

Should Emergency Contraception Be Available without Prescription?

HIGHLIGHTS

- EC meets all of the criteria for over-the-counter status: it is nontoxic, does not cause birth defects, poses no danger of overdose or addiction, and involves no drug interactions or contraindications to usage.
- Women can use EC correctly and effectively without consulting a medical professional.
- Increased access to EC has no negative effects on the sexual risk-taking behaviors of women or teens.
- Nonprescription access to EC is supported by the broader medical community.

What Is the Difference between Prescription and Over-the-Counter Drugs?

U.S. law requires a prescription for drugs that are addictive or necessitate medical supervision to use, while all other drugs, by default, can be sold over-the-counter (OTC).^{1,2} The Food and Drug Administration (FDA) has the authority to switch a prescription drug to OTC status if the drug is both safe and effective when self-administered; potential users can self-diagnose the condition for which the drug is needed; and the drug's label provides clear instructions for use.^{1,2} As a result, more than 700 prescription products have been moved OTC since the 1970s,³ and in 2006, the FDA granted limited nonprescription status to Plan B[®] emergency contraception (EC) for women aged 18 and older. A prescription-only form of Plan B[®] remains available for women aged 17 and younger.

Until the 1980s, drugs were either only prescription or only OTC. The FDA then decided to allow certain drugs to be sold as a prescription product for one use and as an OTC product for another. Plan B[®] is unusual in that the same drug exists as both a prescription and OTC product for the same indication. To enforce the age restriction, Plan B[®] must be sold “behind the counter” in pharmacies/stores staffed by a licensed pharmacist. In order to purchase the drug, personal identification showing proof of age (18) is required. Plan B[®] is available behind the counter at the pharmacy in order to manage both prescription (17 years and younger) and OTC (18 years and older) dispensing. This means it is not sold at grocery or convenience stores, where other OTC products are routinely available.

EC Is Safe as an OTC Product

EC contains the same hormones as birth control pills, one of the most frequently used and thoroughly studied drugs worldwide.¹ Ample scientific evidence demonstrates that EC meets the safety¹ standards for OTC availability.^{1,3}

- EC is nontoxic and carries minimal side effects, the most common of which are nausea and vomiting.
- Unlike aspirin and some other OTC drugs, there is no danger of overdosing on EC; women who use EC repeatedly are, at worst, likely to experience disruptions to their menstrual cycles, in addition to other minor side effects.
- EC is non-addictive.
- EC is non-teratogenic (i.e., it will not harm an existing pregnancy); if a pregnant woman takes EC, it will not disrupt the pregnancy, nor will it pose any risk to her or the fetus.
- There is no evidence of drug interactions with EC.
- Plan B[®] – the sole dedicated EC product on the U.S. market – is progestin-only and therefore lacks the risks related to combined birth control pills containing estrogen. Additionally, unlike combined pills, there are no contraindications to the use of Plan B[®]; in fact, it is considered safe and appropriate even for women who have medical conditions that prevent them from using combined pills long-term.^{1,4}



In light of this clear safety profile, more than 60 health and medical groups – including the American Academy of Pediatrics, the American Medical Women’s Association, and the American Public Health Association – issued a joint petition to the FDA pronouncing that EC is “safer than aspirin.”⁵

Women Can Use EC Correctly and Effectively without Medical Evaluation or Counseling

A major concern about EC OTC is that women need to consult with a medical professional in order to ensure that they use EC appropriately. However, the EC regimen is simple to use and does not necessitate clinical screening required for other hormonal methods of contraception:

- Women can self-diagnose their need for EC (i.e., having unprotected sex) without consultation.^{1,3}
- Clinical breast and pelvic exams are not necessary for the provision of EC, as the conditions for which they screen (e.g., cancer) are unrelated to EC use.⁶ No major medical organization requires pelvic exams or other clinical screening for the provision of EC.⁷
- EC dosage is the same for all women, obviating the need for a professional to prescribe a correct dose.^{1,3}
- There are no contraindications to using EC aside from pregnancy – in this case only because EC will have no effect.^{1,3} If a woman is concerned that she might be pregnant prior to using EC, she can take an over-the-counter pregnancy test.
- Professional monitoring of EC use has no bearing on EC’s effectiveness¹¹ or side effects.^{1,3}

A number of studies have demonstrated that women can use EC correctly in the absence of medical counseling. For example, a “comprehensibility” study found that after reading a prototype label for an OTC EC product, the majority of women – including young and low-literacy women – understood how to use EC safely and effectively.⁸ In an “actual use” study simulating OTC provision of EC, only 1.3 percent of participants used EC improperly, and minors and less-educated women were no more likely to use EC incorrectly than other women.⁹ The authors of these studies concluded that their findings justify OTC availability of EC, and when reviewing the same data, the FDA advisory committees and technical staff agreed.

