

American Medical Association

Physicians dedicated to the health of America



Michael D. Maves, MD, MBA 515 North State Street 312 464-5000
Executive Vice President, CEO Chicago, Illinois 60610 312 464-4184 Fax

January 24, 2005

Steven K. Galson, MD, MPH
Acting Director
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20852-1436

Dear Dr. Galson:

The American Medical Association (AMA) would like to reiterate its strong support for approval of the pending application from Barr Laboratories to market its Plan B^R emergency oral contraceptive as an over-the-counter (OTC) medication for women 16 years of age and older. It is our understanding that the current proposal is to continue to market Plan B^R by prescription only for women younger than 16 years of age.

Plan B^R meets all of the customary criteria for OTC availability. The drug has a high level of safety for its intended use, it has no potential for overdose or addiction, and, when used as a single-dose, it is not harmful to an existing pregnancy. Furthermore, the need for emergency contraception can be easily self-identified by women, and no additional medical screening is required. There are also no important drug interactions with single-dose Plan B^R. Studies, including results from a randomized controlled trial published in the January 5, 2005, issue of the *Journal of the American Medical Association (JAMA)*, have shown that increased access to this emergency oral contraceptive does not increase the rate of unprotected sexual intercourse or the incidence of sexually transmitted diseases (i.e., there is no evidence of an increase in risky sexual behavior among young women).

Emergency oral contraceptive pills act to prevent, not terminate, pregnancy. Access to emergency contraception decreases the risk of an unintended pregnancy. Plan B^R works better when used within 24 hours after unprotected sex, so not requiring patients to obtain a prescription could lower a potential barrier to accessing the drug in a timely fashion. Nearly half of the pregnancies in the United States are unintended, a number that could be significantly reduced with OTC access to an emergency oral contraceptive.

By keeping Plan B^R as a prescription-only medication for women under 16 years of age, the revised proposal from Barr Laboratories addresses the concerns raised by the Food and Drug Administration regarding OTC access for younger adolescents. The AMA strongly encourages the agency to approve the current proposal.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael D. Maves".

Michael D. Maves, MD, MBA