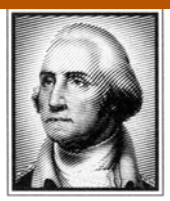

THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER
WASHINGTON DC

SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES
JACOBS INSTITUTE OF WOMEN'S HEALTH
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Jacobs Institute of Women's Health

WOMEN'S HEALTH POLICY ALERT

U.S. District Court Directs FDA to Reevaluate Previous Plan B Decision

Prepared by:
Susan F. Wood, PhD
Executive Director
D. Richard Mauery, MS, MPH
Managing Director

WASHINGTON – Judge Edward R. Korman of the U.S. District Court, Eastern District of New York, issued a decision today in the case of *Annie Tummino et al v. Frank M. Torti, Acting Commissioner of the Food and Drug Administration*. The case involved plaintiffs' claims that the FDA, in deciding that Plan B, known as emergency contraception or the morning-after pill, be made available over-the-counter (OTC) only with age restrictions, was unduly and inappropriately influenced by pressures from the White House among other factors.

The court ruled in favor of the plaintiffs and ordered that the FDA reconsider its decisions regarding the Plan B switch to OTC. In addition, the court ordered the FDA, within 30 days, to permit Barr Pharmaceuticals (the Plan B drug sponsor) to make Plan B available to 17-year-olds without a prescription. Plan B emergency contraception is a form of birth control pill which can prevent pregnancy if taken after unprotected sexual intercourse. Currently, Plan B is available OTC only to women over age 18.

In its lengthy opinion, the Court cited numerous FDA actions that constituted "arbitrary and capricious" decision-making that supported the plaintiffs' allegations that the agency bowed to inappropriate pressures from the Bush Administration and conservative advocates to halt or delay FDA action on Barr Pharmaceutical's requests to switch Plan B from prescription-only to OTC status. Judge Korman noted the following:

- Political and ideological factors played a key role in the nomination and selection process for membership in FDA's Advisory Committee for Reproductive Health Drugs;
- In a clear departure from standard FDA practice, final decision-making for OTC status was controlled at the highest levels of the FDA leadership rather than deferring to the Advisory Committee's recommendations, or the evaluation by FDA scientific and medical review staff;
- FDA leadership issued decisions before the scientific review of the evidence related to adolescent use of Plan B was completed;
- The FDA's decision-making was influenced by political considerations involving the confirmation process of two FDA Commissioners; and,

- The plaintiffs successfully demonstrated injury to the extent that the delays imposed by having to obtain a prescription for Plan B, which must be taken within 72 hours of sexual intercourse, may increase the chance of an unwanted pregnancy.

In sum, Judge Korman wrote:

> *These political considerations, delays, and implausible justifications for decision-making are not the only evidence of a lack of good faith and reasoned agency decision-making. Indeed, the record is clear that the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use, referred to as a "switch application" or an "over-the-counter switch."*

In the court's ruling, Judge Korman cited the plaintiffs' contention that, "This change in leadership can be trusted to conduct a fair assessment of the scientific evidence. Second, a decision whether Plan B, a systemic hormonal contraceptive drug, may be used safely without a prescription by children as young as 11 or 12, is best left to the expertise of the FDA, to which Congress has entrusted this responsibility; it should not be made by a federal district court judge." President Obama has nominated Margaret Hamburg, former New York City health commissioner and assistant secretary for health and human services under President Bill Clinton, to become FDA Commissioner. He has also nominated Baltimore Health Commissioner Joshua Sharfstein as FDA's principal deputy commissioner.

Today's court ruling represents a move toward ensuring scientific integrity and science-based decision making at the FDA, consistent with the recent Presidential memo directing Federal Agencies to maintain the highest scientific standards. It places confidence in the FDA and the new Administration to carry out its public health mission based on the best available evidence. It also provides the opportunity to expand access to contraceptive options for women and their families, and advances the health of women.

A copy of the full text of the court's decision is available at:

http://www.nyed.uscourts.gov/pub/rulings/cv/2005/05cv366mofinal.pdf

The Center for Reproductive Rights, representing the plaintiffs, issued a press release on the case today. It is available at:

http://reproductiverights.org/en/press-room/federal-court-rules-fda-must-reconsider-plan-b-decision