

Access to Plan B Emergency Contraception in an OTC Environment

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On August 24, 2006, the Food and Drug Administration (FDA) approved Plan B, the dedicated emergency contraception (EC) product, for over-the-counter (OTC) sale to individuals ages 18 and older. Women 17 and younger are still required to obtain a prescription to get Plan B. Plan B remains available by prescription for women of all ages from authorized prescribers, such as doctors, nurses, physicians' assistants, and midwives. Plan B is also available to women of all ages via the pharmacy access model, which allows a specially trained pharmacist to provide Plan B directly to women without requiring an advance prescription from a doctor or clinic. The FDA decision to establish a dual-label status for Plan B virtually creates a new, third class of drugs and sets a new precedent with significant impact on the medical and legal professions. This article seeks to illuminate for health care providers and legal experts the implications of providing EC in the new OTC environment.

Keywords: dual-label status; emergency contraception (EC); over-the-counter (OTC) access; pharmacy access

On August 24, 2006, the Food and Drug Administration (FDA) approved Plan B, the dedicated emergency contraception (EC) product, for over-the-counter (OTC) sale to individuals ages 18 and older (FDA, 2006a). This decision marked a three-year effort by Plan B manufacturer Duramed Pharmaceuticals, Inc. (a subsidiary of Barr Pharmaceuticals, Inc.),¹ and EC advocates nationwide to make Plan B available without a prescription. Plan B is the only dedicated EC product on the market in the United States today. Each Plan B tablet (the regimen includes two tablets) contains 0.75 mg of levonorgestrel, a synthetic hormone contained in many traditional birth control pills. Plan B has been proven a safe and effective postcoital way to prevent pregnancy (FDA, 2006d) and is up to 89% effective when taken within the first 24 hours after unprotected sex (Task Force on Postovulatory Methods of Fertility Regulation [TFPMFR], 1998; Von Hertzen et al., 2002). It is packaged for use within up to 3 days after unprotected sex, but research shows that it may be effective up to 120 hours after (Ellertson et al., 2003). The mechanisms of action of Plan B are delay

of ovulation, interference with the ability of sperm to reach an egg, and alteration of the lining of the uterus. While it is widely believed that Plan B does not interfere with the implantation of fertilized egg (i.e., the American Medical Association definition of the process of conception to pregnancy), there currently is no conclusive evidence to prove this perspective (Davidoff & Trussell, 2006). However, it is known that Plan B cannot terminate an existing pregnancy (a fertilized egg already attached to the uterine wall), distinguishing Plan B from the abortifacient RU-486.

PROVIDING PLAN B

Plan B is available through several different models of access. These are detailed here and summarized in Table 1.

With a Prescription From an Authorized Prescriber

Women of all ages can obtain Plan B with a prescription from an authorized prescriber, pursuant to the laws of each state. EC prescribers may include nurse

TABLE 1. Over-the-Counter Versus Prescription Access to Plan B Emergency Contraception^a

WHAT	Plan B OTC	Plan B Prescription	Plan B Prescription via Pharmacy Access ^b
WHERE	All pharmacies that stock Plan B (also available directly from clinics).	Prescription available from authorized prescriber. Product available from pharmacist stocking Plan B.	Participating EC Pharmacies (with EC trained pharmacist working under protocol).
WHO	Women and men 18 years of age or older with proof of age.	Prescription available from authorized prescriber for women of any age. (Prescription may be picked up by anyone.)	Women of any age.
WHEN	Product label indicates use within 3 days after unprotected sex and to take two tablets 12 hours apart. May take up to 5 days after unprotected sex and take both tablets at the same time. Also available for future use.	Product label indicates use within 3 days after unprotected sex and to take two tablets 12 hours apart. May take up to 5 days after unprotected sex and take both tablets at the same time. Also available for future use.	Product label indicates use within 3 days after unprotected sex and to take two tablets 12 hours apart. May take up to 5 days after unprotected sex and take both tablets at the same time. Also available for future use.
HOW	Request product at pharmacy counter and present proof of age.	Request prescription from authorized prescriber. Fill at pharmacy.	Request prescription from pharmacist, complete encounter form, receive counseling from pharmacist, receive state mandated EC fact sheet, where applicable (not all states). ^c
HOW MUCH \$	Out of pocket, price is market driven. Average price is ~ \$40. Insurance coverage unknown.	Product covered by the Title X waiver program and/or Medicaid in some states and private insurance plans that cover prescription drugs (in states with EPICC laws). Average price is ~ \$40.	Product covered by the Title X waiver program and/or Medicaid in some states and private insurance plans that cover prescription drugs (in states with EPICC laws). Average price is ~ \$40.
HOW MANY #	No limit.	Limited for Medicaid enrollees, varies with private insurance. No limit to number of refills for those paying out-of-pocket.	Limited for Medicaid enrollees, varies with private insurance. No limit to number of refills for those paying out-of-pocket.

