# Voicing Concern for Women, Abortion Foes Seek Limits On Availability of Mifepristone

**By Heather Boonstra**

Having failed to prevent the U.S. Food and Drug Administration (FDA) from approving the abortion drug mifepristone (still commonly referred to as RU-486) for use in the United States, antiabortion activists are mobilizing behind legislation to limit the number of physicians able to prescribe it. Sen. Tim Hutchinson (R-AK), chief sponsor of the RU-486 Patient Health and Safety Protection Act in the Senate, contends that the only purpose of his legislation is "to ensure the health and safety of women who are prescribed RU-486." But abortion rights advocates say the bill is a fraud. Shrouded in the guise of a concern for women's health, they say, the restrictive distribution scheme the legislation would impose—which the FDA itself reportedly considered and rejected as unnecessary—is designed strictly for the purpose of impeding American women's access to breakthrough technology that makes it possible to have abortion without surgery in the very earliest weeks of pregnancy.

**COUNTRIES THAT HAVE APPROVED THE USE OF MIFEPRISTONE**

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|---|---|
| Austria (1999) | The Netherlands (1999) |
| Belgium (1999) | Norway (2000) |
| China (1988) | Russia (1999) |
| Denmark (1999) | Spain (1999) |
| Finland (1999) | Sweden (1992) |
| France (1988) | Switzerland (1999) |
| Georgia (2000) | Taiwan (2000) |
| Germany (1999) | Tunisia (2000) |
| Greece (1999) | Ukraine (2000) |
| Israel (1999) | United Kingdom (1991) |
| Luxembourg (1999) | United States (2000) |

## Second–Guessing the FDA

The RU-486 Patient Health and Safety Protection Act would restrict the distribution of mifepristone (sold in the United States under the trade name "Mifeprex") to those physicians who meet four conditions: They must be trained to perform surgical abortions, certified in ultrasound pregnancy dating and detection of ectopic pregnancy, trained to administer Mifeprex through a government-approved program and have admitting privileges at a hospital within one hour of their office.

Upon introducing the measure in the House early this year, Rep. David Vitter (R-LA) declared that it was necessary because the FDA "caved in to political pressure from the abortion lobby and hurriedly approved the abortion drug without crucial health protections for those who use it." Approval of Mifeprex "will not only increase the number of abortions performed each year," he said, "it will create serious and potentially dangerous side effects for women using the drug. The least we can do is ensure that this drug does not endanger the health of the mother."

Vitter's justifications for "patient protections" fly in the face of abundant evidence that use of mifepristone in the early weeks of pregnancy is safe. Approved in 22 countries since 1988 (see box), it has been safely taken in conjunction with the drug misoprostol as an alternative to surgical abortion by more than 650,000 women in Europe alone and millions of women worldwide. In addition, the mifepristone-misoprostol regimen was extensively tested in clinical trials in the United States and found to be safe.

Vitter's contention that the FDA "caved in" to pressure and "hurriedly approved" mifepristone is apparently based on a misunderstanding of the specific set of rules, known as Subpart H, under which the FDA considered the drug. While most often used to provide for expedited marketing of a life-saving medication, in the case of Mifeprex, Subpart H was *not* used to expedite consideration but for another purpose authorized under the provision, to allow the FDA to impose specific restrictions on the way the drug would be distributed. The notion that "short-cuts" were taken is belied by the fact that while then-president Clinton directed the Department of Health and Human Services to "promote testing, licensing and manufacturing in the United States of mifepristone" in January 1993, it was not until September 2000 that final approval was granted.

As for "caving in" to political pressure, the FDA reportedly considered restrictions substantially similar to those proposed in the Vitter-Hutchinson bill but rejected them as medically unjustified. Instead, using its Subpart H authority, it required Danco Laboratories (the company that owns the U.S. rights to mifepristone) to agree not to distribute Mifeprex to pharmacies but only to physicians who certify in advance that they have the necessary knowledge and skills to prescribe the drug appropriately and who agree to provide patients with detailed information about it.

According to those close to the situation, the FDA determined that there is no scientific basis for allowing only physicians who are trained in surgical abortion to dispense mifepristone. Such training is not deemed necessary for physicians treating spontaneous abortions, for

example. Indeed, as a matter of standard medical practice, physicians regularly refer to other physicians for those services they do not provide, including surgical backup.

Likewise, the FDA made the determination that requiring certification in ultrasound dating and ectopic pregnancy detection is not required to administer mifepristone safely. Internationally, ultrasound is not a routine part of medical abortion care. But because it was used to date pregnancies in the U.S. trials, separate research was carried out to examine how strongly to recommend its use. Data published in 1999 in both *International Family Planning Perspectives* and *American Journal of Obstetrics and Gynecology* demonstrate that doctors are able to date pregnancies without ultrasonography by relying on clinical signs, using the parameters of last menstrual period and bimanual examination. Even in those study cases where there were differences in clinical dating and ultrasonographic examination, in the context of medical abortion these variations did not result in lower efficacy, nor did they compromise safety.

Finally, limiting distribution of mifepristone only to those physicians who have admitting privileges at a hospital to which the physician can travel in one hour is also out of step with common medical practice. Abortion rights advocates and medical abortion providers point out that similar restrictions have not been imposed on other drugs that are far more likely to cause complications requiring emergency care. "Should a cardiologist who prescribes drugs to treat heart patients be required to have admitting privileges at their local hospital?" Mitchell Creinin, director of family planning at the University of Pittsburgh, asked rhetorically during a briefing for congressional staff in February. "The proposed restrictions are ludicrous, over and above what is necessary to administer mifepristone safely and correctly."

