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VIEWPOINT

How Can Pharmacies Improve Access To Emergency Contraception?

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Over the past 10 years, leaders of the medical community have played an important—albeit sometimes lonely—role in efforts to increase access to hormonal contraception by arguing for its deregulation. In the mid-1990s, evidence in favor of deregulation of the pill showed that it meets all customary criteria for over-the-counter status: It poses no known health risks, has only minor side effects and can be used without medical supervision.[1] More recently, interest in deregulation has focused on emergency contraceptive pills.[2] The time-sensitive nature of emergency contraception—and the fact that it is for single as opposed to continuous use—has greatly strengthened arguments in favor of deregulation, and has heightened the need for improved public access.

Pharmacies are an ideal access option for emergency contraception. In Washington and California, the method is already offered directly at pharmacies, and statewide organizations have been active in engaging independent and chain retail pharmacies to expand consumer access to other family planning services. These states are demonstrating the significant potential and promise that pharmacies can offer women in need of family planning services.

WHY DEREGULATE EMERGENCY CONTRACEPTION?

Efforts to deregulate emergency contraception received a major boost when the American Medical Association in late 2000 and the American College of Obstetricians and Gynecologists (ACOG) in early 2001 approved resolutions supporting over-the-counter status for the method.[3] Both organizations cited the safety of emergency contraception and the direct benefit to women of making it readily available. Additionally, ACOG stressed that if emergency contraception were available, it could contribute to substantial reductions in the U.S. abortion rate, thus enlarging the benefit of a switch to over-the-counter status to indirectly include public and community health.

Timely access to emergency contraception is not just a matter of convenience, but one of necessity. The method is intended to be used after contraceptive failure or

unprotected intercourse, but before a pregnancy is established. It is most effective if treatment begins within 24 hours after unprotected intercourse,[4] and the current recommendation is that treatment begin within 72 hours; the method may, however, be effective if used within five days.[5] In this very brief window of time, emergency contraception can act by delaying ovulation, preventing fertilization or preventing a fertilized egg from implanting. Once a pregnancy is established, use of emergency contraception is harmless and ineffective; it will not terminate a pregnancy.

The circumstances leading a woman to need emergency contraception also make the method unique. Couples do not plan on having contraceptive failures, and few women who desire to avoid pregnancy plan to have unprotected sex. Thus, as its name implies, the need for emergency contraception most often arises suddenly or unexpectedly, and the potential user knows that immediate action is required.

Clinics and physicians' offices, where women normally obtain prescription contraceptives, present clear access barriers. A woman who experiences a contraceptive failure on Friday night often has to wait until Monday morning to contact her health care provider, and may not be able to get an immediate appointment. Advance provision of the method through a physician or clinic can potentially help women who have a regular provider, but is of little help to others, including many couples who rely on condoms for protection. For these individuals, more immediate access than is typically available for prescription drugs is critical.

OPTIONS FOR DEREGULATION

Currently, the federal government recognizes two classes of drugs—prescription and over-the-counter—which are distinguished by two characteristics. The obvious difference between the two is that prescription drugs cannot be obtained without a prescription.* Moreover, they can be sold only in pharmacies. In contrast, over-the-counter drugs can be sold at any type of commercial site.

This two-class drug system has not always been the norm. Informally, a third category, "at the counter," used to exist in the United States, and made drugs more widely available to the public while still maintaining some level of control.† Similar designations are in place in many countries, including England, Canada and France. In the United Kingdom, emergency contraception is designated a "P" (or pharmacy) medicine, a term applied to drugs that have been partially deregulated; application for that status was made under the general terms of an over-the-counter license for emergency contraception.

Emergency contraception is available without a prescription in registered pharmacies in Britain, and the Royal Pharmaceutical Society has issued practice guidelines for its supply. These guidelines require that the pharmacist obtain enough information to assess appropriateness of use, explain how to use the method and describe possible side effects. In 2001, when the government first allowed pharmacists to provide emergency contraception, the guidelines also had an age restriction of 16 years and older, but this restriction has since been eliminated. Similarly, French guidelines first prohibited pharmacists from providing emergency contraception to teenagers, but in early 2002, the government did away with that restriction.

