# Mifepristone in the United States: Status and Future

*Less than two years after the Food and Drug Administration approved the use of mifepristone for early nonsurgical abortion, a majority of the specialized clinics that provide surgical abortion services in the United States are now offering it. But while many abortion rights supporters had hoped that the drug's approval also would lead substantial numbers of new providers, particularly physicians in private practice, to take up medical abortion, for a number of reasons this has yet to occur. A decade of experience with nonsurgical abortion in Europe indicates that integration of the procedure into a country's medical care system is generally slow and gradual. Moreover, that experience also strongly suggests that the introduction of mifepristone in the United States will not noticeably increase the country's abortion rate but, instead, may well increase the proportion of abortions taking place very early in pregnancy.*

**By Heather Boonstra**

Abortion rights activists in the United States hailed the Food and Drug Administration's (FDA) September 2000 approval of mifepristone as a "momentous step," because the drug would give American women the option of a safe, early abortion where one may not have previously existed. Whereas surgical abortion is generally not performed until about the sixth week of gestation, medical abortion can be initiated as soon as pregnancy is confirmed. Because, theoretically, mifepristone can be prescribed by a woman's private physician and the abortion completed in the privacy of a woman's home, the FDA's approval held out other hopes as well: namely that a range of providers who did not offer abortion before would begin providing medical abortion, resulting not only in women's increased geographical access to abortion, but also to a reduction in the violence directed toward abortion clinics and, ultimately, a defusing of the abortion debate.

Antiabortion activists, on the other hand, considered the FDA action an outrage. Though their public rhetoric stressed the dangers of women's use of mifepristone, their primary concern lay elsewhere. Mifepristone would only make things "more convenient for abortionists." Its availability would make abortion "too easy" for women, leading to a surge in abortion rates.

It is obviously far too early to determine what impact mifepristone will have on abortion provision in the United States. Indeed, the Centers for Disease Control and Prevention's most recent abortion surveillance data are for 1998 and do not reflect the availability of mifepristone. The Alan Guttmacher Institute (AGI) is in the process of gathering information on mifepristone as part of its survey of all known U.S. abortion providers, but these data will not be available until early 2003. In the meantime, some information is available from The National Abortion Federation (NAF), the professional association of abortion providers, and Planned Parenthood Federation of America (PPFA), many of whose affiliates provide abortion services. Both organizations are collecting information from members and affiliates that will shed some light on the availability of medical abortion in specialized clinics, where the overwhelming majority of abortions are performed.

Another source of information is AGI's examination of the experience with mifepristone in France, Great Britain and Sweden, where mifepristone has been available for a decade or longer. In 2001, AGI investigated mifepristone use and policies in these countries on the basis of information from national abortion statistics, professional guidelines and interviews with experts. The results of this research, published in the May/June 2002 issue of *Perspectives on Sexual and Reproductive Health,* offer hints of mifepristone's future in this country.

## Challenges to Providing Medical Abortion

Medical abortion is not the quick and simple act of swallowing a pill, and incorporating the method into clinical practice requires much more than writing a prescription. Indeed, medical abortion is a process that can extend over several days, involves two separate drugs and requires multiple visits to a physician's office (see box). It is not surprising then that, among both women and the medical community, there are several challenges to mifepristone "uptake" having to do with the procedure itself, its economics and state policies for its use.

*The procedure.* While safe and effective, medical abortion is not an easy process for women to undergo—it causes bleeding that is sometimes heavier than menses and, in some cases, side effects that are more pronounced than those of surgical abortion. Many women also experience gastrointestinal discomfort (such as

## The Medical Abortion Regimen and Science-Based Alternatives

*The FDA approved mifepristone on the basis of the regimen used in the U.S. clinical trials, which was first developed in France in the late 1980s. The approved regimen involves three visits to the physician's office: first for counseling and to receive a dose of mifepristone (600 mg), then two days later for an oral dose of misoprostol (400 µg), which produces contractions, and on day 14, for a follow-up exam. The regimen is approved for use up to 49 days' gestation (measured from the onset of the last menstrual period).*

