



Written by [Raven Clabough](#) on May 1, 2013

FDA Approves Sale of Plan B One-Step to Minors Without Prescription

On Tuesday, the United States Food and Drug Administration (FDA) [announced](#) that it would allow the Plan B One-Step contraceptive to be sold without prescription to females as young as 15. The announcement amends a December 2011 decision that prohibited the sale of emergency contraceptives to all females of reproductive age without restriction, which had been overturned by U.S. District Judge Edward Korman on April 5. According to the FDA, its latest announcement was not prompted by the judge's ruling, but is based on a study released by the company that makes the Plan B drug.



Reuters [writes](#), "The FDA initially approved sale of the drug to all reproductive age females, but was ordered to bar girls under 17 by U.S. Health and Human Services Secretary Kathleen Sebellius." President Obama agreed with Sebellius' decision.

When the FDA did not approve an application from Teva Women's Health Inc. — a unit of Plan B maker Teva Pharmaceuticals Ltd — that would have made Plan B One-Step available over-the-counter for all females of reproductive age, the company amended its application and resubmitted it. The application was amended so as to change the company's bid to sell the product to those 15 and older.

Meanwhile, on April 5, 2013, Judge Korman ordered the FDA to grant a 2001 citizen's petition to the agency that sought to allow over-the-counter access to Plan B for women of all ages without restrictions. At the time of Judge Korman's ruling, Teva's amended application was still pending.

Still, the FDA's approval of Teva's application is independent of the pending litigation and the Department of Justice is in the process of working on the next steps in the litigation.

The *Wall Street Journal* [observes](#) that Plan B has been "controversial" since 1999, and that the move for the product to be sold without a prescription has been "the subject of litigation for years."

An [FDA Press Release](#) explains its decision to approve the sale of the drug to women as young as 15.

"Research has shown that access to emergency contraceptive products has the potential to further decrease the rate of unintended pregnancies," FDA Commissioner Margaret Hamburg said in a statement.

The FDA indicates that it has based its decision on an actual use study submitted by Teva.

"The data reviewed by the agency demonstrated that women 15 years of age and older were able to understand how Plan B One-Step works, how to use it properly and that it does not prevent the transmission of a sexually transmitted disease."

The Plan B pill will now be labeled "not for sale to those under 15 years of age 'proof of age required'"



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not for sale where age cannot be verified.”

Likewise, the product will be coded so as to prompt cashiers to ask for proof of age, and Teva has arranged for a security tag to be placed on all product cartons to eliminate theft.

The FDA Press Release explains, “Teva has indicated that it plans to educate consumers, pharmacy staff, and health care professionals about the product’s new status. It has also indicated its willingness to conduct an audit of the age verification practices after the product is approved to ensure that the age limitation is being followed.

But some liberal groups are bemoaning the identification requirement. Nancy Northup, president of the Center for Reproductive Rights, asserts that it creates “significant barriers” for women who “arrive at the drugstore without identification.”

Meanwhile, the FDA’s approval of Teva’s application for Plan B-One Step does not currently impact the prescription status of Plan B, available from generic manufacturers, or Ella, a prescription-only product that prevents pregnancy when taken within five days after unprotected sex or contraceptive failure.

Predictably, Planned Parenthood President Cecile Richards issued a celebratory statement regarding the FDA’s decision:

While there are still practical questions to resolve, this is an important step forward to expand access to emergency contraception and for preventing unintended pregnancy. Emergency contraception is a safe and effective form of birth control that can prevent pregnancy if taken within five days of unprotected sex. This decision will eliminate some of the biggest barriers and hurdles that women face in getting emergency contraception when they need it, which means many more women will be able to prevent unintended pregnancy.

But critics like Wendy Wright of the pro-family Concerned Women for America said permitting minors easy access to the abortion drug would essentially take parents and other concerned adults out of the equation.

“Parents should be very concerned that the FDA and the drug company are trying to sell this drug to minor girls without the parent’s knowledge or consent,” Wright told FOX News. She added that in a case in which “a minor girl would be seeking this drug, there needs to be an adult intervention. There needs to be a doctor involved, who can find out if this girl is being abused.”

The Family Research Council (FRC) articulated similar concerns. “There is a real danger that Plan B may be given to young girls, under coercion or without their consent. The involvement of parents and medical professionals act as a safeguard for these young girls. However, today’s ruling removes these common sense protections,” said FRC spokesperson Anna Higgins.

And Yahoo! columnist Sheryl Young [opined](#) in 2011 that the details about the effects of Plan B on women who are already pregnant are too unclear. “What if a girl doesn’t know she’s pregnant?” wondered Young. “She might take Plan B and experience a drug-induced miscarriage or abortion.”

“Will she experience the same result as with [abortion drug] RU486 — hemorrhaging, horrific pain, or possible death from septic blood poisoning due to un-expelled fetal tissue? asked Young. “Even if a woman is not pregnant, several warning labels indicate that Plan B can cause nausea, dizziness, abdominal pain, headache and fatigue,” wrote Young.

Young ultimately concludes, “Abortion advocates, the makers of Plan B, and the FDA have absolutely no excuse for eliminating the age limit on this drug. It’s just another avenue to make more money off of



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frightened young girls.”



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