Improved Access to EC Does Not Affect Women’s Sexual Risk-Taking

Claims that OTC availability would lead to increased sexual risk-taking or excessive use of EC are not substantiated by EC research.¹¹ U.S. studies in which adult and teenage women received EC in advance of need (“advance provision”) have found that participants:¹⁰⁻¹²

- Did *not* engage in higher levels of unprotected sex
- Did *not* abandon their routine method of contraception or use it less consistently
- Did *not* switch to a less effective method of contraception
- Did *not* have greater numbers of sexual partners
- Did *not* have higher levels of sexually transmitted infections

In Great Britain, where EC has been available without prescription since 2001, women are no more likely to have unprotected sex or to stop using reliable methods of contraception than they were prior to the change in access.¹³ Enhanced access to EC also does not lead to repeated or excessive use. The removal of the prescription requirement in Great Britain has not resulted in a greater proportion of women using EC over the course of a year.¹³ Likewise, the actual use study in the U.S. found that only 1.5 percent of women used EC more than once during the three-month study period.⁹

Numerous Barriers Limit EC Access

OTC availability of EC is not only medically and legally justified; it also eliminates the numerous barriers that currently prevent women from obtaining EC in a timely manner. For example, nearly half (48 percent) of university and college health centers do not offer EC.¹⁴ Moreover, a study of providers listed on the national Emergency Contraception Hotline (1-888-NOT-2-LATE) found that one-quarter of calls did not result in an appointment or telephone prescription for EC within 72 hours, which could have been due to lack of follow-through by providers or callers.⁷

Even if a woman obtains a prescription for EC, pharmacists who are opposed to contraception, or who erroneously conflate EC with abortion,¹⁵ may refuse to fill it. As of 2008, four states (AR, GA, MS, and SD) allowed pharmacists to refuse to dispense contraception, and nine states considered such legislation in 2005.^{15,16} Given the narrow time frame in which a woman can initiate the EC regimen, such refusals can limit her ability to use EC, particularly in rural areas where pharmacists may be scarce.^{16,17} While the majority of pharmacists support making EC available in pharmacies, the delays caused by some pharmacists’ refusals to provide EC can reduce its efficacy, since it is more effective the sooner it is taken after unprotected sex.¹⁸ In light of increased publicity about pharmacist refusals, the American Medical Association passed a resolution supporting legislation that requires pharmacists to fill all prescriptions or provide an immediate referral to an alternative provider.¹⁹

II For additional information about EC efficacy, see the brief in this series titled: *Is Emergency Contraception Effective at Preventing Pregnancy?*

III For additional information about EC and sexual risk behavior, see the brief in this series titled: *Does Emergency Contraception Promote Sexual Risk-Taking?*

IV For additional information on the differences between EC and abortion, see the brief in this series titled: *Does Emergency Contraception Cause Abortion?*

Many hospitals fail to provide EC to rape victims. A survey of hospital emergency departments found that between 1992 and 1998, only 20 percent of women presenting for sexual assault received EC.²⁰ Yet in 2008, only 15 states (AR, CA, CO, CT, IL, MA, MN, NJ, NM, NY, OR, PA, SC, TX, and WA) required hospital emergency rooms (ERs) to provide EC-related services to sexual assault survivors.²¹ Catholic hospitals are especially unwilling to offer EC to women who have been raped: another survey found that 55 percent of Catholic hospitals nationwide do not dispense EC, even in cases of sexual assault, compared with 42 percent of non-Catholic hospitals.²² Despite the California law mandating EC services in the ER, staff at 66 percent of Catholic hospitals in the state reported that they do not provide EC under any circumstance, including rape.²³

Eliminating the prescription requirement for EC helps circumvent these obstacles for women seeking to prevent unintended pregnancy. While OTC status will improve access for women ages 18 and older, the “behind the counter” restriction means that access will still be limited to pharmacies, and only when they are open and staffed by a licensed pharmacist.

