Federal Court Rules FDA Must Reconsider Plan B Decision

FDA Ordered to Make a Decision Based on Scientific Fact, Not Politics

New York (03-23-09) – Today, the U.S. District Court for the Eastern District of New York rejected the Food and Drug Administration (FDA) decision to limit over-the-counter access to the emergency contraceptive Plan B to women over 18, ruling that it was based on politics and ideology, rather than science. The court ordered the agency to reconsider its decision. It also ordered the FDA to act within 30 days to extend over-the-counter access, which is currently limited to 18 year olds and over, to 17 year olds.

"Today's ruling is a tremendous victory for all Americans who expect the government to safeguard public health," said Nancy Northup, president of the Center for Reproductive Rights, which brought the suit against the FDA.

"The message is clear—the FDA should put medical science first and leave politics at the lab door. We are encouraged that the agency, now under new leadership, will take that message to heart."

The Center for Reproductive Rights sued the FDA in 2005 for failing to grant over-the-counter status to Plan B against the advice of scientific experts and in violation of its own procedures and regulations. In 2006, the FDA agreed to make Plan B available without a prescription, but only to women over 18 and only behind the pharmacy counter. The Center continued to pursue its lawsuit, Tummino v. von Eschenbach, to ensure that Plan B would be granted true over-the-counter status and made available to all women, including young women who might benefit most from this form of contraception.

"According to the FDA's own rules, the only legitimate criteria for making a drug available without a prescription are safety and efficacy," said Northup. "Emergency contraception is proven safe and effective and today, all women—including young women for whom the barriers and the benefits are so great—are one step closer to having the access they need and deserve."

The Court found that the FDA "acted in bad faith and in response to political pressure," "departed in significant ways from the agency's normal procedures," and engaged in "repeated and unreasonable delays." In addition, the court found that the FDA's justification for denying over-the-counter access to 17 year olds "lacks all credibility," and was based on "fanciful and wholly unsubstantiated 'enforcement' concerns."

Before its action on Plan B, the FDA had never restricted a non-prescription drug based on a person's age, nor had the Bush Administration ever been consulted by the FDA about an over-the-counter drug application. Depositions of senior FDA officials by the Center in 2006 indicated that the Bush Administration sought to unduly influence the agency during the Plan B application review process. Testimony also indicated that officials involved in the decision-making process were

concerned about losing their jobs if they did not follow the Administration's political directives.

Other evidence uncovered during the lawsuit showed that the agency repeatedly departed from its own established procedures during the FDA case, from filling the reproductive health committee with political "operatives" to making a decision to reject over-the-counter access to Plan B before completion of the standard review.

The Center's battle to make Plan B available over-the-counter to women of all ages began in 2001, when it filed a citizens' petition with the FDA on behalf of over 70 medical and public health organizations to grant the drug over-the-counter status. On January 21, 2005, the Center filed Tummino v. von Eschenbach in the U.S. District Court for the Eastern District of New York on behalf of the Association of Reproductive Health Professionals (ARHP), National Latina Institute for Reproductive Health, individuals from a grassroots advocacy group, the Morning-After Pill Conspiracy, and parents who seek over-the-counter access for their daughters. On March 30, 2007, the Center asked for summary judgment in the case, arguing that the evidence gathered during discovery made it unnecessary for the court to hold a trial and that the court should order the agency to make Plan B available without a prescription to all women.

For more information on this case and the Center for Reproductive Rights, please visit www.reproductiverights.org

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