

Plan B OTC: Not a total solution

Authorizing pharmacists to prescribe EC for patients of all ages could benefit many

August 24, 2006, is an important milestone in pharmacologic birth control. On that date, FDA approved the sale of Plan B (levonorgestrel—Barr) without a prescription. The OTC product was shipped to pharmacies in November, and American women older than 18 years with proof of age can now walk into just about any community pharmacy and obtain emergency contraceptive (EC) tablets without having to see a physician for a prescription.

Plan B has been available by prescription since 1999, and minors continue to need a prescription under this unique dual-status decision. Barr and several other groups had asked FDA to make the product available OTC because doing so would help women obtain it within the critical 72-hour time period when the drug is most effective without having to see a physician, thus saving both time and money.

The Plan B decision created an unusual situation in which an identical product will be dual labeled and available in the United States both with and without a prescription. "There has been considerable controversy about Plan B in the lay press," noted Don Downing, BPharm, Clinical Associate Professor at the University of Washington in Seattle, "as well as several areas of concern that affect pharmacists." Pharmacists are now faced with an entirely new way of providing EC, he said. "It's not just simply the need for checking IDs. It raises some important questions about the influence of the FDA decision on collaborative practice arrangements and access to care for low-income individuals," Downing told *Today*.

Pharmacist-provided EC: A brief history

In Washington state, pharmacists have been authorized since 1979 to enter into collaborative-practice agreements with physicians and nurse practitioners that allow pharmacists to prescribe under protocol. In 1998, based on these agreements, pharmacists in Washington began initiating EC prescriptions for women



who wanted EC in advance of need or who had had unprotected sex within the previous 72 hours and did not want to get pregnant.

Downing, who played a key role in establishing the effectiveness of pharmacist-provided EC, described a typical scenario that occurred even before the recent FDA decision: "A 17-year-old comes to the pharmacy on a Saturday afternoon. She states that the condom broke during intercourse the previous evening, and she is afraid she

might get pregnant. The pharmacist initiates the prescription and provides the young woman the medication she needs within the 72-hour window of opportunity, even though her physician is not available."

Washington State also led the way in developing collaborative agreements that allow pharmacists to initiate prescriptions for regular contraceptive pills, patches, and vaginal rings for women who are in the pharmacy for EC or other reasons.

Before FDA's decision last August, Washington was one of nine states that had taken steps to make Plan B more easily accessible to their residents. The others were Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Vermont. Each enabled pharmacists to provide EC to patients without having them first see a physician. Now in these states, patients younger than 18 who need a prescription for EC can obtain Plan B simply by speaking directly with a pharmacist authorized to initiate an EC prescription under protocol.

ID requirement a roadblock to care

Downing pointed to FDA's requirement that pharmacists check IDs before dispensing EC as a serious inconsistency that can have crucial consequences for patients. Some states still do not require ID for EC, and FDA does not specify what form of proof of age is required.

Since last fall, pharmacists in the nine states authorizing EC prescribing under collaborative agreement can still initiate a prescription for women who appear to be older than 18 but don't have the ID to prove it. In the other states, women without proof of age have to be referred to a physician or clinic to obtain a prescription for Plan B.

Considering this, Downing said, "It makes little sense to me to have pharmacists in some states able to provide the crucial assistance at the time when it is most needed—and most likely to be effective—while other states have

volunteer

Call for volunteers

The APhA Books and Electronic Products Department invites interested APhA members from the fields of pharmacy practice, pharmaceutical science, and pharmacy technician education to apply for positions on the APhA Books and Electronic Products Editorial Advisory Board (EAB). The term of service is 3 years, beginning September 1, 2007. Candidates should have

- Peer reviewed three book proposals/manuscripts
 - Authored five or more journal articles
 - Acquired knowledge of or interest in publishing
- Responsibilities of APhA Books and Electronic Products EAB members are to
- Advise APhA staff on pharmacy education curriculum changes, trends in pharmacy education and practice, and preferable formats for published resources (print, Web)
 - Recommend new books or electronic products
 - Recommend outstanding prospective authors
 - Assist APhA staff in promoting the Books and Electronic Products program
 - Review book proposals and book manuscripts or recommend qualified peer reviewers who can do so
 - Provide concise opinions on timely issues
 - Participate in two EAB meetings per year, one in late September and one during the APhA Annual Meeting

Interested individuals should e-mail or post a letter summarizing their qualifications and a current CV to Julian I. Graubart at jgraubart@aphanet.org or APhA, 1100 15th St., NW, Suite 400, Washington, DC 20005. Applications must be received by July 1, 2007.



roadblocks. In Washington, it wouldn't be against the law for pharmacists with EC collaborative agreements to give Plan B to a woman younger than 18 or who did not have the required identification, while in another state, it would be illegal." According to Downing, it is critical that pharmacists be able to take care of individuals in the pharmacy at the time of the request, with special focus on high-risk patients under 18 or who are otherwise without an ID.

Accessibility is pharmacists' greatest resource

Downing emphasized the importance of other states' guaranteeing pharmacists the ability to serve all who request EC, even when the product is behind the counter. The necessity for consensus among the states that Plan B should be available to all those who request it becomes even more important when a rape victim presents to the pharmacist. In this emergency situation, the pharmacist needs to be able to provide both the product and the counseling and referral without delay.

Pharmacists are often the first point of access for women who need information about reproductive health and supplies, and pharmacists see the provision of information and counseling as crucial parts of their job. In fact, for quite some time, many pharmacists have been counseling patients who take birth control pills about EC; pharmacists frequently tell women who have forgotten one or two of their pills to double up their dose for a day or two to prevent an unintended pregnancy. The double dose of levonorgestrel in Plan B is essentially the same as the single dose of the progestin found in many forms of hormonal birth control formulations; the estrogen is omitted in Plan B to prevent adverse effects.

"Personal consultation between a patient and pharmacist is a very important part of patient education," Downing remarked. "In addition to offering information or counseling at the pharmacy, I frequently refer patients to other health care providers in the community. For example, if someone comes in repeatedly

for EC, it may be appropriate to discuss why their current mode of contraception seems to be failing. And, if more information or services are needed, I might refer someone to a clinic."



Having access to pharmacists empowered to meet their EC needs is especially critical for patients with limited incomes. Medicaid policies differ from state to state. Many do not cover OTC products, including Plan B, and several that do provide Medicaid coverage for OTC products require a prescription for them. Not being able to pay

for OTC Plan B can be a serious problem for low-income patients, but pharmacists with the ability to initiate a Plan B prescription may be able to reduce cost concerns. Although the wholesale cost for Plan B is approximately \$30, the cost to the consumer varies widely.

Also, those younger than 18 often have no income, yet in all but nine states, access to Plan B requires a prescription and office visit. Allowing pharmacists to prescribe EC would significantly reduce the number of these neediest patients who cannot pay for EC.

Downing stated, "Pharmacists play an important advocacy role for the public, especially for those who may not have the ability to pay for what they need. We can be an important point of access for our low-income clients. Pharmacists can advocate for these neediest of patients by supporting collaborative agreement legislation that allows them to address their low-income clients' medication access needs."

"Now that women can use pharmacies as their access point to emergency contraception," Downing concluded, "it is crucial that pharmacists become better educated about this topic and more informed about the kinds of resources available in their community. Like the first link in a chain, pharmacists can provide both the product and counseling about emergency contraception. It is also a critical opportunity to make a referral to another health care provider or social service agency."

—Sarah Zarbock, PA-C
Contributing writer