

Plan B Availability OTC Raises Logistical and Administrative Challenges

FDA approval for emergency contraceptive begs questions of logistics, ethics and public policy

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Food and Drug Administration (FDA) in August finally put to rest questions surrounding the classification of the emergency contraceptive (EC) medication levonorgestrel (Plan B®) by approving it for over-the-counter (OTC) sales to women 18 and over, while keeping it a prescription-only product for women 17 and younger. The drug's unique classification, however, has raised a number of logistical and administrative uncertainties, and, of course, the many ethical and public policy questions surrounding the use of the drug still remain.

BACKGROUND

Since Plan B's introduction, various factors, including a lack of information about EC on the part of both patients and health care providers and the relative inaccessibility of prescribers during nonbusiness hours, have hindered the ability of patients to obtain the product, which must be taken within 72 hours of unprotected intercourse. Because of these factors, and because of the high cost – on many measures, not just financial – of unwanted pregnancies, some groups viewed OTC access to Plan B to be highly desirable. Other groups, concerned that easy access to EC would encourage risk-taking behavior or that EC itself constitutes abortion, opposed the prescription-to-OTC switch. While the August 24 FDA approval was intended to make Plan B more easily available to women within the narrow window of effectiveness, its new dual status as both a prescription and OTC drug raises a number of logistical questions for pharmacists, patients, and regulators. How will the hot-button issue of conscientious objection be affected by Plan B's increased availability? How will



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authorities monitor age verification and record keeping? Will Plan B be available over the Internet? Will counterfeiting be a problem? How will pharmacists receive training on the medication and its distribution? Many of these questions will have to be answered on an ongoing basis, as pharmacists and regulators see how reality plays out in the marketplace. But we have at least the beginnings of answers now, and a basis from which to move forward.

CONSCIENTIOUS OBJECTION

The rights of pharmacists to conscientiously object to filling certain prescriptions due to firmly held moral or religious beliefs (or rather, the right to do so without fear of repercussion) garnered much national attention in the last couple of years, particularly as it related to contraception. (See "Pharmacists' Consciences Take Center Stage," in the June-July 2005 *NABP Newsletter*.)

Some of Plan B's controversial nature stems from a basic misunderstanding of what it is. Many protests registered with FDA during the open comment period regarding Plan B's potential move to OTC status objected to the drug's supposed function as an abortifacient; some comments even referred to Plan B as mifepristone, which is actually an abortifacient (also known as Ru-486). Professionals are less likely than the lay public to confuse levonorgestrel with mifepristone, but Plan B's marketer, Duramed Pharmaceuticals, Inc (a subsidiary of Barr Pharmaceuticals, Inc, its manufacturer), plans a comprehensive education program for health care providers to introduce and educate them about the product.

Even though Plan B acts as a contraceptive, not an abortifacient by traditional legal or ethical standards – it acts primarily by preventing ovulation, though it also may prevent fertilization or implantation of a fertilized egg in the uterus, and will have no effect if a fertilized egg has already been implanted – this by itself violates some pharmacists' moral or religious standards.

Ultimately, though, the status of Plan B as an OTC or prescription drug, alone, does not change the ongoing conscientious objection debate. Moderates – those who advocate respecting the moral and religious standards of pharmacists while still ensuring that patients have access to needed medications – generally concur

with the American Pharmacists Association's official stand on the issue. This position suggests that pharmacists and their employers address the issue long before a patient walks through the door. A pharmacist would file a written statement with his or her employer stating which drugs he or she would refuse to dispense, and why, and include a strategy for ensuring that patients' rights are not impeded.

The Texas State Board of Pharmacy takes a similar stand. While Texas law does not include a conscience clause allowing pharmacists to refuse to sell a product or dispense a prescription based on moral grounds, the Board acknowledges on its website that "a pharmacist does have a professional responsibility to his/her patients." The Board's position states that, "If a pharmacist is unable to sell a medication or fill a particular prescription for any reason, he/she should refer the patient to another pharmacist at the pharmacy, if possible, or refer the patient to a pharmacy where the patient may obtain the medication."

Pharmacists should also consider their career trajectory in light of their moral views; for example, a pharmacist with strong beliefs against contraceptive drugs might prefer to work in a setting that would not normally dispense EC. Whether some states will enact legislation or promulgate rules attempting to force all retail pharmacies to carry EC, as Illinois' governor did in a controversial emergency measure in 2005, which has since become a permanent rule, is another question, and one with no easy answers.

