

Objections, Confusion Among Pharmacists Threaten Access To Emergency Contraception

By Susan A. Cohen

Emergency contraception—which basically amounts to taking a high dose of “regular” oral contraceptives very shortly after unprotected intercourse—is now widely acknowledged as capable of making a dramatic contribution toward reducing unintended pregnancies and, therefore, abortions. However, it is equally clear that a concerted public education effort is necessary for this medical technology, which has long been used in other countries, to live up to its full public health potential in the United States.

Over the past several years, such a campaign has been under way in the United States. According to a 1997 survey by the Kaiser Family

Oral contraceptives, whether taken on a daily basis or in a concentrated dose in an emergency, prevent pregnancy and do not cause an abortion.

Foundation, educational efforts directed at physicians and women about the existence and efficacy of emergency contraception have resulted in a marked increase in knowledge, and use, of the method nationwide. These efforts undoubtedly were bolstered by last year’s approval by the Food and Drug Administration (FDA), for the first time, of an oral contraception regimen to be packaged and marketed in the United States specifically for postcoital use.

However, on a variety of fronts, there remain significant obstacles to

widespread knowledge about and access to emergency contraception. Among them is a new, largely unanticipated hurdle concerning pharmacists. In isolated cases nationwide, individual pharmacists have refused to fill prescriptions for these emergency contraceptive pills (ECPs), presumably on the grounds that to do so is to facilitate abortion.

Initially, these were considered fluke occurrences, but the problem has received increasing attention following a recent decision by Wal-Mart, one of the nation’s largest drug retailers, to not sell ECPs.

These actions are largely based on confusion over what emergency contraception is and how it works—specifically, on the widespread misperception that emergency contraception is actually a method of abortion. This confusion has impeded not only the availability of ECPs vis-à-vis pharmacies but also the formulation of responsible public policy to address issues of pharmacist “conscience.” Clearly, the situation calls for an immediate expansion of public education efforts around emergency contraception targeted specifically at pharmacists. A simultaneous challenge is ensuring that the development of public policy around this issue strikes an appropriate balance between any legitimate conscience claims of individual pharmacists and the ability of women to purchase legal contraceptive drugs in order to avoid unintended pregnancy.

Contraception, Not Abortion

In September 1998, FDA gave its long-awaited final approval to an

emergency contraception “kit”—marketed under the name Preven—containing four oral contraceptive pills and a pregnancy test. Preven remains the only kit specifically packaged and marketed for emergency contraception in the United States, but 11 other regimens of oral contraceptives have been declared by FDA safe and effective for postcoital use. Since those regimens are not specifically *labeled* for that purpose, however, they are prescribed by providers as regular oral contraceptives, with special instructions on how to take the pills. Indeed, ECPs have been prescribed this way—“off label” and without special packaging—for decades.

Traditionally known as the “morning-after pill,” ECPs actually can prevent pregnancy if taken within 72 hours of intercourse where there was known or suspected contraceptive failure or where no birth control was used. The regimen usually involves taking two or four oral contraceptive pills at first, followed by two or four more 12 hours later.

Whether oral contraceptive pills are taken on a daily basis as an ongoing method of pregnancy prevention or in a concentrated dose in an “emergency” situation after unprotected intercourse, their potential modes of action remain the same. The best scientific evidence suggests that ECPs most often work by suppressing ovulation. But depending on the timing of intercourse in relation to a woman’s hormonal cycle, they—as is the case with all hormonal contraceptive methods—also may prevent pregnancy either by preventing fertilization or by preventing implantation of a fertilized egg in the uterus (*TGR*, Vol. 1, No. 5, October 1998).

In the media and in political debates, ECPs are often confused with mifepristone, commonly known as RU-486. However, mifepristone—as currently being reviewed for approval by FDA—is clearly a method of abortion. Unlike mifepris-

tone, ECPs cannot disrupt an established pregnancy and, therefore, cannot, under any circumstances, cause an abortion.

Time Is of the Essence

Having had unprotected sex and fearing the possibility of becoming pregnant, a woman—who must know that there is something she can still do to avoid becoming pregnant—has 72 hours in which to obtain and begin taking ECPs. First, she must contact a health care provider who is knowledgeable enough and willing to write her a prescription for the contraceptive. Then, she must find a pharmacist to fill her prescription.

(It is in light of the inherent challenge to complete these steps within

the narrow window of opportunity that moves are under way in some states to allow pharmacists themselves to directly *prescribe* as well as dispense ECPs—see box.)

By the time a woman connects with a medical provider and obtains a prescription for ECPs, she may have only a few hours to actually acquire and take them. In an urban area, a woman encountering a pharmacist who refuses to fill her prescription may well be able, within the time constraints, to find either another pharmacist at that drugstore or one at another drugstore who would be willing to do so.

Encountering a refusing pharmacist may present more significant access

barriers, however, in a small town or rural area in which the number of pharmacists within reach may be very small.

Similarly, the problems are compounded when an entire drugstore chain will not provide them. This case arose recently when, shortly after FDA approved Preven last fall, Wal-Mart made a “business” decision, never publicly announced, not to provide the contraceptive.

Planned Parenthood of New York City, which learned of the decision through a survey it conducted of pharmacists in the New York City area, recently urged Wal-Mart to reconsider its policy, asking it to take into account the “significant health and social consequences” of effectively blocking access to this pregnancy prevention method even when it might be needed by a woman who has been raped. Wal-Mart issued a curt reply on April 30, stating that it remains firm in its position, but adding that “in the interest of serving and meeting the needs of our customers, our pharmacists will refer any request for the drug to a pharmacy that does carry it.”

