



Tough Questions and Answers about Adolescents and Over-the-Counter Emergency Contraception

Background:

After several years of delays and a series of questionable actions by the Food and Drug Administration (FDA), on August 18, 2006 Plan B® emergency contraception (two .75mg levonorgestrel tablets) was finally granted over-the-counter (OTC) status for women 18 and older. Justification for an age restriction was based on concerns cited by top FDA officials regarding the limited amount of research done on the use of emergency contraception (EC) among young teens. Contrary to those concerns, other FDA staff, advisory committee members and outside experts recommended approval without restrictions based on the existing safety and usage data.

In March 2009, a Federal court decision, *Tummino v. von Eschenbach*, directed the FDA to lower the OTC age restriction on Plan B from 18 to 17 years of age. It also required the FDA conduct a re-review of existing scientific evidence and decide whether an age restriction is necessary at all. The FDA has complied with the first directive, and two levonorgestrel emergency contraceptive products, Plan B One-Step® and Next Choice®, are available to women 17 and younger.

Although we have come a long way, the age restriction on the OTC sale of levonorgestrel emergency contraceptive products has no scientific rationale and remains a barrier to access for many adolescents. The following question and answer document provides the facts and figures based on the available scientific research on the relationship between levonorgestrel emergency contraception and adolescents.

Q. Is there evidence that teens can safely understand emergency contraceptive product labeling for use without the supervision of a health care professional?

- YES -

Two studies conclude that adolescents demonstrate label comprehension equal to adults on the key points necessary for safe and effective use of emergency contraception.

Two studies were published in 2009 regarding emergency contraceptive label comprehension for teens. Raymond et al. found that 79% or more of adolescents aged 12-17 correctly understood six key concepts found in labeling: 1) EC prevents pregnancy after unprotected sex 2) it should be taken as soon as possible 3) it should be taken within 72 hours 4) it should not replace regular contraception 5) it does not protect against sexually transmitted infections (STIs) 6) it should not be used by women who are already pregnant.¹ Cremer et al. found that older teens (aged 16-17) were a bit more likely to understand the key comprehension points of the study than the younger girls (aged

12-15), but the younger girls understood a majority of the points with very high accuracy, including the reason to use EC and that it does not protect against HIV/AIDS.²

Q. Would over-the-counter access to emergency contraception cause teens to engage in “risky” sexual behaviors?

- NO -

EC use is not associated with increased risk taking behaviors among adolescent women.

On the other hand, if adolescents perceive obstacles to obtaining contraception and condoms, they are more likely to experience negative outcomes to sexual activity, such as an unintended pregnancy or a sexually transmitted infection.

Studies of EC use among young women show that increased access to emergency contraception among adolescents does not result in inappropriate use of EC as a routine form of contraception, nor an increase in the number of sexual partners, the frequency of unprotected intercourse, or the frequency of STIs.^{3,4,5} Young women who have increased access to EC are also no more likely to use EC repeatedly than women who obtain it from a clinic or healthcare provider; but they are more likely to use it sooner, thereby increasing the efficacy of the treatment.⁶

Q. Does making emergency contraception available over-the-counter increase young women’s risk for sexually transmitted infections?

- NO -

EC use is *not* associated with increased risk for future STIs or sexual risk taking behavior among adolescent women.

Women – regardless of age – are able to understand that emergency contraception does not protect against STIs or HIV.

The available scientific research suggests that use of emergency contraception – whether or not a woman is supervised by a licensed prescriber – is *not* associated with increased risk for future STIs or sexual risk taking behavior among adolescent women. In fact, studies show that women who have emergency contraception on hand are more likely to use EC, but are *not* more likely to have unprotected intercourse, to have more sex partners, or to acquire an STI than women who obtain emergency contraception from a clinic or healthcare provider.^{7,8,9,10} Studies have specifically found that easier access to and use of emergency contraception do not put adolescents at a higher risk for STIs^{11,12,13} Major medical and public health organizations are committed to ensuring that women know how protect themselves against STIs.¹⁴

Q. If emergency contraception is available over-the-counter, will healthcare providers be able to educate their young patients about abstinence and contraception?

- YES -

Health care providers can and *should* still counsel their patients about sexual behavior and other pregnancy prevention strategies.

Health care providers are important source of information for teens about contraceptive options and sexual behavior. In terms of EC, unfortunately, few providers routinely discuss it with patients, even when it was prescription only.¹⁵ Having expanded access to EC does not deter women from seeking care from health care providers. In a recent study of young women (aged 13-21), researchers found that EC use may even initiate routine gynecological care.¹⁶

Q. Does making emergency contraception more easily available to teens send a mixed message on abstinence?

- NO -

Making emergency contraception more widely and easily available is consistent with a message that abstinence is the most effective way to avoid unwanted pregnancy.

We can still inform teens that abstinence is the most effective form of birth control, but should also recognize the importance of removing barriers to EC access so teens who have unplanned or unwanted sex or who experience contraceptive failure are able to avoid unintended pregnancy.¹⁷ In addition, one study suggests that *not* providing emergency contraception to adolescents in advance does *not* increase rates of abstinence or postponement of sexual activity.¹⁸

Q. If recent studies of emergency contraceptive use have not shown a decline in pregnancy rates, will EC reduce unintended pregnancy?

- YES -

Especially when given over-the-counter access, a woman who uses EC can decrease her chance of unintended pregnancy.

