

DRUDP Tracked Correspondence # 74

MEMO: to RPS lead Mitchell Weitzman

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Through: Susan Allen, MD, MPH
Director, DRUDP

Susan Allen, MD 3/30/01

Subject: Citizen Petition, Docket Number 01P-0075/CP1
Re: Emergency Contraception Rx-to-OTC Switch

Date: February 28, 2001

Summary of Petition:

This citizen petition is a request to switch two emergency contraception drugs (Preven™ and Plan B®) and any subsequent ANDAs [because of the drug's equivalence to Preven or Plan B] from prescription to OTC status. The petition has been submitted on behalf of 68 different health care, family planning, and professional organizations through their counsel, the Center for Reproductive Law and Policy.

In addition, the petition includes supportive statements from four other sources:

1. The American Pharmaceutical Association wrote a letter dated 2/14/01 stating that pharmacists under the purview of collaborative practice agreements can provide emergency contraception services, can act as principal investigators, and are in a good position to work with both health care providers and consumers to improve patient outcomes. This letter also noted that consumer understanding of proposed nonprescription product labeling is essential to support the transition from prescription-only to nonprescription status.
2. A declaration dated 2/8/01 from two obstetrician/gynecologists, David Grimes, MD, and Elizabeth Raymond, MD, MPH, that advocate an immediate switch of the two FDA-approved regimens for emergency contraception pills (ECP) from prescription to OTC status. They carefully outline and discuss how both ECP regimens fulfill all the customary criteria for OTC distribution:
 - low toxicity
 - no potential for overdose and addiction
 - no teratogenicity or danger in pregnancy
 - no contraindication requiring screening by a medical professional
 - no need for screening to recognize indication for therapy
 - no need for professional monitoring of treatment
 - same dose for all women
 - simplicity of treatment regimen
 - no important drug interactions

3. The American Medical Association on 12/5/00 released a statement that "if the FDA determines that ECPs are safe for over-the-counter use, the AMA would support the increased access."
4. The American College of Obstetricians and Gynecologists (ACOG) on 2/14/01 released a statement that "we believe that emergency oral contraception can meet the FDA criteria for OTC availability. Then, at last, women would have access to an important method of preventing pregnancy."

Discussion:

The petition clearly outlines how the current prescription ECPs, Preven and Plan B, meet all the criteria for OTC availability: they are safe for and effective with self-medication; the treatment condition is easily self-diagnosed, and the drug's labeling is tailored to self-administration [there is only one dosing regimen for all women].

In general, the statements in the current petition are referenced by a U.S.C. and C.F.R. site, and are supported by scientific data and the cited literature. Furthermore, the four supportive statements are current and accurate. Several national organizations, including the AMA, ACOG, Am. Acad. of Pediatricians, Am. Medical Women's Assn., Am. Public Health Assn., Assn. of Reproductive Health Professionals, Family Planning Councils of America, NARAL, National Asian Women's Health Org., National Assn. of Nurse Practitioners, National Black Women's Health Project, Planned Parenthood Federation of America, POP Council, and SIECUS, have endorsed the petition or concept.

The petition proposes that the two approved products and future bioequivalent products could be switched to OTC status now because the existing patient labeling is "simple, clear, comprehensive and easy to follow." DRUDP agrees with much of the scientific information presented in the supporting statements contained in the Petition. DOTCDP typically requires an evaluation of data from both a labeling comprehension study and an actual use study prior to an Rx-to-OTC switch for a drug product. DRUDP will defer to DOTCDP an assessment of the adequacy of arguments made in the petition to support an Rx-to-OTC switch without submission of data from the two studies noted.

In summary, the petition as presented is concise and rational, is supported by the medical literature, and supported by 70 organizations and the sworn Declaration of two highly recognized contraceptive experts. DRUDP appreciates the information presented in the Petition and will consider any application for an Rx-to-OTC switch of an emergency contraceptive product.