



7262 04 JUL -7 P135

July 2, 2004

PHARMACY
access
partnership

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
Food and Drug Administration
14-71 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: Dismay at non-approvable letter for Plan B Emergency Contraception

A Center
of the Public
Health Institute

Dear Dr. Crawford,

The Pharmacy Access Partnership, a non-profit center of the Public Health Institute, decries the FDA's decision to deny over-the-counter status to Emergency Contraception (EC), sold under the brand name *Plan B*.

This decision flies in the face of the recommendations of the FDA's own expert Advisory Committees, who examined all of the evidence and declared *Plan B* safe and effective for over-the-counter use. It is obvious that this was a political decision, not a public health decision. Public health officials and researchers around the world widely agree that EC is a safe and effective means to prevent an unintended pregnancy after contraceptive failure or unprotected sex.

This decision is a significant setback in the public health arena, where preventing unintended pregnancies is a critical component of helping women, couples and families have control of their physical, emotional and economic health.

Pharmacy Access Partnership has been working in California for the past three years to make it possible for women to receive EC from a pharmacy without first obtaining a prescription from their doctor or clinic. There are now approximately 800 participating pharmacies in California; in 2003, approximately 135,000 California women obtained EC directly from participating pharmacists. There were no restrictions for young women to access EC in these programs and there have not been any adverse incidents.

We have seen first hand from California's EC Pharmacy Program the benefits of women and couples having easier access to EC when they need it, which is often not when a doctor's office is open. Five other states have enacted similar EC pharmacy programs and 10 states introduced legislation to improve access to EC in their states in 2004. However, these efforts are no substitute for federal action. Making EC available over-the-counter eliminates the need for a designated pharmacist to provide the pills and makes it more easily available when it is needed.

We hope that the FDA will reverse its decision to deny Barr Laboratories' application for over-the-counter status for *Plan B*, so that all women will have access to such an important drug in a timely manner.

Respectfully,

Sharon Cohen, MPH
Acting Director

OIP-0075

C1873

cc: Division of Dockets Management