Recent studies are conflicted as to the overall potential for EC to reduce unintended pregnancy rates.^{19,20} Several studies have failed to show a decline in pregnancy rates due to EC access. While we know EC reduces an individual woman's risk of pregnancy, its population-level effects are harder to detect. Regardless of population-level effects, the emergency contraceptive options available on the market are highly effective and are a valuable resource for women who use them.

Q. Should we remove the current age restriction for over-the-counter emergency contraception?

- YES -

There is no medical or public health justification for restricting young women's access to emergency contraception.

The FDA did not impose age restrictions on Plan B when it was approved for prescription sale in 1998. Dr. John K. Jenkins, Director of the Office of New Drugs in the FDA, later said, "While OTC access to Plan B for adolescents may be controversial from a societal perspective, I cannot think of any age group where the benefit of preventing unplanned pregnancies and abortion is more important and more compelling."²¹ The ruling in *Tummino v. von Eschenbach* found that the FDA's age limit on over-the-counter EC was a "strong showing of bad faith" and a highly politicized decision, and not based on sound medical facts.

Most major medical and public health organizations, including the American College of Obstetrics and Gynecology and the American Academy of Pediatrics, *oppose* placing an age restriction on emergency contraception.²²

¹ Raymond E, Engle K, Tolley E, Ricciotti N, Arnold M, Park S. Comprehension of a prototype emergency contraception package label by female adolescents. *Contraception* 79 (2009) 199-205.

² Cremer M, Holland E, Adams B, Klausner D, Nichols S, Ram R, Alonzo T. Adolescent comprehension of emergency contraception in New York City. *Obstetrics and Gynecology* 113-4 (April 2009). 840-844.

³ Harper CC, Cheong M, Rocc CH, Darney PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. *Obstetrics & Gynecology* 2005;106(3): 483-91.

⁴ Raine T, et al. Emergency Contraception: Advance Provision in a Young, High Risk Clinic Population. *Obstetrics and Gynecology* 2000; 96: 1-7.

⁵ Belzer M, Yoshida E, Tejjirian T, Tucker D, Chung K, Sanchez K. Advanced supply of emergency contraception for adolescent mothers increased utilization without reducing condom or primary contraception use. *Research Presentations. Journal of Adolescent Health* 2003; 32: 122-123.

⁶ Gold, MA, Wolford JE, Smith KA, Parker Am. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *Journal of Pediatric and Adolescent Gynecology*. 2004 Apr; 17(2): 87-96.

⁷ Raine T, et al. Emergency Contraception: Advance Provision in a Young, High Risk Clinic Population. *Obstetrics and Gynecology* 2000; 96: 1-7.

⁸ Belzer M, Yoshida E, Tejjirian T, Tucker D, Chung K, Sanchez K. Advanced supply of emergency contraception for adolescent mothers increased utilization without reducing condom or primary contraception use. *Research Presentations. Journal of Adolescent Health* 2003; 32: 122-123.

⁹ Gold, MA, Wolford JE, Smith KA, Parker Am. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *Journal of Pediatric and Adolescent Gynecology*. 2004 Apr; 17(2): 87-96.

¹⁰ Raine TR, Harper CC, Rocca CH, Fischer R, Padian N, Klausner JD, Darney PD. Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs. *Journal of the American Medical Association*. 2005; 293(1): 54-62.

¹¹ Harper CC, Cheong M, Rocc CH, Darney PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. *Obstetrics & Gynecology* 2005;106(3): 483-91.

¹² Stewart HE, Gold MA, Parker AM. The impact of using emergency contraception on reproductive health outcomes: A retrospective review in an urban adolescent clinic. *Journal of Pediatric and Adolescent Gynecology* 2003; 16: 313-18.

¹³ Raymond E, Weaver M. Effect of emergency contraceptive pill intervention on pregnancy risk behavior. *Contraception* 2008 May; 77(5): 333-336.

¹⁴ Bajos N, Goulard H, Job-Spira N. Emergency contraception: from accessibility to counseling. *Contraception* 2003 Jan; 67(1): 39-40.

¹⁵ Henry J. Kaiser Family Foundation. National Survey of Women About Their Sexual Health, 2003, Menlo Park, CA: Kaiser Family Foundation, 2003.

¹⁶ Stewart HE, Gold MA, Parker AM. The impact of using emergency contraception on reproductive health outcomes: A retrospective review in an urban adolescent clinic. *Journal of Pediatric and Adolescent Gynecology* 2003; 16: 313-18.

¹⁷ FDA, Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, December 16, 2003, Meeting Documents. <http://www.fda.gov/ohrms/dockets/ac/cder03.html#ReproductiveHealth>

¹⁸ Gold, MA, Wolford JE, Smith KA, Parker Am. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *Journal of Pediatric and Adolescent Gynecology*. 2004 Apr; 17(2): 87-96.

¹⁹ Foster DG, Raine TR, Brindis C, Rostovtseva DP, Darney PD. Should Providers Give Women Advance Provision of Emergency Contraceptive Pills? A Cost Effectiveness Analysis. *Women's Health Issues* 2010; 20: 242-247

²⁰ Polis, CB, Raymond EG, Trussell J. Facing the facts on advance provision of emergency contraception. *Contraception* 2010; in press.

²¹ Obtained from an Office Director Memorandum, Office of New Drugs, FDA. Jan.21, 2004.

²² RHTP website: <http://www.rhtp.org/documents/DearCommissionerECOTC.pdf>