

December 8, 2011

In This Update

About us

Contact us

Dear Working Group Member,

As many of you have probably heard, in an <u>unprecedented</u> <u>move</u> yesterday the US Department of Health and Human Services Secretary Kathleen Sebelius overruled the Food and Drug Administration's (FDA) recommendation to make Plan B One-Step emergency contraception (EC) available over the counter for women of all ages. Instead, the product will remain 'behind the counter,' requiring a prescription for women younger than 17 years old. This is a decision clearly driven by politics not science, as the data convincingly show that Plan B One-Step is safe for women of all ages and that the instructions on the label are easy to follow. The American Medical Association, American Congress of Obstetricians and Gynecologists, and American Academy of Pediatrics have all endorsed OTC access to EC and agree that the age restriction is unnecessary.

The Secretary's decision not only affects teens who need access to EC in order to prevent unintended pregnancy, it affects all women in the US. Keeping EC behind the counter and forcing a woman to speak with a pharmacist who is available only during certain hours add significant barriers to access.

Furthermore, this sets a disturbing precedent that could stifle efforts to develop new drugs and make existing drugs better or easier to use. In her <u>statement</u>, the FDA Commissioner Margaret Hamburg said that upon careful review the FDA's Center for Drug Evaluation and Research (CDER) determined the product was safe and effective in adolescent females, and that Plan B One-Step should be approved for nonprescription use for all females of childbearing potential. The fact that the final decision was

not based on CDER's scientific assessment removes all semblance of transparency in our drug approval process.

The White House signed a <u>memo</u> on scientific integrity and transparency in March 2009, and we should hold the Administration accountable to the standards it has set for itself. You can get involved by completing one of several online petitions:

- Tell the Obama Administration Its Decision on Plan B Is Unacceptable (NARAL Pro-Choice America)
- Don't Play Politics with the Health of Women and Young People (Advocates for Youth)
- <u>Don't Let Politics Trump Science</u> (Created by Dr. Megan Evans)

Thanks,

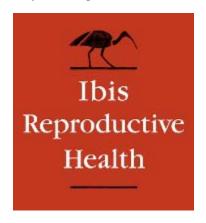
Daniel Grossman

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About us

The Oral Contraceptives (OCs) Over-the-Counter (OTC) Working Group is an informal coalition of reproductive health and rights organizations, nonprofit research and advocacy groups, university-based researchers, and prominent clinicians who share an interest in women's health and access to contraception. Our goal is to evaluate objectively the risks and benefits of demedicalizing contraceptive care, with an eye toward improving access to OCs and potentially other hormonal contraceptive methods by making them available without a prescription.

The working group is coordinated by Ibis Reproductive Health.



www.ibisreproductivehealth.org

Contact us

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