^a Source. Pharmacy Access Partnership (2007).^b Pharmacy access is a model currently available in nine states (Alaska, California, Hawaii, Massachusetts, Maine, New Hampshire, New Mexico, Vermont, and Washington) that allows specially trained pharmacists working under standing order or collaborative protocol with an authorizing prescriber to provide Plan B to a woman requesting it, eliminating the need for an advance prescription from a doctor or clinic. ^c State laws vary in requirements of pharmacy access programs (Pharmacy Access Partnership, 2006b).

practitioners, nurse midwives, physicians' assistants, osteopathic doctors, physicians, pharmacists, and state boards of pharmacy, medicine or nursing.² In a medical facility with an on-site pharmacy (e.g., a clinic), women may obtain Plan B directly from the prescriber. More common, however, is to take a prescription to a pharmacy to have the prescription filled.

The expansion of low-cost and free clinics has improved access to health care services for greater populations, with fewer geographical and economic

barriers for women with limited income and transportation options (Self & Peters, 2005). Nonetheless, doctors' offices and clinics are often not open in the evenings or on weekends or holidays, presenting a significant barrier to timely access to EC. Research shows that Latina, African American, and especially adolescent women are more likely to experience delays in obtaining EC than their White counterparts (Foster et al., 2006). These limitations make pharmacies—which are often open late (some 24 hours) and more widespread in most

communities—an essential point of access for EC. In a national survey of women's attitudes toward pharmacy access to hormonal contraceptives, 76% of women said that not having to pay for a doctor's visit would be a significant personal advantage of the option for pharmacy access (Landau, Tapias, & Taylor-McGhee, 2006).

OTC Access (for Individuals 18 and Older)

The desire to reduce barriers to EC access led Plan B's manufacturer³ to submit a supplemental new drug application (sNDA) to the FDA in 2003 for nonprescription status for the drug. After numerous delays and escalating public attention to the application, the FDA in August 2006 authorized Plan B for dual-label status sales in pharmacies and clinics. The FDA decision required a number of conditions be met for the sale of Plan B without a prescription, described here (FDA, 2006f):

- Plan B may be sold in pharmacies without a prescription to individuals ages 18 and older who present a government-issued (state or federal) identification for proof of age. Plan B must be kept behind the pharmacy counter, and only pharmacy or store staff with access to these products may provide Plan B to customers 18 and older with proper identification. No special training is required to provide Plan B OTC.
- Plan B may be sold to women ages 17 and younger by prescription from an authorized prescriber only.
- Pharmacists may only dispense Plan B as an OTC product with the relabeled dual-label-status packaging.⁴ Older packages of Plan B that do not have the new labeling may be sold only as a prescription product.
- In clinics, Plan B may be furnished to clients as a prescription product for women of any age or as an OTC product for individuals 18 and older.
- Men can buy Plan B if they show proof of age that they are 18 or older; men under 18 do not have the option to obtain a prescription for Plan B.
- Barr will be required to conduct periodic "Point-of-Purchase Monitoring" using anonymous shoppers to track how Plan B is being sold at the time of purchase. Barr will report repeat violators of the age restriction to the relevant state boards of pharmacy.

When an individual purchases Plan B OTC (either in a clinic or in a pharmacy), no consultation, special forms, or provision of fact sheets are required. These

steps are often required only for pharmacy access to EC (see the following discussion). However, clinicians, pharmacists, and pharmacy store staff are encouraged to obtain specialized EC training⁵ to better answer client questions and assess candidacy.