The existence of a pharmacy or at-the-counter designation for drugs can clearly be

very useful. It enables the public to more easily obtain important medications while ensuring some level of professional consultation. For contraceptive drugs, including emergency contraception, where debate surrounding availability has tended to focus more on attitudinal issues than on evidence-based medicine, this option has another value: It permits social and political compromise.

Deregulation of drugs in this country can be addressed through both federal and state measures. The most potent way to deregulate a drug is to change its status from prescription to over-the-counter—an action that can be taken only at the federal level, by the Food and Drug Administration (FDA). Action to grant over-the-counter status for emergency contraception was attempted in early 2001, when a citizens' petition was filed with the FDA on behalf of 65 medical and advocacy groups. The FDA failed to take action, and the Women's Capital Corporation—the distributor of Plan B, one of the two dedicated emergency contraception products on the market—is planning a second attempt, buttressing its argument with data from "labeling comprehension" and "actual use" studies, both of which are normally required by the FDA before a drug is switched from prescription to over-the-counter status.[6]

States have more limited authority. They can decide what types of providers (e.g., physicians, nurse practitioners or pharmacists) may prescribe medications and under what circumstances. In Florida, for example, pharmacists may prescribe certain medications, and they are not required to follow any standard protocol. In Washington, pharmacists may prescribe virtually any prescription medication, but they must adhere to a protocol outlining their collaborative practice with a physician or another individual who has prescribing authority.

However, both of these states are atypical. In most states, prescriptive authority for pharmacists derives from a collaborative practice arrangement with a prescriber,[‡] and significant restrictions limit the utility of these arrangements for widespread distribution of emergency contraception. For example, these restrictions can limit where the collaborative protocols can be used (e.g., a health maintenance organization) or can limit services to specific patients currently in the care of the authorizing provider, thus preventing pharmacists from serving the general community.

To date, collaborative protocol arrangements have been used in two states, Washington and California, to help deregulate emergency contraception and permit direct access through pharmacies. In 1998, Washington established emergency contraception programs in pharmacies by using legislation enacted in the late 1970s that covered a broad range of collaborative practice agreements. In California, new legislation was needed; the state's prior law governing collaborative protocols between pharmacists and physicians had limited application for allowing general access to emergency contraception in pharmacies.[§] In 2001, the governor signed into law a very brief, but noteworthy amendment that marked the first time a state had enacted legislation specifically designed to deregulate a form of hormonal contraception.[**]

Activity regarding pharmacy-based access to emergency contraception in Alaska, Florida, Hawaii, New York, North Carolina and Oregon suggests that the number of states that permit consumers to obtain this form of contraception directly from pharmacists may soon grow.[††]

OBTAINING EMERGENCY PILLS IN U.S. PHARMACIES

In Washington, more than 50,000 women have obtained emergency contraceptive services through pharmacies since 1998; increased accessibility to this method may have contributed to a dramatic reduction in the number of unintended pregnancies and abortions in the state, and a significant improvement in access to the health care system.[7] The California law permitting trained pharmacists with signed collaborative protocols to offer emergency contraception to the community at large went into effect in January 2002, and by April, more than 700 pharmacists had been trained and 130 pharmacies activated for service—a strong indication of the interest among pharmacy stakeholders in providing this service.[‡‡]

California's emergency contraception pharmacy program began on a demonstration basis in 2000, and data from pilot sites,[8] while representing only a limited sample of 531 women, are revealing:

• Thirty-five percent of visits with a pharmacist for emergency contraception resulted in a referral to a clinic or physician, most often for ongoing contraception, but also for screening for sexually transmitted infections and for primary care.

• The average client was 21.5 years old.

• Forty-eight percent of women seeking emergency pills were white, 30% Hispanic, 10% Asian and 6% black; 6% belonged to "other" racial or ethnic groups. This demographic profile is similar to the state's overall.

• Fifty-two percent of women requested emergency contraception because they had had unprotected sex, 45% because their contraceptive had failed and 3% because they wanted the method on hand in case of future need.

• Forty-two percent requested emergency contraception within 24 hours of contraceptive failure or unprotected sex, including 17% who sought help within 12 hours.

• Thirty percent of requests for emergency contraception came on a Monday.