Clearly, where there are a variety of pharmacists and pharmacies, willingness to refer a woman seeking ECPs to another individual or store is critical. At the same time, even with a referral, an objection to dispensing ECPs in the best-case scenario creates hassle, and in the worst case may be tantamount to access denied altogether.

Policy Responses

Pharmacists are regulated by state boards of pharmacy, which have long-standing policies that in general, a pharmacist is obligated to dispense all medications for which he or she is licensed. There are only two significant exceptions to this rule: either when a pharmacist has sufficient reason to doubt that a prescription is valid or when use of the

In Some States, Meanwhile, Pharmacists Are Actively Working to Facilitate ECP Access

Even as women’s ability to obtain emergency contraceptive pills (ECPs) is being hampered by the refusal of some pharmacists to provide them, in other cases, pharmacists are actively working with women’s health proponents to facilitate access to ECPs. In 1997, pharmacists in Washington State became the first in the country to secure the authority to prescribe ECPs as well as dispense them to women.

In Washington, as in 21 other states, existing law authorizes pharmacists to prescribe and dispense certain drug therapies on the basis of a set of protocols and the development of “collaborative agreements” between pharmacists and physicians or nurse practitioners. Prior to their application to emergency contraception, these laws were used to allow pharmacists to provide patients with, for example, immunizations and critical pain-relief therapy.

In July 1997, a group of organizations in Washington—including the State Board of Pharmacy, the State Pharmacy Association, family planning organizations and a public relations firm—began an innovative effort to make emergency contraception more widely available. The effort, which targeted the Puget Sound area, included educating pharmacists about ECPs, facilitating links between pharmacists and practitioners, and educating women in the state about emergency contraception. A major goal of the campaign was to spawn the development of collaborative agreements, which must be approved by the Washington State Board of Pharmacy. By August 1998, 117 such agreements had been submitted for review by the board.

The success of the Washington program has inspired other states to follow suit. Paving the way for a pharmacist-dispensation initiative in its state, the Oregon Medical Association House of Delegates in April reportedly passed a resolution backing the prescription of ECPs by pharmacists. Meanwhile, in California, the legislature currently is considering legislation that specifically would allow pharmacists to prescribe and dispense ECPs.

drug being prescribed could be against the patient's best interests, generally because it could provoke a harmful interaction with another drug the patient is taking.

The increasing popularity of ECPs, however—coupled with pharmacists' concerns over their potential obligations in legal assisted-suicide situations—appears to be spurring some pharmacists around the country to take issue with this obligation. This, in turn, is creating the perceived need to adjust both industry policies and state laws.

For example, the American Pharmaceutical Association (APhA), the professional association of pharmacists, adopted a policy last year that seeks to achieve balance between the rights of individual pharmacists to abide by their personal moral convictions and patients' needs for legal medications. Under the new policy, APhA "recognizes the individual pharmacist's right to exercise conscientious refusal *and* supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal" (emphasis added).

Some state associations, in implementing this policy, are recommending that such "systems" ensure that at least one pharmacist in a given store be willing to dispense the medication. At a minimum, they call for the pharmacy, if not the individual pharmacist, to refer to another store that is known to provide full services.

Bills recently introduced in state legislatures, however, do not follow the APhA lead. For example, a 1998

South Dakota law permits any pharmacist to refuse to dispense medication if there is reason to believe it would be used to "destroy an unborn child"—which, under state law, is

According to the professional association of pharmacists, any pharmacist 'conscience' provision must also ensure patient access to legally prescribed therapies.

defined to include a fertilized egg even if it has not yet implanted in the uterus. As a result, in South Dakota, not only are ECPs available only at the option of individual pharmacists but so are all other methods that may act to prevent implantation of a fertilized egg—that is, all other hormonal contraceptive methods and the IUD. Furthermore, the South Dakota law does not address the access needs of the patients who are seeking legal medical therapy to which a pharmacist may object.

Pharmacist "conscience" legislation has been introduced this legislative session in Indiana, Kansas, Louisiana, Oregon and Wisconsin. Some of the measures are generic, allowing pharmacists to decline to provide any medication on conscience grounds, while others apply only to so-called abortion-inducing drugs—variously defined. The bill in Oregon is the broadest, applying to all drugs and to pharmacists as well as drugstore owners and operators.

A Question of Balance

While these measures were largely triggered by increasing use by American women of emergency con-

traception—and, specifically, by FDA approval of Preven—the impetus for them largely arises from some pharmacists' objections to participating in or facilitating *abortion*. It is logical to assume, then, that if pharmacists understood that ECPs are contraception and not abortion, much of the perceived need for changes in public policy would dissipate. After all, oral contraceptives and other hormonal methods—all of which are scientifically indistinguishable in their modes of action from ECPs—have been around for many years, and the overwhelming majority of pharmacists evidently have not objected to filling these prescriptions. To bring about this clarification will require a concerted education effort specifically targeting pharmacists.

At the same time, in crafting any policies that may be deemed necessary to address the conscience claims of pharmacists—in relation to ECPs or any other legal pharmaceuticals for that matter—policymakers would do well to heed the policy statement of pharmacists' national professional association. And that means any pharmacist conscience provision must also provide for the "establishment of *systems* to ensure patient access to legally prescribed therapy" (emphasis added). As some state pharmacist associations are coming to realize, implementation of the national policy may require—at a minimum—that at least one pharmacist in any given pharmacy be willing to dispense the medication in question or that the pharmacy itself be willing to refer the patient to a pharmacy that will. ☉