The Medical and Public Health Communities Support OTC Access for EC

The American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Medical Association, the American Public Health Association, and the International Planned Parenthood Federation have all endorsed OTC availability of EC.²⁴⁻²⁸ In addition, both the American Academy of Pediatrics and the Society for Adolescent Medicine support OTC access for adolescents without age restrictions.^{29,30} When considering the OTC application for EC in 2003, the FDA’s own advisory committees voted overwhelmingly (23 to 4) to switch EC to OTC status.³¹

Many States and Countries Have Sought to Improve EC Access

Though the FDA granted EC nonprescription status for women aged 18 and older in 2006, a number of states had already taken steps to improve EC access for residents. Prior to the FDA decision, nine states (AK, CA, HI, MA, ME, NH, NM, VT, and WA) had allowed pharmacists to dispense EC directly to women without an advance prescription from a doctor.²¹ Worldwide, access to EC is also improving. As of 2008, EC was available without prescription in at least 50 countries: available OTC in India, the Netherlands, Norway, and Sweden and directly from a pharmacist (“behind the counter”) in countries including Australia, Canada, China, France, Israel, South Africa, and the United Kingdom (see Table 1).³²

Table 1: Countries in which EC Is Available from a Pharmacist without Prescription

Antigua	French Polynesia	New Zealand
Aruba	Gabon	Niger
Australia	Ghana	Norway*
Belgium	Guinea-Conakry	Portugal
Belize	Iceland	Senegal
Benin	India*	Slovakia
Burkina Faso	Israel	South Africa
Cameroon	Ivory Coast	Sri Lanka
Canada	Jamaica	St. Lucia
Chile	Latvia	Sweden*
China	Lesotho	Switzerland
Congo	Libya	Tajikistan
Cyprus	Luxembourg	Togo
Denmark	Mali	Tunisia
Estonia	Mauritania	United Kingdom
Finland	Mauritius	United States**
France	the Netherlands*	

* Available over-the-counter

** Ages 18 and older

EC Should Be Available OTC for Women of All Ages

The FDA’s decision to keep EC a prescription product for teens aged 17 and younger ignores the scientific evidence and hinders access for a population that could benefit greatly from OTC availability.^v Allowing equal access for women of all ages should be the next step in the broader effort to prevent unintended pregnancy.

^v For additional information about EC and teens, see the brief in this series titled: *Should Teens Be Denied Equal Access to Emergency Contraception?*

