

The FDA Gets a Plan B [minus]

By ACSH Staff — April 5, 2013

A federal judge today blasted the Food and Drug Administration's refusal to allow emergency contraception to be sold over-the-counter without any limit on age, and gave the agency 30 days to lift its restrictions.

Judge Edward Korman ruled that the government's insistence on age restrictions on the pill requiring a prescription for girls 16 and younger was arbitrary, capricious, and unreasonable.

Judge Korman [called](#) ^[1] Health and Human Services Secretary Kathleen Sebelius intervention in 2011, when FDA Commissioner Margaret Hamburg was poised to lift the age restrictions, unprecedented and obviously political.

Pointing to a statement by President Obama about 10- and 11-year-olds potentially being able to walk into a pharmacy and buy Plan B, Judge Korman wrote, This case is not about the potential misuse of Plan B by 11-year-olds. These emergency contraceptives would be among the safest drugs sold over-the-counter [and] the number of 11-year-olds using these drugs is likely to be miniscule. Instead, the invocation of the adverse effect of Plan B on 11-year-olds is an excuse to deprive the overwhelming majority of women of their right to obtain contraceptives without unjustified and burdensome restrictions.

Other drugs, including the weight-loss drug Alli and Prilosec, have been allowed to be sold over-the-counter, even though there was no research showing they were safe for pediatric populations, the judge wrote.

Twelve years have passed since the plaintiffs, a group of women's health advocates, first petitioned the FDA to allow the morning after pill to be sold over the counter, Korman noted. The FDA has engaged in intolerable delays in processing the petition. Indeed, it could accurately be described as an administrative agency filibuster.

The FDA has not said whether it will appeal.

ACSH's Dr. Gilbert Ross had this to say: It's about time, and thanks to Judge Korman, young women seeking to avert an unplanned and unwanted pregnancy now have this option easily accessible. Better late than never! Ten years ago, the Bush administration hindered this move out of religious/moralistic fervor, mistakenly believing that access to morning-after contraception would promote sexual laxity. Recently, HHS Secretary Sebelius vetoed the FDA's move out of purely political motives. I am certain the Administration will not appeal it.

Source URL: <https://www.acsh.org/news/2013/04/05/the-fda-gets-a-plan-b-minus>

Links

[1] <https://www.nyed.uscourts.gov/sites/default/files/opinions/Tummino%20SJ%20memo.pdf>