



MEMORANDUM

Department Of Health and Human Services
Food and Drugs Administration
Center For Drug Evaluation and Research
Division of Over-the-Counter Drug Products (HFD-560)

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To: Mitchell Weitzman, J.D.
Regulatory Policy Staff, (HFD-7)

Subject: Consult for response to Citizen Petitions Requesting Switch of Emergency Contraceptive Prescription Drug Products to Over-the-Counter Marketing Status [Docket Number: 01P-0075/CP1]

Introduction

This is a review of Citizen Petitions submitted by the American Pharmaceutical Association and another submitted jointly by 66 different organizations. Both of these Petitions request that the FDA switch emergency contraceptive pills (ECP) from prescription to over-the-counter status.

American Pharmaceutical Association Petition

The petitioner makes many points with which we can agree, however, there are several points of difference. We agree with the petitioner that consumer understanding of proposed nonprescription product labeling is essential to support the transition from prescription-only to nonprescription status and we also support methods to assess consumer understanding of the product. Therefore, actual use and label comprehension studies to demonstrate if consumers can use ECP safely and effectively without a learned intermediary are necessary.

The OTC division is aware that there are collaborative practice agreements between pharmacists and physicians authorized by state law. However, we need to see the research that supports the statement of the petitioner that "pharmacists can very effectively manage the provision of emergency contraception services working with physicians under a collaborative practice protocol." We disagree that "pharmacists can act as principal investigators to evaluate compliance and persistence by consumers self-selecting to receive a product being considered for transition to nonprescription status." We agree that pharmacists could play a valuable role in Phase IV and post-marketing surveillance clinical trials under the leadership of a physician principal investigator.

Current drug federal regulations do not provide for a "behind-the-counter" mechanism of drug availability.

Petition from 66 Organizations

Unintended pregnancy is a major health problem in the United States and many of the points the petitioners raise are reasonable. As the petitioner states, the primary principal of medical care is "first, do no harm." Following this principal, the OTC division recognizes safety issues that must be addressed through Actual Use Studies before an ECP switch from prescription to OTC status could be accomplished. The issues include:

1. Whether consumers would use ECP off label as post-coital contraception instead of more effective forms of birth control;
2. Whether consumers who are already pregnant would use ECP;
3. How effectively the special population of sexually active pre-teen and teenage girls under the age of 18 could comprehend and use ECP. Because many potential ECP consumers are young, literacy requirements for the label would need to be reduced to a maximum of a 6th grade reading level. Could this be accomplished? ;
4. Whether the availability of ECP would dissuade consumers having unprotected sexual relations from seeing their gynecologists to learn if they have been exposed to a sexually transmitted disease;
5. Whether, without the assistance of a learned intermediary, consumers would use ECP within the proper time intervals;
6. What consumers would do if they vomit shortly after taking either dose of ECP;
7. What consumers would do if they develop unexpected vaginal bleeding prior to or after using ECP.

It is not inherent that PrevenTM and Plan B[®] would both be safe and effective for OTC use. Each must be evaluated separately through Actual Use Studies with regard to the above issues. PrevenTM,

The sponsors of both PrevenTM and Plan B[®] have expressed a willingness to work with the Agency to address these concerns. }

Conclusion:

The OTC division finds many points of agreement and some areas of disagreement with the petitioners. There are several potential safety issues that need to be examined through Actual Use Studies before a recommendation can be made to switch either or both ECP from prescription to OTC availability.

We recommend that the Division of Reproductive and Urologic Drug Products (HFD-580) be consulted for an opinion about these petitions, as well.

note: information about interactions with the specific product sponsors may be confidential; would not disclose in a petition response unless sponsors have already made the information public. RD.