



## **FDA URGED TO HEED SCIENCE AND STOP DELAYING OVER-THE-COUNTER EMERGENCY CONTRACEPTION**

### ***Health and Regulatory Experts Argue FDA Should Abandon Unnecessary "Rule-making" Process and Approve Plan B<sup>®</sup> Without a Prescription***

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WASHINGTON, DC – Today, a contingent of the nation's top medical and public health organizations urged the Food and Drug Administration to heed the scientific consensus supporting over-the-counter emergency contraception and abandon a bureaucratic "rule-making" process that has needlessly delayed making Plan B available without a prescription. According to a letter submitted by four dozen groups – including the American College of Obstetricians and Gynecologists – studies show that women of all ages can safely and effectively use over-the-counter Plan B and that requiring a prescription creates a medically unjustified barrier to getting this back-up birth control method in time for it to work.

"The evidence is clear: Plan B belongs on the drug store shelves today," said Kirsten Moore, President of the Reproductive Health Technologies Project. "The longer the FDA drags its feet, the more it denies women a second chance to prevent an unintended pregnancy."

The letters, filed at the close of an FDA-mandated "public comment" period, are among scores of documents advocating immediate action on the 30-months'-old request to make Plan B available without a prescription. In late August, the FDA found that Plan B is safe for over-the-counter use for the majority of women, but refused to make a final ruling on the product's status. Additional comments filed by former FDA chief counsels Nancy Buc and Peter Barton Hutt and the National Women's Law Center – on behalf of a dozen women's health organizations and experts – cite FDA precedent showing how the FDA could quickly approve the pending over-the-counter application for Plan B (which would limit non-prescription access to women 16 and older).

"The FDA's insistence that it needs more input before it can rule on over-the-counter Plan B is a stall tactic that compromises women's reproductive health options," said Marcia Greenberger, Co-President of the National Women's Law Center. "The agency already has both the scientific data and the legal authority to make emergency contraception available without a prescription."

In December 2003, the FDA's expert advisory panel voted overwhelmingly (23-4) to recommend that Plan B become available without a prescription for women of all ages – a view shared by the agency's professional staff and the nation's leading medical and public health organizations, including the American Medical Association and the American Academy of Pediatrics. But since then, the FDA has repeatedly denied and delayed approval of over-the-counter Plan B – often citing unsubstantiated concerns about teenagers' use of this back-up birth control method. News reports and agency insiders indicate that politics influenced the FDA's actions. Fifteen-year FDA veteran Dr. Susan Wood, who resigned in protest from her post as Assistant Commissioner for Women's

Health and Director of the FDA Office of Women's Health over the agency's response to Plan B, also signed onto the comments submitted today by the National Women's Law Center.

Additional contacts:

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