dr. Crawford unexpectedly resigned weeks later, the two senators refused to let Dr. von Eschenbach’s nomination as commissioner advance without a Plan B decision. On Thursday, they said that they would lift their hold.

Plan B is made from a synthetic hormone found in regular oral contraceptives. There are two pills, the first of which should be taken within 72 hours of unprotected sex and the second 12 hours later. Like regular contraceptive pills, Plan B generally acts by preventing ovulation or fertilization, according to the F.D.A.

Plan B may in rare circumstances prevent a fertilized egg from becoming implanted, something abortion opponents decry. But regular oral contraceptives do that, too.

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