REFERENCES

1. Grimes DA, Raymond EG, Scott Jones B. Emergency contraception over-the-counter: the medical and legal imperatives. *Obstet Gynecol.* Jul 2001;98(1):151-155.
2. Anderson M. What makes a drug "OTC?" The case of Plan B. *Medscape.* Available at: <http://www.medscape.com/viewarticle/505440>. Accessed February 2, 2008.
3. Grimes DA. Switching emergency contraception to over-the-counter status. *N Engl J Med.* Sep 12 2002;347(11):846-849.
4. Westhoff C. Clinical practice. Emergency contraception. *N Engl J Med.* Nov 6 2003;349(19):1830-1835.
5. Center for Reproductive Rights. Center for Reproductive Rights petitions FDA to change emergency contraception from prescription to over the counter. Available at: http://www.crip.org/pr_01_214ecpetition.html#petitioners. Accessed July 13, 2005.
6. Stewart FH, Harper CC, Ellertson CE, Grimes DA, Sawaya GF, Trussell J. Clinical breast and pelvic examination requirements for hormonal contraception: Current practice vs evidence. *JAMA.* May 2 2001;285(17):2232-2239.
7. Trussell J, Duran V, Shochet T, Moore K. Access to emergency contraception. *Obstet Gynecol.* Feb 2000;95(2):267-270.
8. Raymond EG, Dalebout SM, Camp SI. Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product. *Obstet Gynecol.* Aug 2002;100(2):342-349.
9. Raymond EG, Chen PL, Dalebout SM. "Actual use" study of emergency contraceptive pills provided in a simulated over-the-counter manner. *Obstet Gynecol.* Jul 2003;102(1):17-23.
10. Harper CC, Cheong M, Rocca CH, Darney PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. *Obstet Gynecol.* Sep 2005;106(3):483-491.
11. Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *J Pediatr Adolesc Gynecol.* Apr 2004;17(2):87-96.
12. Raine TR, Harper CC, Rocca CH, et al. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. *JAMA.* Jan 5 2005;293(1):54-62.
13. Marston C, Meltzer H, Majeed A. Impact on contraceptive practice of making emergency hormonal contraception available over the counter in Great Britain: repeated cross sectional surveys. *BMJ Online First.* Available at: <http://bmj.bmjournals.com/cgi/rapidpdf/bmj.38519.440266.8Fv2>. Accessed July 12, 2005.
14. McCarthy SK. Availability of emergency contraceptive pills at university and college student health centers. *J Am Coll Health.* Jul 2002;51(1):15-22.
15. The Guttmacher Institute. State policies in brief: refusing to provide health services. Available at: http://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf. Accessed February 25, 2008.
16. Dailard C. Beyond the issue of pharmacist refusals: pharmacies that won't sell emergency contraception. *The Guttmacher Report on Public Policy.* August 2005;8(2):10-12.
17. Cohen SA. Objections, confusion among pharmacists threaten access to emergency contraception. *The Guttmacher Report on Public Policy.* June 1999; 2(3):1-3.
18. Piaggio G, von Hertzen H, Grimes DA, Van Look PF. Timing of emergency contraception with levonorgestrel or the Yuzpe regimen. Task Force on Postovulatory Methods of Fertility Regulation. *Lancet.* Feb 27 1999;353(9154):721.
19. American Medical Association House of Delegates. Report of reference committee on amendments to constitution and bylaws. Available at: <http://www.ama-assn.org/meetings/public/annual05/refcomccbannotateda05.pdf>. Accessed August 4, 2005.
20. Amey AL, Bishai D. Measuring the quality of medical care for women who experience sexual assault with data from the National Hospital Ambulatory Medical Care Survey. *Ann Emerg Med.* Jun 2002;39(6):631-638.
21. The Guttmacher Institute. State policies in brief: emergency contraception. Available at: http://www.guttmacher.org/statecenter/spibs/spib_EC.pdf. Accessed February 25, 2008.
22. Harrison T. Availability of emergency contraception: a survey of hospital emergency department staff. *Ann Emerg Med.* Aug 2005;46(2):105-110.
23. Polis C, Schaffer K, Harrison T. Accessibility of emergency contraception in California's Catholic hospitals. *Women's Health Issues.* Jul-Aug 2005;15(4):174-178.
24. Women's Capital Corporation. Briefing document: nonprescription drugs and reproductive health drugs advisory committee meeting, 16 December 2003. Plan B® (levonorgestrel) for emergency contraception, Rx-to-OTC switch. Available at: http://www.fda.gov/OHRMS/DOCKETS/ac/03/briefing/4015B1_01_WCC-Briefing%20Document.htm. Accessed February 2, 2008.
25. American College of Obstetricians and Gynecologists. ACOG supports safety and availability of over-the-counter emergency contraception. Available at: http://www.acog.org/from_home/publications/press_releases/nr02-28-01-2.cfm. Accessed June 21, 2005.
26. American Medical Association. Policy statement D-75.997: access to emergency contraception. Available at: http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/DIR/D-75.997.HTM. Accessed February 2, 2008.
27. American Public Health Association. Support of public education about emergency contraception and reduction or elimination of barriers to access. Available at: <http://apha.org/legislative/policy/policysearch/index.cfm?fuseaction=view&id=1252>. Accessed June 21, 2005.
28. International Medical Advisory Panel of the International Planned Parenthood Federation. Statement on emergency contraception. Available at: <http://content.ippf.org/output/ORG/files/5609.pdf>. Accessed July 13, 2005.
29. American Academy of Pediatricians. Plan B should be over-the-counter for adolescents: safety data adequate. Available at: http://www.aap.org/advocacy/washing/Plan_B.htm. Accessed August 3, 2005.
30. Society for Adolescent Medicine. Provision of emergency contraception to adolescents: position paper of the Society for Adolescent Medicine. *J Adolesc Health.* 2004;35(1):66-70.
31. Grimes DA. Emergency contraception: politics trumps science at the U.S. Food and Drug Administration. *Obstet Gynecol.* Aug 2004;104(2):220-221.
32. Trussell J, Wynn L. Emergency contraceptive pills worldwide. Available at: <http://ec.princeton.edu/questions/dedicated.html>. Accessed February 25, 2008.

Suggested citation:

Weiss DC, Harper CC, Speidel JJ, Raine TR. *Should Emergency Contraception Be Available without Prescription?* Bixby Center for Global Reproductive Health, University of California, San Francisco. April 2008. Available at: <http://bixbycenter.ucsf.edu/>.



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