Women in both California and Washington who obtain emergency contraception directly from a pharmacy can expect a very limited assessment. The pharmacist asks a few questions to rule out an established pregnancy and assess the need for treatment. Although both states permit pharmacists to serve minors, protocols almost always require the pharmacist to obtain the client's date of birth. This basic information is collected through a self-administered screening tool or during a consultation between the woman and the pharmacist. The consultation, including the provision of education and information about contraception (emergency and ongoing) and sexually transmitted infections, is conducted either in a partitioned counseling area (a growing trend) or in another area that permits privacy. The standard practice in both states is to require signed consent forms. Altogether, the assessment, consultation and supply of the product generally takes about 10-15 minutes. Pharmacist trainings on emergency contraception strongly encourage pharmacists to make referrals to local physicians and clinics; as the data above show, pharmacists take action to encourage women to seek clinical care.

PHARMACIES AS FAMILY PLANNING PARTNERS?

Emergency contraception programs have paved the way for other forms of collaboration. Many states, including Washington and California, permit pharmacists to administer injectable drugs.[§§] In Washington, pharmacists administer injectable hormonal contraceptives through a referral system with medical providers, and pharmacies are starting to directly provide ongoing contraception through a project funded by the National Institutes of Health.[9] Pharmacists and physicians taking part in this project are using collaborative agreements to provide women with oral contraceptives when they need effective, long-term contraception and they come to pharmacies requesting emergency pills or seeking contraceptive assistance. Women initiating contraception through the program have access to medical collaborators for physical exams, but these exams are not required for contraception initiation. A self-administered screening tool has been developed to ensure that the pill is provided to women for whom it is appropriate.

California is developing a pilot program for pharmacist provision of injectable contraceptives and is using a collaborative process involving both physicians and pharmacists to produce standard practice guidelines. Additionally, demonstration projects, carried out by the Pharmacy Access Partnership, are focusing on using retail merchandise space in both chain and independent pharmacies to promote family planning and the prevention of sexually transmitted infections. Objectives include enhancing educational opportunities, improving retail promotion of products such as condoms and increasing public awareness of the reproductive health services offered by pharmacists.

California efforts are also addressing another critical issue—access to over-the-counter contraceptive products covered by government insurance programs. As in many states, public insurance in California covers over-the-counter products if beneficiaries have a prescription. Otherwise, low-income residents must pay out of pocket for supplies that would otherwise be covered. This regulation was enacted in the late 1960s, when the Medicaid program was created, and was intended to monitor utilization in that preautomated era. Now, with computerized databases, there are more effective ways to monitor fraud, and the regulation stands as a needless barrier to improved access.[*†]

The medical community's perspective on expanded scope of practice for pharmacists is mixed,[10] and the same may be true for the family planning community. Or so it appeared in the course of five informal meetings that the Pharmacy Access Partnership and the Center for Health Training conducted throughout California in 2001 to update family planning staff about emergency contraception and promote support for new access options. At all sites, participants generally agreed that deregulation would mean easier availability of the method, fewer barriers to obtaining it, and greater control of fertility. Yet they also noted several drawbacks, particularly missed opportunities for clinical services, including education, potential for misuse, cost to the recipient and loss of revenue for clinics. Interestingly, confidentiality was cited as a concern for both clinic and pharmacist provision of emergency contraception.

With time and greater awareness of the benefits deregulation would offer to women,

attitudes toward enhanced pharmacy access to contraception will probably soften. In California, for example, some medical groups initially resisted supporting legislation for pharmacist provision of emergency contraception through collaborative protocols. A year later, in an April 2002 Pharmacy Access Partnership advisory meeting, when the issue of future legislation came up, a number of physicians in the group were reluctant to support elimination of such protocols: They were not concerned about further deregulation of emergency contraception. Rather, they saw the current collaborative protocols as a useful tool for promoting direct pharmacy access to other prescription contraceptives, including injectables and pills, and they were reluctant to lose this opportunity.