PATIENT ISSUES AND AGE MONITORING

The push behind making Plan B available as an OTC product was, of course, to ease patient access to the drug and to make it possible for more women to take it within its effective window, reducing unwanted pregnancies, abortions, and their high emotional and monetary costs. This easier access, however, also raises a number of questions, many of which will not be answered immediately, and some of which will undoubtedly result in legislative and regulatory, if not judicial, actions.

One question arises on the social level. While easy access to EC may reduce unwanted pregnancies, will it result in other

social costs, such as increased sexually transmitted diseases (STDs), as women feel freer to engage in more risk-taking behaviors? While the Plan B packaging and insert clearly state, more than once, that it is not a substitute for routine forms of birth control and does not prevent STDs, will patients heed this warning?

While no one knows a firm answer to these questions at this point – though past studies tracking women who were given a supply of EC to keep on hand in advance of potentially needing it indicated that access to EC did not result in riskier sexual behavior – Barr Pharmaceuticals has its eye on the issue. As part of the company's proposed marketing, education, distribution, and monitoring plan presented to FDA, Barr Pharmaceuticals states that it will monitor relevant survey data regularly collected by such entities as the Centers for Disease Control and Prevention, the Youth Risk Behavior Safety Surveillance, and nongovernmental organizations to track data and trends in STDs as well as pregnancy and abortion rates. "[Barr Pharmaceuticals] will monitor for potential indicators that Plan B is being used in an inappropriate manner," the proposal states. The company also plans to conduct surveys among health care professionals to determine such issues as trends among EC users, including STD incidence and reliance on EC instead of regular contraception.

The dual prescription/ OTC status of Plan B is meant to address at least some of these concerns, if not completely alleviate them. FDA indicated during the initial application process that research adequately indicated women 17 and over could responsibly use EC as intended; the research did not, however, provide much evidence on younger girls. Presumably, researchers will now be able to more fully test assumptions regarding both older and younger users of EC.

FDA set the age for OTC purchase as "18 and older" (rather than the initially proposed "17 and older") in large part because "retail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of certain products," wrote Dr Andrew C. Von Eschenbach, then acting commissioner of FDA, in an August 23, 2006 memo. He noted that "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, eg, tobacco products and non-prescription cough-cold products like pseudoephedrine, are restricted to consumers 18 and older."

Von Eschenbach noted in his memo that Barr Pharmaceuticals had proposed selling Plan B only in state-licensed pharmacies (or clinics), with health care personnel present. Indeed, Barr Pharmaceuticals has specified that the drug will only be stocked "behind the counter," available upon request. "Leveraging well-established state and private-sector infrastructures will allow for comprehensive and effective enforcement of the age-based restrictions," the memo states. "As a result, this approach should minimize the likelihood that younger girls . . . will have access to the product without professional supervision."

Other questions have been raised, as well. What is to prevent a 17-year-old girl from getting her 18-year-old friend to purchase the drug? How about her 18-year-old boyfriend? Or what if she carries fake identification? (And ultimately, how important are these inevitable lapses in the system?) Will the buyer's age be checked at the register by a simple glance at, say, a driver's license, or does the buyer's information need to be recorded in a log – creating more work for busy pharmacists and technicians?

Some of these questions will be decided by company policy or state rules and regulations. Others, revolving around the behavior of the women who need the medication, may be partially answered by Barr Pharmaceuticals' ongoing examination of survey data, discussed above.

Barr Pharmaceuticals, meanwhile, plans a point-of-purchase monitoring program that aims to track how Plan B is being sold. The program will use anonymous shoppers, ages 15 to 18, to visit locations around the country where Plan B is available, to purchase the product. "These findings would provide concrete information on how the prescription age requirement for Plan B is being addressed at the pharmacy and if it is properly being followed," the plan states. "[Barr Pharmaceuticals] will use these findings

to identify areas where more education on the prescription age requirement is needed and will focus their efforts on improving the level of understanding among pharmacists and the pharmacy staff.”

Barr Pharmaceuticals anticipates eventual involvement on the part of regulatory authorities only if necessary. “Findings from the study will be communicated to the pharmacy, and the corporate office, if appropriate, since education and retraining will be the first course of remedial action,” the proposal states. “In the case of repeat violators, the violator’s State Board of Pharmacy will be notified.” Meanwhile, Barr Pharmaceuticals will provide the monitoring program’s results to FDA on a regular, ongoing basis.