## Science-Based Alternatives

The FDA gave its final approval for mifepristone based on the specific regimen used in the U.S. clinical trials. That regimen involved three visits to the physician's office: first for counseling and to receive an oral dose of mifepristone (600 milligrams (mg)), then two days later for an oral dose of misoprostol (400 micrograms (µg)) and once again, on day 14, for follow-up. Based on this clinical-trial regimen, 92% of women experienced a complete abortion. (In the French trials, complete medical abortion occurred in 95% of all cases.)

As early as 1991, however, the World Health Organization began advocating for the use of a lower dose of mifepristone, on the grounds that lower doses could decrease side effects—and costs—while providing similar efficacy. Indeed, an analysis involving 2,000 U.S. women, published in *Human Reproduction* in 1998, found that mifepristone was equally effective at one-third the standard dose. The study regimen consisted of 200 mg of mifepristone followed by 800 µg of misoprostol (administered vaginally rather than orally), resulting in a complete abortion rate of over 95%. Other studies using the same low-dose regimen have reported similar findings.

While research into the doses of mifepristone and misoprostol progressed, other investigators were examining in-home administration of vaginal misoprostol. Studies conducted in countries as diverse as Tunisia, Vietnam and the United States indicate that women overwhelmingly would choose in-home self-administration if given a choice—and that they can do so successfully without sacrificing safety or efficacy. In a 1999 study reported in *Contraception,* no significant complications occurred and rates of side effects were comparable to those reported with administration at a clinic. As for efficacy, among the 933 U.S. women enrolled, 97% had complete abortions.

In light of these new findings, most medical abortion providers in the United States have begun to provide women more choices, such as a lower dose of mifipristone or in-home administration of misoprostol, on a case-by-case basis. Such modifications of the regimen originally used in clinical trials are fully consistent with the FDA's approval of Mifeprex, which, as with all drugs, leaves administration to the discretion of individual physicians. Moreover, it is common practice for physicians to offer "science-based alternatives" when prescribing and dispensing FDA-approved drugs, so long as the alternatives are supported by adequate study.

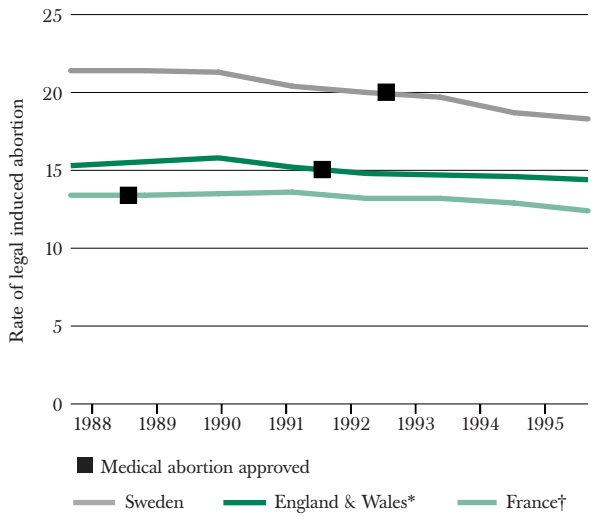
## A Very Early Option

Although antiabortion leaders warn of "dangerous side effects" for women and the need for "patient

*(Continued on page 7)*

## No Increase

***Abortion rates have declined during the 1990s in countries where medical abortion has been approved.***




*Residents only. †Data not considered complete. *Note:* A fourth country, China, approved medical abortion prior to 1999. Reported abortion rates in that country have also dropped considerably since approval (in 1988), but it is uncertain how much of the drop results from incomplete reporting. *Source:* Henshaw SK, Singh S and Haas T, Recent trends in abortion rates worldwide, *International Family Planning Perspectives,* 1999, 25(1):44–48.

## *Availability of Mifepristone…*

***Continued from page 4***

protections," the safety of mifepristone by now has been well-established in medical literature as well as in real-world use. In truth, opponents of abortion object to the drug's effectiveness. Unable to block mifepristone's approval, they are now attempting to rewrite the FDA guidelines that they believe have only "made things more convenient for abortionists." Weighing in on the subject during last year's election campaign, then-governor George W. Bush called the decision "wrong," saying, "I fear that making this abortion pill widespread will make abortions more and more common, rather than more and more rare."

These fears are likely unfounded; at a minimum, they are not supported by trends in abortion incidence in countries with available data. Indeed, a report published in *International Family Planning Perspectives* in 1999 shows that declines in the rate of abortion in England and Wales, France and Sweden during the 1990s coincided with the introduction of early medical abortion in those countries (see chart, page 4).

But if medical abortion is unlikely to spur an increase in the overall incidence of abortion, it is much more likely to have an effect on abortion timing. Even in the absence of the early medical abortion option, fully half of all abortions in the United States were performed in the first eight weeks of pregnancy, and almost nine in 10 in the first 12 weeks. The widespread availability of medical abortion could allow American women to have abortions even earlier than they already do. That would no doubt be welcome news to a public that is clearly most approving of abortion when it is performed early in pregnancy. (On the 25th anniversary of *Roe v. Wade,* 61% of respondents to a *New York Times*/CBS News poll in the United States said they thought abortions should be permitted during the first three months of pregnancy, but that support dwindles thereafter.) In short, opponents may see the availability of a very safe, very early option for abortion as a serious problem; most people would view it as real progress.