However, it also needs to be noted that retail pharmacies in the United States have their own culture, their own professional traditions and their own influences, which today are often strongly tied to corporate practices. Engaging these stakeholders in family planning objectives is complex, requiring time and a basic understanding of their needs. The family planning community has sometimes misunderstood the practices of retail pharmacies. For example, with thousands of FDA-approved drugs available, pharmacies have to choose which ones to stock; in most pharmacies, those decisions are driven largely by demand. Pharmacies may not stock emergency contraception simply because demand is low, yet family planning advocates may assume that the decision was a moral one.

CONCLUSION

With their easy accessibility and their open hours on evenings, weekends and holidays, pharmacies clearly are an ideal source of emergency contraception, as well as other forms of contraception. Expanding consumer access to contraception is a fundamental part of family planning programs, both domestically and internationally. Deregulation of emergency contraception represents an opportunity to continue the tradition of empowering individuals and expanding access. Steps in this direction at the state level are already occurring.

Nationwide, deregulation of emergency contraception seems inevitable, as this is not an evidence-based medical debate: The most vocal arguments against over-the-counter status of emergency contraception continue to be formed on a social and political stage. Opposing concerns include risks posed to minors by direct access of emergency contraception. However, evidence from California shows that the average user is a woman in her 20s. Additionally, the same products dispensed for emergency contraception are freely available to adolescents in clinical settings throughout the country. However, to document the minimal risk that the method presents to minors, Women's Capital Corporation is sponsoring a study in conjunction with the University of California at San Francisco to examine the pharmacology of emergency contraception in adolescents.[11]

Another socially and politically charged position against deregulating emergency contraception is that women would abuse it and fail to use regular forms of contraception. The experiences of pharmacists in California and Washington do not support this reasoning. Women who use emergency contraception are highly motivated to prevent pregnancy. Common sense argues against frequent use of the method: It is more expensive than other routinely used contraceptives, it is

significantly less effective and its use is associated with greater discomfort.

Expanding consumer access to this method not only is widely supported by well-respected health care professionals and medical organizations; more important, it offers women an opportunity to respond to their family planning needs in a private and timely way. Deregulation of emergency contraception seems certain in the near future. But how this will be done and the type and extent of deregulation that will occur remain to be seen.

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*For an excellent description of how the Food and Drug Administration established prescription drug status for contraceptive methods, see Trussell J et al., Efficacy implications of making the pill available over the counter, in:

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†The distinction between prescription and over-the-counter drugs in the United States emerged with the 1938 federal Food, Drug and Cosmetic Act, and was institutionalized 13 years later, with the Durham-Humphrey Amendment. A number of drugs that are classified as prescription today were dispensed at the discretion of the pharmacist before 1951, and prior to 1938, prescriptions were not necessary for nonnarcotic drugs.

‡As of March 2002, 36 states allowed pharmacists some form of prescriptive authority—more accurately described as "collaborative drug therapy management" authority. This authority is established through state pharmacy board regulations in five states (Alaska, Idaho, Louisiana, Tennessee and Vermont) and by statute in 31 (Arizona, Arkansas, California, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, Wisconsin and Wyoming).

§Under California law, pharmacists could initiate emergency contraception only for clients of the authorizing health care facility and only for conditions for which they had already been seen. Because the authorizing health care facilities were generally family planning clinics, and their enrolled patients obtained services related to pregnancy prevention, "fertility" was deemed to be the condition for which they were being treated, and thus served as the bridge for pharmacist-administered emergency contraception.

**For more information about this legislation and to view the text of the provision, visit <www.PharmacyAccess.org>.

† †On April 25, 2002, Alaska's state pharmacy board approved the use of collaborative protocols for emergency contraception. Pharmacists in Alaska can now provide emergency contraception to the general community, including individuals without an established relationship with a clinic, physician or nurse provider. (Source: Murphy C, Emergency Contraception Project, Anchorage, AK, personal communication, Apr. 26, 2002; and Wells E, Planned Parenthood of Alaska, Anchorage, AK, personal communication, May 10, 2002.)

‡ ‡For a listing of these pharmacies and information about pharmacy-based family planning services, visit the consumer Web site <www.EC-Help.org>.

§§A number of states use pharmacies and pharmacists to offer communitywide immunization services, particularly to booster public immunity against influenza and pneumonia.

* *For an overview on pharmacist reimbursement for over-the-counter products in California, visit <www.PharmacyAccess.org/>, and search "OTC products."