



U.S. District Court Finds the FDA's Actions on Plan B[®] Tainted by Politics

**For immediate release:
March 23, 2009**

**Contact: Aparna Krishnaswamy
akrishnaswamy@rhtp.org
202-530-4401**

Washington D.C. – Today a U.S. District Court ruled that the Food and Drug Administration (FDA) allowed politics to taint their decision to make Plan B[®] available over-the-counter (OTC) for individuals age 18 and older. The judge recognized that the FDA gave into political pressure and did not rely on the sound science that supported making Plan B available without a prescription for all age groups. Calling the FDA's procedure for approving the drug "capricious" and "arbitrary", the court ordered the FDA to reconsider its decisions regarding the Plan B switch to OTC use and ordered the FDA to permit Plan B's availability to 17 year olds without a prescription beginning in 30 days.

"This ruling validates what we have known all along - politicians trumped the scientists when it came to the FDA's handling of Plan B," said Kirsten Moore, President and CEO of the Reproductive Health Technologies Project. "Plan B is a safe and effective back-up contraceptive method that gives women of all ages an option to prevent unintended pregnancy. We urge the FDA and Duramed to work together to lift the unnecessary age restriction and put Plan B on pharmacy shelves to make timely access a reality for anyone who needs it."

This ruling comes in response to a lawsuit filed by the Center for Reproductive Rights against the FDA for its failure to make emergency contraception Plan B available over-the-counter. The lawsuit claimed that the FDA broke its own rules and regulations, ignored medical consensus, as well as the expertise of its own scientists and advisory committees by holding Plan B to an arbitrarily higher standard than other OTC products. The plaintiffs asked the court to order the FDA to make Plan B available over-the-counter for women of all ages.

Plan B is an FDA-approved, back-up birth control method that can prevent pregnancy in the first few days after sex. Containing a concentrated dose of the progestin hormone found in daily birth control pills, Plan B can reduce the risk of pregnancy by up to 89 percent when taken within 72 hours of sexual intercourse (the sooner a woman takes it, the more effective it is). Critics have argued that increased access to Plan B would lead to promiscuity or other risky health behaviors but these concerns are misplaced. Real world experience with EC and other contraceptives show that reducing barriers to access is important but not sufficient when it comes to reducing unintended pregnancy. Access must be coupled with information and education to help individuals make healthy choices throughout their lifetime.

For more information including a complete timeline of the approval process for Plan B OTC please visit: <http://www.rhtp.org>

###

Kirsten Moore, President and CEO, RHTP and Susan Wood, Ph.D., Research Professor, School of Public Health and Health Services, George Washington University are available for interview upon request.