

US: Morning-after pill OK for ages 15 and up (Update)

April 30 2013, by Lauran Neergaard



This undated image made available by Teva Women's Health shows the packaging for their Plan B One-Step (levonorgestrel) tablet, one of the brands known as the "morning-after pill." The Plan B morning-after pill is moving over-the-counter, a decision announced by the Food and Drug Administration just days before a court-imposed deadline. On April 30, 2013, the FDA lowered to 15 the age at which girls and women can buy the emergency contraceptive without a prescription—and said it no longer has to be kept behind pharmacy counters. Instead, the pill can sit on drugstore shelves just like condoms, but that buyers would have to prove their age at the cash register. (AP Photo/Teva Women's Health)

The U.S. government on Tuesday lowered to 15 the age at which girls can buy the morning-after pill without a prescription and said the emergency contraception no longer has to be kept behind pharmacy counters.

The decision by the Food and Drug Administration is an attempt to find middle ground just days before a court-imposed deadline to lift all age restrictions on the drug.

Today, Plan B One-Step is sold behind pharmacy counters, and buyers must prove they're 17 or older to buy it without a prescription. Tuesday's decision lowers the age limit to 15—and will allow the pill to sit on drugstore shelves next to condoms and spermicides or other women's health products. But customers must prove their age at the cash register.

Teva Women's Health, which makes Plan B, said it would begin over-the-counter sales in a few months.

The question is whether Tuesday's action settles a larger court fight. Earlier this month, U.S. District Judge Edward Korman of New York blasted the Obama administration for imposing the age-17 limit, saying it had let election-year politics trump science and was making it hard for women of any age to obtain the emergency contraception in time. He ordered an end to all age restrictions by Monday, for Plan B and its generic versions.

The FDA said Tuesday's decision was independent of the court case and wasn't intended to address it. Technically, the FDA approved Teva's application to sell Plan B in this manner.

The Justice Department remained mum on whether it planned to appeal Korman's decision, and the White House had no immediate comment.

The women's group that sued over the age limits said Tuesday's action is not enough, and it will continue the court fight if necessary.

Lowering the age limit "may reduce delays for some young women but it does nothing to address the significant barriers that far too many women of all ages will still find if they arrive at the drugstore without identification," said Nancy Northup, president of the Center for Reproductive Rights.

The FDA said the Plan B One-Step will be packaged with a product code that prompts the cashier to verify a customer's age. Anyone who can't provide such proof as a driver's license, birth certificate or passport wouldn't be allowed to complete the purchase. In most states, driver's licenses, the most common form of identification, are issued at age 16.

Other contraceptive contraception advocates called the move promising.

Social conservatives had opposed any efforts to loosen restrictions on sale of the morning-after pill, arguing that it was important for parents and medical professionals to be involved in such decisions involving young girls.

The group Concerned Women for America charged that health officials were putting politics and so-called progress ahead of the health of children as well as women.

Half of U.S. pregnancies every year are unintended, and doctors' groups say more access to morning-after pills could cut those numbers. The pills contain higher doses of regular contraceptives, and if taken within 72 hours of unprotected sex, can cut the chances of pregnancy by up to 89 percent. But it works best if taken in the first 24 hours.

The FDA had been poised to lift all age limits and let Plan B sell over-

the-counter in late 2011, when Health and Human Services Secretary Kathleen Sebelius, in an unprecedented move, overruled her own scientists. Sebelius said some girls as young as 11 are physically capable of bearing children but shouldn't be able to buy the pregnancy-preventing pill on their own.

President Barack Obama supported Sebelius' move and a spokesman said earlier this month that the president's position hadn't changed.

The Justice Department could appeal Korman's ruling and seek a stay. If granted, the appeals process would move through the courts, while Plan B is sold over the counter whenever Teva has the product repackaged to meet FDA's requirements.

Absent a stay, "we will want to go back to court as quickly as possible and ask the judge to hold them in contempt," said Janet Crepps, a senior counsel for the Center for Reproductive Rights.

The FDA said Tuesday that Teva had provided data proving that girls as young as 15 could understand how Plan B works and use it properly, without the involvement of a health care provider. Teva plans to conduct a consumer-education program, and indicated it is willing to audit whether stores are following the age requirement, the agency said.

FDA said its ruling applies only to Plan B One-Step, and not to generic versions of the pill which would remain behind pharmacy counters with the age-17 restriction.

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Citation: US: Morning-after pill OK for ages 15 and up (Update) (2013, April 30) retrieved 11 May 2024 from <https://medicalxpress.com/news/2013-04-fda-morning-after-pill-over-the-counter.html>

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