*U.S. physicians are legally permitted to adapt the approved protocol, and a large majority have done so on the basis of scientific studies conducted over the last decade. In 1998, an analysis involving 2,000 U.S. women, published in* Human Reproduction, *found that mifepristone was equally effective at one-third the standard dose (200 mg). Medical researchers have also examined the prospect of eliminating the second visit, by permitting women to self-administer misoprostol. Studies of the practice have found in-home administration to be as safe and effective as at a clinic and that women find it acceptable. On the basis of these findings, the medical standards for mifepristone abortion published by NAF and by PPFA allow the low-dose regimen and in-home administration, and such modifications have become common practice (see table).*

*Research also indicates that medical abortion is effective up to 56 or even 63 days' gestation (about nine weeks), although efficacy may decrease as gestation advances. Because a substantial proportion of abortions take place between 49 and 63 days, extending the gestation limit to 63 days would increase the proportion of women eligible for medical abortion—by as much as three times. Experts in the field expect medical abortion at 8–9 weeks to become more common in the future. Both PPFA and NAF guidelines allow this practice.*

**COMPARISON OF MEDICAL ABORTION REGIMENS IN THE UNITED STATES**

| | *FDA-Approved* | *Science-Based Alternative* |
|---|---|---|
| **Mifepristone dosage** | **600 mg** | **200 mg** |
| **Gestational limit** | **Up to 49 days** | **Up to 63 days** |
| **Home administration of misoprostol** | **No** | **Yes** |

nausea, vomiting, cramps and diarrhea) that lasts from a few hours to several days. Other side effects may include headache, dizziness and chills.

For these and other reasons, not all women prefer medical over surgical abortion, and the proportion of early abortions involving mifepristone varies among countries. Mifepristone is used less frequently in England and Wales than in France, Scotland and Sweden, where over half of women having early abortions choose medical abortion. In the United States, only a handful of abortion clinics report high levels of mifepristone use (with more than 40% of eligible women choosing it).

However, despite the side effects of the procedure, a majority of women who have undergone a medical abortion say that it was a good choice for them. Several studies involving U.S. women in clinical trials have examined women's views about medical abortion. A recent study, published in the January/February 2002 issue of *Perspectives on Sexual and Reproductive Health,* for example, asked women who had a medical abortion using mifepristone and home administration of misoprostol to describe their feelings about the procedure. This study confirms past findings that many women choose medical abortion for its naturalness, for the privacy it affords and to avoid the perceived pain and trauma of surgical abortion. Another study found that many list "timing"—the option to have an abortion at the very earliest stages of pregnancy—as very important in their decision.

*Providers' concerns.* Some physicians whose experience is limited to surgical abortion express concerns about incorporating medical abortion into their practices; some even question why anyone would want to go through the cramping and bleeding of medical abortion instead of the quick surgical procedure. Many physicians worry that start-up costs (which could range from staff training to the purchase of an ultrasound machine) will be unmanageable. Others fear that on-call staff will be burdened by a high volume of phone calls from women experiencing heavy bleeding (which is normal, but may be perceived by some women to be an emergency) or that, in the cases of home use of misoprostol, patients will fail to follow instructions.

Providers also may be concerned about the expense involved, which includes the cost of mifepristone and, perhaps more important, the extra time spent in counseling and follow-up. Moreover, some providers have also found malpractice insurance to be either unavailable or excessively expensive because of mifepristone's brief record in the United States. Indeed, despite mifepristone's long record of safety in Europe, where the drug has been used by more than 500,000 women,

some physicians may be waiting to see if any serious adverse events (such as hospitalization, birth defects or deaths) occur among women here.

*Cost considerations.* Because of the cost of mifepristone and the extra time spent in counseling and follow-up, medical abortion in most cases costs more than a first-trimester surgical abortion, and many providers are in a quandary as to what to charge for the procedure. Some charge the same amount, on the basis of their strong belief that women should choose according to what method they judge best for them, rather than cost. However, anecdotal evidence indicates that most providers do charge more—in the range of $50 to $100 above the average surgical abortion cost of $316.