Pharmacy Access to EC

A third option to obtain Plan B in some states is via pharmacy access. Pharmacy access allows specially trained pharmacists working under standing order or collaborative protocol with an authorizing prescriber to provide Plan B, eliminating the need for an advance prescription from a doctor or clinic. In nine states (Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington), all women, regardless of age, can obtain EC directly from pharmacists participating in a pharmacy access program (see Table 2 for legal statutes in these states). In this model, pharmacists may write prescriptions with no limit to the number of refills and can also furnish Plan B to a woman in advance of need to have on hand "just in case." This service is especially crucial for teens under 18 or women without proof of age trying to prevent pregnancy within the short window of time when EC is effective. Today, 88% of California counties have at least one EC pharmacy access pharmacy. Pharmacists in California provide pharmacy access to EC more than any other clinical service (Pharmacy Access Partnership & the American Pharmacists Association, 2005).

Although Plan B is available OTC for individuals ages 18 and over, women of all ages, including teens, may still access EC directly from pharmacists participating in the EC pharmacy access program in states where such a model exists. Because most EC pharmacy access protocols require the pharmacist to initiate a prescription for the patient who will use the product, pharmacy access to EC is not applicable to men.

In some states, a pharmacist may charge a consultation fee if a woman is obtaining EC via pharmacy access (but not if purchased OTC). In California, for example, prior to the approval of Plan B for OTC use, the maximum fee allowed by statute for this consultation fee was \$10 and applies to in-person, telephone, and Internet-based consultations (California Business Code § 4052). This provision in statute was to sunset by operation of law when approval for OTC sales was achieved. Consequently, there is no longer a statutory maximum on how much a pharmacist can charge for

TABLE 2. State Regulatory and Statutory Authorities Allowing Pharmacy Access to Emergency Contraception ^{a,b}

State	Year Effective	Regulatory/Statutory Authority
Washington State	1997	Washington Revised Code Ann. § 18.64.011
California	2002	California Business and Professions Code § 4052
New Mexico	2002	New Mexico Statute Ann. § 16.19.26.9
Alaska	2003	Alaska Administrative Code 12 AAC § 52.240
Hawaii	2003	Hawaii Revised Statute § 461-1
Maine	2004	Maine Revised Statute Ann. Title. 32, § 13821–13825
New Hampshire	2005	New Hampshire Revised Statute Ann. § 318:47-e
Massachusetts	2005	Chapter No. 91 of the Acts of 2005.
Vermont	2006	Vermont Statute, Title 26, Chapter 36, Subchapter 7, § 2077–2079

^a Pharmacy Access Partnership (2006c). ^b National Conference of State Legislatures (2006a).

consultation before furnishing EC via the pharmacy access model.

TEEN ACCESS TO EC

Research shows that women of all ages are more likely to use EC if it is readily available and that, despite the age restriction on access to Plan B OTC, there are no negative health or behavioral effects to making EC more available for young women and there is no medical reason for keeping Plan B a prescription drug for teens under 18. A randomized, single-blind control trial of women 15 to 24 years of age showed that easier access to EC did not increase riskier sexual behavior, did not increase sexually transmitted infections (STIs), and did not reduce use of regular ongoing contraception (Raine, 2005). Reducing unnecessary barriers to EC access has been shown to increase contraceptive use among teens and decrease the likelihood of unintended pregnancy (Belzer et al., 2003). This is especially true for young women, who may have limited modes of transportation to access health care services or may be hesitant to request assistance from a parent or guardian. Furthermore, teens may be less likely to seek EC in environments where they feel threatened by provider bias or lack of confidentiality (Pharmacy Access Partnership & the Pacific Institute for Women's Health, 2005). Leading medical organizations, including the American Academy of Pediatrics (2005), the American Medical Association (2004), and the American College of Obstetricians and Gynecologists (2001), agree that access to Plan B should not be restricted by age.

NEXT STEPS: ANSWERING THE UNANSWERED QUESTIONS

The FDA's action to approve dual-label status for Plan B sales has caused considerable confusion among providers and the legal community about the parameters for OTC access to Plan B. By establishing age restrictions on a product that has been scientifically proven safe and effective for women of all ages, the FDA set a precedent that presents implementation challenges and new policy implications. Public health and legal experts are working to find answers to a number of remaining questions about the provision of EC OTC.

Historic Precedent of the Dual-Label Status

The FDA decision to establish a dual-label status for Plan B set a new precedent for the provision of a pharmaceutical product. First, Plan B is considered over-the-counter for individuals 18 and older but is federally mandated to be kept "behind the counter" where individuals need to request and show proof of age to obtain it. This is different from other behind-the-counter placement practices that may be implemented by retail establishments (e.g., condoms). This concept of requiring the pharmacist (or other qualified pharmacy staff) to control OTC access to the product essentially creates a third class of drugs that is neither prescription-only nor traditionally OTC (i.e., available directly in store aisles).

