

Judge OKs morning-after pill for all ages

NEW YORK TIMES / April 5, 2013 / Updated: April 5, 2013 9:50pm



The Plan B One-Step (levonorgestrel) tablet, one of the brands known as the "morning-after pill," will be available over-the-counter **without age restrictions.**

Photo: Uncredited, HOEP / Teva Women's Health, Inc.

A federal judge ruled Friday that the government must make the most common morning-after pill available over the counter for **all ages, instead of requiring a prescription for girls 16 and younger.** In his ruling,

he also accused the federal government of "bad faith" in dealing with the requests to make the pill universally available, and said its actions had been politically motivated.

The decision, on a politically controversial subject, comes after a decade-long fight over who should have access to the pill and under what circumstances. It also counteracts an unprecedented move by the Obama administration's [Health and Human Services](#) secretary, [Kathleen Sebelius](#), who in 2011 overruled a recommendation by the [Food and Drug Administration](#) to make the pill available for all ages without a prescription.

In a decision in a lawsuit filed by advocates, the judge, [Edward Korman](#) of U.S. District Court, ruled that the government's refusal to lift restrictions on access to the pill was "arbitrary, capricious, and unreasonable."

Korman ordered the FDA to lift any age and sale restrictions on the pill, Plan B One-Step, and its generic versions, within 30 days.

"More than 12 years have passed since the citizen petition was filed and 8 years since this lawsuit commenced," the judge wrote. "The FDA has engaged in intolerable delays in processing the petition."

He added, "The plaintiffs should not be forced to endure ... an exercise that permits the FDA to engage in further delay and obstruction."

No decision on appeal

The FDA and the Department of Health and Human Services declined to comment on the ruling or the judge's harsh criticisms Friday morning or indicate whether the government would appeal.

Scientists, including those at the FDA, have been recommending unrestricted access for years, as have major medical groups.

They contend that the restrictions 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.

In 2011, the FDA commissioner, Dr. [Margaret Hamburg](#), declared Plan B One-Step safe to sell over the counter for all ages. But she was overruled by Sebelius, the Health and Human Services secretary, the first time such a public countermanding had ever occurred.

Sebelius said Plan B's 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. Her decision was widely interpreted in a political context because allowing freer access to adolescents would prompt critics to accuse the Obama administration of supporting sexual activity for girls of that age.

72-hour window

The drug's manufacturer, [Teva Pharmaceuticals](#), had petitioned the FDA for Plan B to be available over the counter as far back as 2003.

Plan B One-Step consists of one pill with the active ingredient levonorgestrel, which can block fertilization if taken within 72 hours of sexual intercourse. It reduces the chance of pregnancy to 1 in 40; without the pill, women have about a 1 in 20 chance of pregnancy after unprotected sex.

Two other drugs - Next Choice and Levonorgestrel Tablets - contain levonorgestrel in a two-pill version.

The judge's order also applies to those drugs, although he said that if the FDA "actually believes there is any significant difference between the one- and two-pill products, it may limit its over-the-counter approval to the one-pill product."

First Take: On 'Plan B' ruling, politics turns upside down

Richard Wolf, USA TODAY 12:24p.m. EDT April 5, 2013

Reagan-appointed judge blisters the Obama administration ... for siding with social conservatives.



(Photo: AFP/Getty Images)

Story Highlights

- A Reagan appointee takes Obama to task ... for kowtowing to conservatives
- 'Plan B' morning-after pill would be sold without an Rx, regardless of age
- Federal judge overturns HHS ruling that limited sales to women 17 and older

WASHINGTON — Conventional politics flew out the window Friday in a federal judge's scathing attack on the Obama administration for banning the sale of over-the-counter contraceptives to young girls.

Usually, when a conservative court takes President Obama to task, you can bet it's for being too liberal. But in this case, federal District Court Judge Edward Korman — appointed to the Eastern District of New York by Ronald Reagan — castigated the administration for kowtowing to conservatives.

Korman ordered that "morning-after" contraceptives be sold nationwide without a prescription regardless of age, within 30 days. (The pill, popularly known as "Plan B," typically works up to 72 hours after intercourse.) That overturns a decision made by Health and Human Services Secretary Kathleen Sebelius in 2011 that limited over-the-counter sales to women 17 and older.

THE STORY: [Judge OKs over-the-counter sales for girls under 17](#)

Sebelius had overruled her own Food and Drug Administration, which has consistently ruled that the drugs are safe, citing the need to protect young girls from unwanted pregnancies. She was backed by Obama himself, the father of two young girls, who said it was only "common sense" that the drug not be available "alongside bubble gum or batteries."

"Common sense" weren't the words that came to Korman's mind in his blistering, 59-page ruling. He called Sebelius' decision "obviously political." He said she forced the FDA to "ride roughshod" over its own policies. He said her reasons were "so unpersuasive as to call into question her good faith."

Korman's frustration stems in part from the duration of the case. He has been dealing with it for a decade, since the White House under President George W. Bush interfered with FDA decision-making. As a result, a drug considered safe by health and science advocates has been denied to many preteens and younger teens — in a country with declining but still higher teen pregnancy rates than any other developed nation.

So we have Korman, the Republican appointee, ordering the morning-after pill made available without a prescription to young girls — over the protestations of the Obama administration. And now we await the administration's response — on a day when politics as usual was anything but.