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Judge Strikes Down Age Limits on Morning-After Pill

By **PAM BELLUCK**

A federal judge on Friday ordered that the most common morning-after pill be made available over the counter for all ages, instead of requiring a prescription for girls 16 and younger. But his acidly worded decision raises a broader question about whether a cabinet secretary can decide on a drug's availability for reasons other than its safety and effectiveness.

In his ruling, [Judge Edward R. Korman](#) of the Eastern District of New York accused the Obama administration of putting politics ahead of science. He concluded that the administration had not made its decisions based on scientific guidelines, and that its refusal to lift restrictions on access to the pill, Plan B One-Step, was “arbitrary, capricious and unreasonable.”

He said that when the Health and Human Services secretary, Kathleen Sebelius, [countermanded](#) a move by the Food and Drug Administration in 2011 to make the pill, which helps prevent pregnancy after sexual intercourse, universally available, “the secretary’s action was politically motivated, scientifically unjustified, and contrary to agency precedent.”

Ms. Sebelius said at the time that she was basing her decision on science because she said the manufacturer had failed to study whether the drug was safe for girls as young as 11, about 10 percent of whom are physically able to bear children. But her decision was widely interpreted as political because emergency contraception had become an issue in the abortion debate and allowing freer access for adolescents would prompt critics to accuse the president of supporting sexual activity for girls of that age.

At the time, Mr. Obama was campaigning for re-election, and some Democrats said he was conscious of avoiding divisive issues that might alienate voters. He said then that he was not involved in the decision but [supported it](#). “I think it is important for us to make sure that we apply some common sense to various rules when it comes to over-the-counter medicine,” he said.

And he reiterated that position on Friday through the White House press secretary, Jay Carney, who said, “He believed it was a common-sense approach when it comes to Plan B and its

availability.”

Mr. Carney declined to comment on whether the administration would appeal the decision. A Justice Department spokeswoman, Allison Price, said the department was reviewing the 59-page order and the appellate options and “expects to act promptly.” Judge Korman gave the F.D.A. 30 days to lift any age and sale restrictions on Plan B One-Step and its generic versions.

Many groups that are part of Mr. Obama’s political base praised the decision to make the emergency contraceptive pill more easily available, saying the change would also make it easier for all women to obtain the pill because stores often keep it behind the counter or in pharmacy sections that may close at night.

Removing the restrictions is in some ways more consistent with the administration’s position on other women’s reproductive health issues, including the free provision of contraceptives through Mr. Obama’s health care overhaul.

Scientists, including those at the Food and Drug Administration, have recommended unrestricted access for years, as have the American Medical Association, the American Congress of Obstetricians and Gynecologists, and the American Academy of Pediatrics. They contend that the restrictions effectively keep many adolescents and younger teenagers from being able to use a safe drug in a timely way to prevent pregnancy, which carries greater safety risks than the morning-after pill.

Conservative and anti-abortion groups assailed the judge’s decision, suggesting that it may allow the pill to be given to young girls without their consent. They also say that girls who can skip the requirement to visit a doctor for a prescription may have sexually transmitted infections that go undiagnosed and untreated.

“This ruling places the health of young girls at risk,” said Anna Higgins, director of the Center for Human Dignity at the Family Research Council.

The judge’s decision, a rare case in which a court has weighed in to order that a drug be made available over the counter, could test the question of who gets the final say in such matters.

“Technically the secretary under the law has the right to make the decision,” said Daniel Carpenter, a professor of government at Harvard. “But there is other long-established law that says the decision is supposed to be based on the safety and efficacy of the drug.”

Some legal experts said the decision sent a strong signal to the White House.

“If they’re going to interfere with decisions of expert regulatory agencies, they must find credible scientific justification; otherwise judges will be inclined to step in and stop them,” said Lewis A. Grossman, a law professor at American University.

In his ruling, Judge Korman accused the federal government of “bad faith” in dealing with the requests over more than a decade to make the pill universally available.

“The F.D.A. has engaged in intolerable delays in processing the petition,” the judge wrote. “Indeed, it could accurately be described as an administrative agency filibuster.”

He added, “The plaintiffs should not be forced to endure, nor should the agency’s misconduct be rewarded by, an exercise that permits the F.D.A. to engage in further delay and obstruction.”

The drug’s manufacturer, Teva Pharmaceuticals, declined to comment on the decision on Friday. In a separate order, the judge denied a motion filed by the company to preserve market exclusivity.

Plan B was approved in 1999 as a prescription-only product, and in 2001, the Center for Reproductive Rights filed a citizens petition for it to be made available over the counter or without a prescription. Scientists, including an expert advisory panel to the F.D.A., gave early support to that request. But top agency officials rejected the application because, some said later, they worried they would be fired if they approved it.

President George W. Bush’s administration in 2006 allowed over-the-counter sales to women 18 and older but required a prescription for those 17 and younger. In 2009, Judge Korman directed that the pill be made available over the counter for those 17 and older.

A former Health and Human Services official during Mr. Obama’s first term said that when Ms. Sebelius overruled the F.D.A. in 2011, she was concerned about the lack of research about how the drug would affect very young girls. But the official, who declined to be named in order to discuss internal deliberations, said the secretary was also being pragmatic by not taking a stand that would have immediately drawn intense criticism from abortion opponents.

“We would have been fighting the contraception fight over whether we let a 7-year-old girl walk into Walgreens and get the morning-after pill,” the official said. “Let’s have it on terms we can win it on, rather than something that’s easy to mock.” The official said Ms. Sebelius would probably feel the same way today.

Several supporters of the judge's decision on Friday, including representatives of women's reproductive health groups and the American Academy of Pediatrics, said they believed that since the election was over, the Obama administration would have less of a political reason to oppose expanded access to the pill.

Susannah Baruch, interim president of the Reproductive Health Technologies Project, said advocates met with officials at the F.D.A. and the Health and Human Services Department soon after the election "around the question of whether they would do what the court is now ordering them to do." But she said it had been "hard to read the tea leaves" to determine if those efforts had been making headway.

Michael D. Shear and Sabrina Tavernise contributed reporting.



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