



Reproductive Health Technologies Project 25 May 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. 00N-1256: "FDA Regulation of OTC Drug Products Hearing"

To Whom It May Concern;

I am writing to inform you that I will offer oral comments at the June 28-29 meeting, "FDA Regulation of OTC Drug Products," Docket No. 00N-1256 on behalf of the Reproductive Health Technologies Project.

Kirsten Moore, Project Director
Reproductive Health Technologies Project
1818 N St., NW / Suite 450 / Washington, DC 20036 / t: 202.530.2900

The Project is a nonprofit advocacy organization whose mission is to advance the ability of every woman of any age to achieve full reproductive freedom with access to the safest, most effective, appropriate and acceptable technologies for ensuring her own health and controlling her fertility.

The Project has been in the forefront of efforts to promote women's awareness of and access to dedicated emergency contraceptive products in the U.S. If taken within 72 hours of unprotected intercourse, emergency contraceptive pills (ECPs) can significantly reduce the risk of an unintended pregnancy. ECPs are indicated for a self-diagnosable condition (unprotected sex within the past 72 hours) and have fewer side effects or contraindications than other medications currently available over-the-counter. Moreover, recent clinical data from the World Health Organization shows that the sooner women take ECPs the more effective they are.

A recent quality review of clinicians listed on the national Emergency Contraception Hotline found that 14% of calls made under the most favorable of conditions (e.g., during regular business hours to a self-selected pool of providers) resulted in a failure to get an appointment or prescription within the necessary 72 hours. The current prescription-only status for ECPs acts as a barrier to access and we believe the FDA should move ECPs over the counter.

I would appreciate five minutes of the panel's time during the hearing to expand on these comments. On behalf of the board of the Reproductive Health Technologies Project, thank you for this important opportunity to comment on the FDA's OTC Drug Review Process.

Sincerely,

Kirsten Moore
Kirsten Moore
Project Director

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