The cost differential may be significant from a woman's perspective. Most U.S. abortion clients (approximately three-quarters) pay cash for their abortions. Some may later seek insurance reimbursement, but anecdotal evidence suggests that even when they have insurance, many women opt to pay out-of-pocket. The issue of cost is even more critical for low-income women with no insurance or those on Medicaid. In 17 states, Medicaid programs cover medically necessary abortions, but in most states, Medicaid does not pay for abortion (either surgical or medical) except in cases of life endangerment, rape or incest. Thus, for low-income women who must scrape together the funds to obtain an abortion, the extra charge for a medical abortion may be too much, making the option one in name only.

By contrast, cost plays a minor role in women's choice of abortion method in Europe, where national health care systems cover most abortions. French women pay 20% of total costs, while Swedes pay no more than $30 for either medical or surgical abortion. Coverage in Great Britain is inconsistent, but still broad: In 2000, public health insurance paid for 75% of all abortions in England and Wales and 98% of them in Scotland.

*Impact of policies.* As if the medical and economic issues were not enough, the politics of abortion in the United States are another challenge for providers considering mifepristone. Contrary to expectations, few restrictions specifically targeting mifepristone have materialized. Nevertheless, providers interested in adding medical abortion to their services would need to be aware of the intricacies of state policies governing abortion care, and how they might relate to mifepristone. A patchwork of state policies on abortion may require parental involvement for minors, state-directed counseling, waiting periods and various reporting requirements. For most providers of mifepristone, these restrictions and regulations are not new, and they already have systems in place to comply with them. However, the same cannot be said for providers who have never offered abortion services, particularly those in private practice. For this group of providers, concerns about the difficulties in complying with a host of new requirements and restrictions, even if not entirely realistic, may deter them from offering medical abortion.

A specific disincentive may be "physician-only" laws, enacted in 44 states. Under such laws, midlevel health care professionals can provide counseling, perform sonograms and review medical histories, but cannot actually administer mifepristone. France, Great Britain and Sweden also require that medical (and surgical) abortion be administered exclusively by a physician; however, practices have been developed in all three countries so that physician involvement can be minimized. Allowing midlevel health care professionals to provide medical abortion under physicians' supervision is appropriate for a procedure that requires extensive patient education and counseling, explains Mary Fjerstad, mifepristone training coordinator for PPFA. "The physician-only laws—all enacted long before medical abortion was an option—simply do not make sense for medical abortions, which require clinical, rather than surgical, skills," she says. "Clinical assessment and communication with patients are emphasized in the education of midlevel clinicians. For this reason, midlevel providers are just as qualified to provide medical abortion."

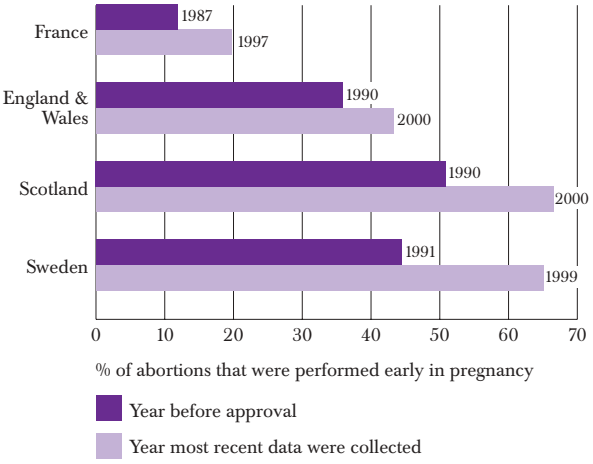
## Future Directions

There are just over 2,000 known abortion providers in the United States. In 1997, 70% of abortions were performed at specialized clinics and only 3% at physicians' offices. To date, it would appear that the medical community has been content to leave the provision of mifepristone to the small community of abortion providers. However, among specialized clinics especially, medical abortion has taken off. Seventy percent of NAF members currently provide medical abortion, and among PPFA affiliates, 78% of those that provide surgical abortion services also offer the medical option.