THE INTERNET

Age monitoring also remains relevant for Internet purchases of Plan B as an OTC product. How will legitimate online pharmacies ensure that the buyer is of age?

According to Jonathan Tinter, vice president of marketing and strategy at drugstore.com, a Verified Internet Pharmacy Practice Sites™ (VIPPS®)-accredited online pharmacy, at press time his company was planning to sell Plan B OTC, but had not yet begun to do so. “We verify age by requiring that the customer have a valid credit card – federal law requires that credit card holders be over the age of 18,” he stated. He noted that the site states that customers under age 18 may not purchase age-restricted products. Meanwhile, he stated, “Prior to launching Plan B as an OTC product, we have posted a special page [www.drugstore.com/planb] that serves to educate our customers on Plan B dosage and precautions.”

While legitimate Internet pharmacies, such as those accredited by NABP’s VIPPS program, can provide convenient access to Plan B, the Internet also makes it easy for rogue sites to sell counterfeit Plan B – much as it currently facilitates the sale of other counterfeit drugs. And it is logical to assume that greater awareness of Plan B could lead to greater demand, increasing its attractiveness to counterfeiters.

Efforts on the part of boards of pharmacy to increasingly protect the prescription drug supply chain through the more stringent regulation of wholesale drug distributors may counter some of these

concerns, at least for those who purchase Plan B from legitimate, licensed brick-and-mortar or Internet pharmacies.

PHARMACIST TRAINING

Educating health care providers about Plan B forms one of the central elements of Barr Pharmaceuticals’ “CARE” (Convenient Access, Responsible Education) program outlined to FDA. The company plans to introduce and explain Plan B to providers, both to raise awareness and knowledge levels regarding EC, as well as to encourage such entities as pharmacies and clinics to carry the product, easing women’s access to EC. “Physicians, physician assistants, nurse practitioners, office staff, pharmacists and pharmacy staff are the primary audiences for this educational program,” the plan states. “Pharmacists and pharmacy staff are especially important because they will need to be prepared to answer questions at the point of purchase and follow the protocol, when appropriate, for asking customers to provide government-issued identification of their age.” Pharmacy education will also focus on the prescription requirement for patients 17 and younger and on proper dispensing of Plan B by prescription or OTC.

According to the Barr Pharmaceuticals plan, the education program includes continuing education by certified professionals and educational materials. Barr Pharmaceuticals “will make available to the state boards of pharmacy continuing education programs for use at annual meetings and other regional programs,” the plan states. Barr Pharmaceuticals “will also encourage state boards of pharmacy to provide information to their members regarding the availability and appropriate use of Plan B, as well as the prescription only requirement for women age 17 years and younger. In addition, [Barr Pharmaceuticals] will work closely with retail pharmacies to ensure that they have access to appropriate training materials for their pharmacists and pharmacy staff.”

After health care workers have been introduced to Plan B, Barr Pharmaceuticals plans to roll out a consumer education campaign targeted at 18- to 44-year-olds. The company estimates that this will begin “about six months following product launch.”

A CALL FOR A THIRD CLASS OF DRUGS

Plan B’s “pharmacy-only” status has once again raised the idea, long advocated by NABP and NABP Past President Ruth Vandever, of a third or “transitional” class of drugs. These drugs would be those that would not require a prescription but would require patient counseling, particularly as the drugs move from prescription to OTC status. In theory, this class of drugs would be available only from persons legally authorized to prescribe and/or dispense prescription medications. (See “Increase of Prescription-to-OTC Drugs May Endanger Patients; NABP’s Call for Transitional Class Revisited,” in the April 2004 *NABP Newsletter*.)

Pharmacists have an important role to play in counseling patients regarding Plan B use.

As NABP has noted in the past, requiring patients to be counseled by a pharmacist before receiving medications such as Plan B would not decrease access to the drug but may prevent misuse and protect patients from possible harm.

The many questions raised by Plan B’s unique status as both a prescription and OTC medication will not be answered immediately. The state boards of pharmacy will be drawn into the issue by assisting in professional education efforts, enacting new rules and regulations, weighing in on state legislation, and more. As what might be considered the first FDA-sanctioned transitional drug, Plan B should offer an educational journey. ●

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