

# The Philadelphia Inquirer

## Limits remain on Plan B

Sebelius blocks FDA on lifting age restriction on sales of morning-after pill.

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In an unprecedented move, the head of the U.S. Department of Health and Human Services on Wednesday ruled that Plan B One-Step, the emergency contraceptive, may not be sold without a prescription for females of all ages — even though the Food and Drug Administration was poised to approve over-the-counter sales.

The eleventh-hour intervention by Secretary Kathleen Sebelius was reminiscent of the political wrangling that delayed easier access to Plan B, sometimes called “the morning-after pill,” under the Bush administration.

In 2006 — three years after the manufacturer asked for over-the-counter status — the FDA said only women 18 or older could get it without a prescription; younger females needed a doctor’s order. In 2009, that age

See **FDA** on A18

**Plan B will remain behind the drugstore counter.**

restriction was dropped to 17.

However, the product remained behind the pharma-

cist’s counter, which added obstacles if the pharmacy was closed — or the woman was embarrassed. The change that Sebelius rejected would have put Plan B on the shelf, like condoms and pregnancy tests, for females of all ages.

Under the law, Sebelius has the authority to overrule the regulatory agency, but an FDA spokeswoman said this was the first time it had ever happened.

“I’m feeling completely outraged and betrayed,” said Princeton University population researcher James Trussell, who has worked since 1992 to make emergency contraception readily available. “I don’t know which is worse, what the Bush administration did or what this administration did. At least the FDA wasn’t compromised. But it’s still politics trumping science.”

FDA Commissioner Margaret Hamburg said she agreed with FDA experts who advised over-the-counter status.

“There is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing” age, Hamburg said in a statement.

In overriding the FDA, Sebelius drew the opposite conclusion:

“Because I do not believe enough data were presented to support the application to make Plan B One-Step available over the counter ... I have directed the FDA to issue a ... letter denying” the request, submitted last February by Teva Pharmaceuticals.

Israel-based Teva, which has its Americas headquarters in North Wales, Montgomery County, acquired Plan B in 2008 from another company. The pill contains levonorgestrel, a hormone used in many oral contraceptives. Plan B can be taken up to 72 hours after sex to reduce — although not eliminate — the

chance of pregnancy.

“We commend the FDA ... and we are disappointed that at this late date, the Department of Health and Human Services has come to a different conclusion,” Teva said in a statement.

The product will remain on the market, but females under 17 will continue to need a prescription.

Emergency contraception has had a contentious history ever since 1992, when Princeton’s Trussell and colleagues published a mathematical model that suggested making the post-intercourse contraceptive method widely available could reduce abortions and unintended pregnancies in the United States by half.

At the time, there was no branded product for the method; women had to know how and when to take a slight over-



MATT ROURKE / Associated Press

**Kathleen Sebelius**, secretary of Health and Human Services, cited a lack of data.

dose of regular birth-control pills. As a result, emergency contraception was little known and hardly used.

An army of public-health and medical groups waged a campaign that gradually led to today’s dedicated, FDA-approved product.

While hardly a blockbuster, Plan B One-Step — a one-pill product that retails for \$40 to \$50 each — had nonprescription sales in the last year of \$99.4 million, according to SymphonyIRI Group, a market tracking company in Chicago. Prescription sales for last year brought an additional \$80 mil-

lion, according to IMS Health in Plymouth Meeting.

On the other side of the campaign were conservative religious and political groups. They believed easy access to emergency contraception would lead teenagers to have earlier, riskier sex; overuse the backup method while neglecting more reliable birth control; avoid consulting physicians; and become victims of sexual abuse.

With about a thousand studies of emergency contraception now in the medical literature, there is no evidence to support those beliefs, but conservatives continue to hold them.

Jeanne Monahan, director of the Family Research Council's Center for Human Dignity, issued a statement praising Sebelius' decision. Over-the-counter access, Monahan said, "would have bypassed necessary routine medical care for sexually active girls," leading to more unplanned pregnancies and sexually transmitted diseases. And "there is a real danger that Plan B could be given to young women ... under coercion or without their consent."

Monahan also raised the issue of abortion, saying "Plan B can act in a way that can destroy life by preventing implantation."

Medical authorities such as the American College of Obstetricians and Gynecologists say pregnancy begins after — not before — implantation of a fertilized egg, but those who disagree insist emergency contraception is tantamount to an abortion agent.

Sarah Brown, head of the National Campaign to Pre-

vent Teen and Unplanned Pregnancy, lamented Sebelius' decision while acknowledging parents' uneasiness. "Making emergency contraception easily available to young teens and preteens would have been of great concern to many parents," she said in a statement.

"Even so ... there is simply no evidence to suggest that making contraception, including emergency contraception, available to teens encourages them to begin having sex, have sex at younger ages, or have more sexual partners."

Perhaps ironically, there is also no evidence that emergency contraception has fulfilled hopes of reducing unintended pregnancy and abortion. Researchers around the world have found that, while easing access increases use of the method, it doesn't make women more careful overall.

"Everybody hoped it would be a cheap, easy way to reduce unwanted pregnancy," Trussell said. "It hasn't been, for two reasons. It's not 100 percent effective. Even if one took it every time one had unprotected sex, a significant fraction would still get pregnant in a year.

"But the other reason is there's just so much unprotected sex. Even in the studies, a lot of women who had emergency contraception on hand didn't use it because they didn't perceive they were at risk" of pregnancy.

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