

PHYSICIANS FOR



REPRODUCTIVE  
CHOICE AND HEALTH

August 29, 2002

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 10-61  
5630 Fishers Lane  
Rockville, MD 20857

Docket No. 001P-0075/CP 1

To Whom It May Concern:

On behalf of the more than 5,000 members of *Physicians for Reproductive Choice and Health*<sup>®</sup>, I am writing in further support of the petition by the Center for Reproductive Law and Policy to request a change in status of the emergency contraceptive drugs, Preven and Plan B, from prescription to over-the-counter. Reclassifying these FDA-approved treatments has the potential to transform the landscape of our nation's public health by enabling women to command a proactive position on their reproductive options.

From a medical perspective, there is no evidence to suggest that this shift will result in adverse health consequences for the public. On the contrary, there is sufficient reason to believe that the removal of the prescription-only barrier will serve to lower the level of unintended pregnancy and abortion in this country. There are an estimated 6.3 million pregnancies every year in the United States, approximately 48 percent of which are unintended. 47 percent (accounting for roughly 1.3 million women) of those unplanned pregnancies will end in abortion. With easier dissemination of emergency contraception (EC), women will have a very important early option in planning their reproductive health.

Moreover, emergency contraception is an extremely safe and straightforward method of birth control. The hormones used are identical to those found in oral contraceptives, pills whose safety and efficacy have been well established and consistently proven for decades. Misuse, an important consideration for any medication, is also not considered a threat: it could only lead to the common side effects, which, while uncomfortable, are manageable by the patient and should assuage fears of those who are concerned about the use of EC for longstanding birth control. On the patient end, there is evidence to suggest that women easily understand the EC regimen: a study with a sample population including young women, women of color and women of low literacy found that, when given a prototype of an emergency contraceptive package label, an extremely high percentage (between 93 and 98 percent depending upon the question posed) understood the purposes and related information about the product.

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Emergency contraception is clearly of significant benefit to women who are at risk of pregnancy from consensual intercourse; however, we must also consider those women for whom consent was not an option. A consensus to make EC routinely available to sexual assault victims is growing. California's state legislature recently passed such a bill. As important as this legislation is, it is essential to remember that many sexual assault victims do not even enter our health care systems. Many remain silent and untreated; over-the-counter emergency contraception would be able to provide at least the reassurance that pregnancy is most likely avoidable. Approximately 300,000 women are raped each year in the United States. Roughly 25,000 will become pregnant as a result. It is estimated that 20,000 of those pregnancies could be prevented through the administration of emergency contraception (Preven reduces the risk of pregnancy by 75 percent, Plan B by 89 percent).

With aggressive public outreach campaigns already underway in areas where EC is provided through pharmacist-physician partnerships, most notably Washington, over-the-counter access to emergency contraception has the potential to reduce the national level of unintended pregnancy and abortion. Countries including Finland, Israel, Norway and Sweden have already taken this beneficial public health care measure. We urge the Food and Drug Administration to consider strongly the Rx-to-OTC switch, as well.

Sincerely,



Wendy Chavkin, M.D., M.P.H.

Board Chair

*Physicians for Reproductive Choice and Health*<sup>®</sup>

The mission of *Physicians for Reproductive Choice and Health*<sup>®</sup> is to enable concerned physicians to take a more active and visible role in support of universal reproductive health. PRCH is committed to ensuring that all people have the knowledge, access to quality services, and freedom of choice to make their own reproductive health decisions. PRCH is a national organization with 5,000 members.