Second, the restriction of OTC access to Plan B to individuals 18 or older is based not on scientific

evidence of drug safety, as in the case of other drugs with age restrictions, but instead on the precedents set by the age restrictions for other products available in retail outlets (e.g., cigarettes). Different from other products with age restrictions, Plan B was approved for prescription use among women of all ages (Government Accountability Office, 2005). As part of the nonprescription application requirements, the original Plan B OTC application submitted in 2003 included data from a double-blind randomized study among nearly 2,000 women showing that Plan B was safe and effective for use without a prescription for women of varied ages (TFPMFR, 1998). Moreover, a joint meeting of two FDA scientific advisory panels voted 23 to 4 in December 2003 to grant OTC status to the drug (FDA, 2006b). Despite these conclusions, in May 2004 the FDA rejected its own advisory panels' recommendation (an unusual departure from tradition) and issued a "not approvable" letter to the OTC application based on the agency's determination that there were too little data on teen girls to show safety among this population. During repeated delays of the decision on the application, the FDA indicated that it required additional time to evaluate the product safety for 16- and 17-year-olds. In an effort to address the FDA's concerns, Barr submitted a revised application for limited OTC access for women 16 and older. The FDA, however, raised the age limit to 18 and older in its approval for OTC sale. In a memo about the age restriction for Plan B OTC, then acting FDA commissioner Andrew von Eschenbach addressed why the age limit was set at 18 despite the lack of medical indications for this age limit:

In an August 26, 2005 memo written by Dr. Steven Galson, the Director of the Center for Drug Evaluation and Research (CDER), CDER found that for women 17 and older the existing Rx dispensing requirements for Plan B are not necessary to protect the public health and that an Rx-only to non-prescription switch for those consumers is authorized under 21 U.S.C. 353(b)(3) and 21 CFR 310.200. CDER also determined, however, that Barr had not established that Plan B could be used safely and effectively by young adolescents—girls 16 and younger—for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug.... In considering the difficulty of enforcing an age-based restriction on the availability of this oral hormonal contraceptive, I have concluded that 18 (rather than 17) is the more appropriate cutoff point to best promote and protect the public health. The state-regulated pharmacies are more familiar with 18 as a cutoff age. I understand that in all 50 states, 18 is the age of majority (i.e., the legal delineation between minor and adult), and retail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of certain products. With regard to drug products, for example, the legal age

to purchase FDA approved non-prescription nicotine replacement therapy products is 18. Moreover, I also understand that as a matter of state law many products routinely sold by pharmacies, e.g., tobacco products and non-prescription cough-cold products like pseudoephedrine, are restricted to consumers 18 and older. (FDA, 2006e)

The restrictions for pseudoephedrine provide a relevant comparison with the historic precedent of establishing a dual-label status for Plan B. The Combat Methamphetamine Epidemic Act of 2005 restricts the sale of products containing pseudoephedrine (commonly found in OTC cold medications) to behind the counter or from a locked cabinet. Providers furnishing such drugs must also limit monthly sales to any individual, require photo identification to purchase such medications, and keep personal information about customers for at least 2 years after the purchase of these medicines (FDA, 2006c). Some states, such as Ohio, have also added age restrictions (Ohio Revised Code § 3719 and § 4729).

The decision to restrict OTC access to pseudoephedrine (after it was originally approved for OTC access for all ages) was based on the fact the pseudoephedrines can be used to create methamphetamines, a highly addictive and potentially lethal substance. Although some state laws establish age restrictions for pseudoephedrine sales, the FDA does not indicate a specific age requirement despite evidence showing the drug's harmful potential (FDA, 2006c). In contrast, Plan B emergency contraception has been determined by two FDA medical advisory panels to be highly safe and effective for women of all ages, with no incident of overdose or fatalities (Davis, 2003; TFPMFR, 1998; Von Herzten et al., 2002). Basing the restriction on OTC access for Plan B on subjective opinion rather than on scientific evidence sets a dangerous precedent. In a time when increasingly sophisticated pharmaceutical treatments come to market each day, the safety of the public's health depends on FDA decisions based on sound scientific evidence.

