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Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1093
Rockville, MD 20852

Docket Number 01P-0075

To Whom It May Concern:

The American Academy of Pediatrics (AAP), an organization of 57,000 pediatricians, and the Society for Adolescent Medicine (SAM), a multidisciplinary organization of 1,400 health professionals who care for adolescents, are pleased to provide comments to the Food and Drug Administration on the application to switch status of Emergency Contraceptive (EC) from prescription to over-the-counter (OTC). The AAP and SAM support switching EC to OTC as an important step to providing young women safe and effective treatment for reducing unexpected pregnancies.

It has long been the policy of the AAP and SAM to encourage abstaining from intercourse as the surest way to prevent sexually transmitted diseases (STDs) and pregnancy, however we also know that both ensuring access to contraception and helping adolescents understand how to use contraception more effectively when they do become sexually active are essential components of preventing STDs and unintended pregnancies. For patients already engaged in sexual intercourse or who are contemplating having sexual intercourse, pediatricians and other adolescent health care professionals provide appropriate counseling about sexual behaviors and the risks associated with unprotected sex. Despite these medical efforts, the majority of US adolescents begin having sexual intercourse by mid- to late adolescence, with an average age of first intercourse between 15 and 17 years.ⁱ It should be noted that approximately half of all adolescent pregnancies occur within the first six months after the adolescent becomes sexually active, and one-fifth of pregnancies occur within the first month.ⁱⁱ There is no evidence to suggest that refusal to provide contraception to adolescents results in abstinence or postponement of sexual activity. In fact, if adolescents perceive obstacles to obtaining contraception and condoms, they are more likely to have negative outcomes to sexual activity.ⁱⁱⁱ

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It is important to provide easily accessible and affordable emergency contraception for adolescents whose contraception fails or is not used during the most recent sexual encounter. It is essential that EC products are available for all adolescents and women of reproductive age. The age of onset of menarche varies; therefore AAP and SAM would oppose any age limitations on product availability, as well as any efforts to limit accessibility via location placement within a store or clinic. Similarly, EC must be affordable to the adolescent population.

AAP and SAM acknowledge that, though EC does not prevent sexually transmitted diseases, it can prevent pregnancy if it is readily available and used in a timely manner. Our organizations are committed to ensuring that adolescents understand the proper use of EC, including that it should not be substituted for other methods of contraception or protection from STDs.

As noted in the 2001 petition to the Food and Drug Administration urging a switch in status for emergency contraceptives, AAP and SAM believe EC should be made available over-the-counter for the following reasons:

- EC is safe for self-medication because it is not toxic to the young woman (or to the embryo or fetus if a pregnancy had been previously established in the woman); its side effects are minor and well known (e.g., nausea, breast tenderness, lower abdominal pain, fatigue, headache, heavier or lighter menstrual bleeding, dizziness, and vomiting, and diarrhea); it has a low risk of abuse or overdose and in the event of an overdose, the side effects are similar to those reported after regular doses of EC (see above).
- EC is effective when self-administered. Its administration is simple and relies only on assessments as to time elapsed since sexual intercourse that can be independently made by the young woman. Any interaction between EC and other drugs would be nonfatal and unlikely to seriously affect EC's efficacy.
- The only condition EC treats – contraception failure or failure to use contraception during intercourse -- is one that is diagnosable by a young woman and has no contraindications that would pose a danger to the patient.
- Contacting a physician and obtaining and filling a prescription hinders women from obtaining EC in a timely fashion^{vi}. Making EC available OTC will allow more adolescents and women to use the treatment and prevent unexpected pregnancies.


We thank the Food and Drug Administration for the opportunity to comment on this important issue and urge the FDA to switch Emergency Contraception to over-the-counter status.

Sincerely,



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CJ/ehv



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ⁱ Smith CA. Factors associated with early sexual activity among urban adolescents. *Soc Work.* 1997;42:334-346.

ⁱⁱ Zabin LS, Kanter JF, Zelnik, M. The risk of adolescent pregnancy in the first months of intercourse. *Fam Plann Perspect.* 1979;11:215-222.

ⁱⁱⁱ Guttmacher S, Lieberman L, Ward D, Freudenberg M, Radosh A, Jarlais D. Condom availability in New York City schools: relationships to condom use and sexual behavior. *Am J Public Health* 1997;87:1427-1433.

^{vi} Grimes DA. Emergency contraceptives over the counter. Allowing easy access is important [published erratum appears in *West J Med* 2000 May;173(5):340]. *West J Med* 2000;172:148-9.