Judge Rules ‘Morning-After’ Pill Can Sell Without Prescription to Minors

A federal judge on Friday ordered the U.S. Food and Drug Administration to make “morning-after” emergency contraception pills available without a prescription to all girls of reproductive age, while blasting top Obama administration officials for interfering with the process.

The ruling in a Brooklyn court is the latest step in the years-long legal saga over the pill known as “Plan B,” which has sparked political controversy.

Currently, only women age 17 or older can obtain emergency contraception pills without a prescription. Point-of-sale restrictions require that all women present identification to a pharmacist before obtaining the drug.

In his ruling, U.S. District Judge Edward Korman said the FDA’s rejection of requests to remove age restrictions was “arbitrary, capricious and unreasonable.”

FDA spokeswoman Erica Jefferson declined to comment on the ruling, saying it was an ongoing legal matter.

The Center for Reproductive Rights and other groups had petitioned the FDA to strike down age and access limits, saying there was no scientific proof that girls younger than 17 could not safely use the drug without supervision.

Nancy Northup, president of the Center for Reproductive Rights, hailed the ruling. “Women all over the country will no longer face arbitrary delays and barriers just to get emergency contraception,” she said.

The ruling is also likely to be well received by medical

groups like the American Academy of Pediatrics, which recommended last year that pediatricians write advance prescriptions for patients under 17.

But opponents of **abortion** decried the ruling and warned that the pill's widespread availability could spur criminal activity.

"When these are right out there with the bubble gum, they're going to be part of the date rape cocktail," said Karen Brauer, president of Pharmacists for Life.

Some pharmacists across the United States have refused to dispense emergency contraceptives because it violates their religious faith. Making the pills available over the counter removes the pharmacist's role in dispensing the drug, which Brauer welcomed.

Political Controversy

Teva Pharmaceuticals Ltd's Plan B in 1999 became the first emergency contraceptive available for prescription use in the United States. The company also markets **Plan B** One-Step, a one-pill version of Plan B.

"Teva has received the Court's decision and we are currently reviewing it," said company spokeswoman Denise Bradley. "We have no additional comment at this time."

Emergency contraceptives generally sell for $10 to $80. Although they can work as long as 120 hours after unprotected sex, they are most effective in the first 24 hours.

Sanford Bernstein analysts estimate Teva's 2013 sales for Plan B at just $1.5 million, though, because of generic competition like Next Choice from Actavis Inc.

In 2005 the FDA declined to approve over-the-counter sales of the drug, overruling its panel of outside experts as well as its own scientists.

In December 2011 the FDA reversed that stance and moved to approve over-the-counter sales with no age limits. But Health and Human Services Secretary Kathleen Sebelius overruled it, ordering that girls under 17 could only get the pills with a prescription.

As a result of that policy, women well beyond their teens are often asked to present proof of age to show that they are old enough to purchase the pills without a prescription, Judge Korman said.

‘Question Her Good Faith’

In his ruling on Friday, Korman said Sebelius’ actions were clearly political.

“Nevertheless, even with eyes shut to the motivation for the secretary’s decision, the reasons she provided are so unpersuasive as to call into question her good faith,” he wrote.

Representatives of the Department of Health and Human Services were not immediately available to comment on the ruling.

One FDA veteran praised the decision, though.

“This has been a 10-year saga during which the FDA was not allowed to do its role properly, not allowed to make science-based decisions,” said Susan Wood.

Wood resigned from the FDA as assistant commissioner for women’s health in 2005 over its decision not to approve over-the-counter sales of emergency contraception. She is now director of the Jacobs Institute of Women’s Health at George Washington University in Washington.

“This decision gives the FDA the chance to reclaim its ability to make decisions based on science, medicine and evidence,” Wood said, “not politics.”

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