The Role of Pharmacists in a New Access Model

The precedent set by the behind-the-counter status of Plan B essentially creates a new, third class of drugs and gives pharmacists (and other qualified pharmacy staff) a more central role in the provision of health care products and services. By requiring individuals to request the OTC Plan B product from the pharmacist, pharmacists have more control over the dispensing of the drug in a way that they do not for other OTC products available directly in pharmacy aisles. Numerous states already have laws on the books allowing pharmacists to

decline to fill prescriptions for certain products based on a belief that a drug may be harmful to the patient or based on personal or religious beliefs (Boonstra, 2006). For example, Arkansas, Colorado, Florida, Georgia, Maine, Mississippi, South Dakota, and Tennessee allow clinicians and pharmacists to refuse to dispense EC for personal or religious beliefs (National Conference of State Legislatures, 2006b). Other states, such as California, have laws that require pharmacies to dispense or otherwise make available through referral all FDA-approved contraceptives (California Business Code § 733). It is beyond the scope of this article to determine whether legal precedent exists to require the sale of Plan B as an OTC product since the requirements on pharmacist sales of Plan B vary widely by state and have thus far been based on Plan B as a prescription product. However, the nuances of these state laws will likely be further explored as new scenarios arise in this OTC environment.

New Pharmacy Access Legislation

Pharmacy access programs continue to offer improved access to EC in pharmacies for women under 18. While nine states have established laws or regulations to facilitate this program, a dozen others have also introduced similar legislation in previous sessions. Various states, including Illinois and New York, again have introduced new pharmacy access legislation this year—despite its current OTC availability—with a particular focus on increasing access for teens, women who need a prescription for state-funded insurance coverage, and women without proper identification.

Health Plan Coverage

It is not yet determined if private insurance plans will cover Plan B as an OTC product. Typically when products switch from prescription to OTC, they are no longer covered under insurance plans. Lack of insurance coverage would be another significant barrier to EC access. Nonetheless, if a woman has a doctor's prescription for Plan B or gets EC via pharmacy access, the pharmacist can bill private insurance or government-funded insurance programs. Some states have passed laws requiring equity in prescription insurance and contraceptive coverage that require health insurance plans that cover other prescription drugs from excluding coverage of contraceptive products, including emergency contraception (Center for Reproductive Rights, 2005). Several states also provide coverage for EC under state Medicaid programs. The majority of state programs require a woman to obtain a prescription for Medicaid coverage,

thereby eclipsing the benefit of easier access gained by making Plan B available OTC (Lopez, Rivera, Hooton, & Schaffer, 2005). A national working group has convened to explore EC coverage in state Medicaid programs and will make the most current information available to the public as soon as it is updated.

CONCLUSION

Additional policy changes will be necessary to further broaden access to EC for all women, especially women in underserved communities, women of color, and young women. Nonetheless, the availability of Plan B EC without a prescription is a notable milestone on the path to increasing contraceptive access for women. Reducing unnecessary restrictions to reproductive health services is essential to decreasing rates of unintended pregnancy. Relabeling Plan B for use up to 5 days after sex, for example—a protocol shown to be effective and already in place informally in some states—would increase the window of time during which women could prevent an unintended pregnancy. Moreover, while the current package label regimen recommends taking the two pills 12 hours apart, research has shown that taking the two pills at once is safe and effective. Standardizing the Plan B regimen to a single dose of both tablets taken at one time—and reflecting such a standard in the instructions for use of the new dual-label-status product—may decrease user error and compliance and thus increase the effectiveness of the drug. Finally, removing the age restrictions on OTC access to Plan B would minimize prohibitive delays that can impact a woman's ability to prevent an unintended pregnancy.

NOTES

1. A supplemental new drug application (sNDA) was filed formally by Duramed Research Pharmaceuticals, a wholly owned subsidiary of Barr Pharmaceuticals. From this point forward, the Plan B manufacturer will be referred to as Barr (FDA, 2006e).

2. State boards of pharmacy, medicine, or nursing serve as the legal prescriber with which a nonprescriber (i.e., pharmacist) could establish a collaborative protocol to be able to furnish EC to a client.

3. Women's Capital Corporation (WCC) owned Plan B at the time the OTC application was submitted; WCC subsequently sold the product to Barr Pharmaceuticals, the company that currently holds the rights to the product.

4. Pursuant to the FDA decision, the product was relabeled with language that states "Rx only for age 17 and younger" to reflect the prescription requirement for

women 17 and younger. The newly packaged product was shipped to providers nationwide in November 2006.

5. A 1-hour online training program is available for CE units at <http://www.pharmacyaccess.learnsomething.com>.

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