In addition, there are indications that the use of mifepristone for early abortion is growing. According to Danco Laboratories (the company that owns the U.S. rights to mifepristone), drug sales in the first quarter of 2002 were up 39% compared with the first quarter in 2001. As mentioned above, there are only a few U.S. facilities providing medical abortions that report high levels of use. Over time, the proportion of early abortions performed with mifepristone is expected to increase steadily, as it has in Europe every year since the drug's introduction. As physicians gain more experience with the method and come into contact with patients and colleagues with positive reports about medical abortion, they will likely become increasingly interested in providing this option to their patients.

## EARLIER ABORTION

***The proportion of abortions that are performed early in pregnancy has increased in countries where mifepristone has been approved for medical abortion.***




*Notes:* For France, data represent the percentage of abortions performed up to 49 days' gestation. For England and Wales, Scotland and Sweden, data represent the percentage of abortions performed up to 63 days' gestation. *Source:* Jones RK and Henshaw SK, Mifepristone for early medical abortion: experiences in France, Great Britain and Sweden, *Perspectives on Sexual and Reproductive Health,* 2002, 34(3):154–161.

Some providers are already expanding their medical abortion services. According to PPFA's Fjerstad, some PPFA affiliates may be able to provide surgical services at some of their more remote clinic sites only one day per week—or even per month—when a physician is available. To better meet the needs of their patients, some of these sites in states unencumbered by physician-only laws are using midlevel health care professionals to provide mifepristone throughout the week. Other PPFA affiliates are integrating mifepristone into individual clinic sites that previously offered only family planning services. In these areas, women now do not need to travel as far as they would have had previously to obtain an abortion, and they may now obtain an abortion from staff they may already know and trust.

However, at least to date, early medical abortion is being offered almost exclusively by providers that were already performing surgical abortions. There were early indications, prior to FDA approval, that one in three physicians who did not or had never performed abortions would begin to prescribe mifepristone. One year after approval, however, only 6% of private gynecologists and 1% of general practice physicians did so, according to the Henry J. Kaiser Family Foundation.

In each of the European countries AGI studied, it has taken a decade or longer for mifepristone to be fully recognized and integrated as a method of abortion, and use of the drug is still increasing. Some of the reasons adoption of mifepristone has been slow in Europe have no comparison in the United States; others are very similar to the challenges faced in this country. In either case, the European experience suggests that acceptance of the method will take time.

One problem unique to the United States is that abortion services in this country are largely confined to a relatively small group of clinic-based providers that are located in only about 15% of U.S. counties. Many abortion rights advocates had hoped that mifepristone would attract substantial numbers of physicians in private practice who would be willing to offer very early abortions in previously unserved areas. Whether mifepristone can live up to this promise remains a big question—one that the European experience is not particularly helpful in answering.

However, the European experience does appear to contradict antiabortion activists' prediction that the widespread availability of mifepristone would lead more women to terminate their pregnancies. To the contrary, the abortion rates in France, Great Britain and Sweden—which were substantially lower than those in the United States before the introduction of mifepristone—remained virtually unchanged following its approval. In France, 13 per 1,000 women ages 15–44 had an abortion the year before mifepristone's approval and 10 years thereafter as well. Likewise, the rate in England and Wales was at 16 per 1,000 women both the year before mifepristone's introduction and 10 years later. The rate increased slightly in Scotland, from nine to 11 per 1,000 women between 1990 and 2000, but decreased in Sweden, from 21 in 1990 to 18 in 1999.

While the introduction of medical abortion did not increase the overall incidence of abortion in Europe, it does appear to have prompted a change in the timing of women's abortions. A larger percentage of women in each of the European countries in which mifepristone is available are now having abortions at earlier gestations than they were before the drug was introduced (see chart). There is no reason to believe that, over time, the U.S. experience will be substantially different from that of Europe: As knowledge and availability of mifepristone increase, U.S. women are likely to have abortions at approximately the same overall rate, but even earlier in pregnancy, than they do now.

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