



NARAL
Pro-Choice America

Bill Imposing Unnecessary, Burdensome Restrictions on Mifepristone Would Block Women's Access to Safe, Early Abortion Option

After eight years of clinical trials and tests, in September 2000, mifepristone (originally known as RU 486) was finally approved by the Food and Drug Administration for use as a non-surgical early abortion option. The drug represents a significant step forward for American women's reproductive health. However, having failed to block FDA approval of this proven safe and effective drug, anti-choice lawmakers have mounted a multi-front legislative campaign against it. One such proposal, S.3939, introduced by anti-choice Sen. David Vitter in the 109th Congress, would impose a number of onerous and unnecessary restrictions on the drug's availability – making it virtually impossible for any provider to meet all its requirements. Furthermore, the bill is designed to scare women seeking early abortion care by requiring doctors to give their patients misleading information regarding the drug's safety record.

As a presidential candidate in 2000, George W. Bush said he opposed mifepristone and would not support its availability in the United States. (This threat was subsequently downplayed when it was observed that a president lacks unilateral authority over drug-approval matters.) A president may, however, sign legislation imposing restrictions on the drug, and then-candidate Bush did state his support for this type of bill. Later, as president, Bush further demonstrated his hostility toward mifepristone with his appointment in late 2002 (and reappointment in 2004) of W. David Hager to the FDA's advisory panel on women's health, which was influential in the approval of mifepristone in 2000. Hager, an avowed opponent of legal abortion and common forms of contraception, in 2001 helped the anti-choice Christian Medical Association spearhead a "citizen's petition" calling for the FDA to revoke approval for mifepristone.

American medicine is the envy of the world because of our investment in biomedical research, and because cutting-edge American medical practice is allowed to evolve constantly, without unnecessary government interference. In addition, FDA approval is the universally recognized gold standard of a drug's safety and efficacy. In attempting to impose further regulation on the FDA's approval of mifepristone, anti-choice lawmakers are challenging the integrity of medical practice as well as the FDA's decision-making process. Anti-choice politicians should not insert Congress into matters properly delegated to physicians and FDA scientists.

Mifepristone has repeatedly been proven safe and effective:

- It has been used for approximately two decades and is available to women in 36 countries, including France, the United Kingdom, Sweden, Austria, Belgium,

Denmark, Finland, Germany, Greece, Norway, Switzerland, Luxemburg, China, Israel, the Netherlands, Russia, Ukraine, and Spain.

- It is safe. Side effects are the same as common complications of a natural miscarriage and, in the rare case when the abortion is incomplete, the remedy is the very common and safe procedure of dilation and curettage.
- Mifepristone is as safe or safer than other commonly used medications. The number of adverse events associated with mifepristone is less, for example, than for such common medications as Viagra and Tylenol.
- Patient satisfaction rates are very high. According to a recent study, 96 percent of women who have used mifepristone would recommend the medication to others considering abortion care.
- Women might prefer to use mifepristone over traditional, surgical abortion for a variety of reasons, including that it does not require an invasive procedure or surgery, and requires no anesthesia. In addition, many women feel it gives them greater control over the process and increases their privacy.
- More than 800,000 American women have used the drug since its approval in 2000.

Myths and Facts

Anti-choice lawmakers claim the FDA approval conditions are insufficient.

Fact: PhRMA, the trade association representing the country's leading pharmaceutical and biotechnology companies, states clearly: "The U.S. system of new drug approvals is perhaps the most rigorous in the world." In attempting to re-write the FDA's approval of mifepristone, anti-choice members of Congress are threatening the integrity of the FDA and its scientific approval process.

Anti-choice lawmakers claim that more restrictions are needed to protect women's health.

Fact: The claim that anti-choice lawmakers want to protect women's health is utterly disingenuous. Key sponsors of such restrictions want to ban abortion altogether - clearly the most dangerous option for women. Not surprisingly, given the sponsors' goals, the effect of this legislation will be to severely restrict the number and kind of providers who can prescribe mifepristone. The following are just some examples of the practical effect of these restrictions:

- A woman who seeks a medical abortion at her HMO is told that there are 15 OB/GYNs on staff, but, as is often the case, only one performs surgical abortions. The woman must wait weeks for an appointment with the one surgical abortion provider, pushing her beyond the 49-day limit for using mifepristone.
- Eighty-seven percent of all U.S. counties currently have no identified abortion provider. Accordingly, many women must wait days, or even weeks, and travel far distances to get an appointment. Under these circumstances, the proposed restrictions may effectively prevent many women who want to use mifepristone from doing so in the narrow window available.

This legislation's effect will be to continue exposing women to harassment, intimidation, and violence at the very same reproductive-health clinics that now provide surgical abortion. A primary reason mifepristone is an historic milestone is that it should allow women to conduct their reproductive-health affairs with privacy and dignity, conditions that are often difficult to achieve in the current anti-choice climate.

Anti-choice lawmakers allege the availability of mifepristone will increase the number of abortions.

Fact: This anti-choice claim that the availability of mifepristone increases the abortion rate is baseless and unproven - in fact, evidence indicates otherwise. In France, where the drug has been in use since 1988, there has been no increase in the country's abortion rate. If anti-choice lawmakers want to reduce the number of abortions, they should join NARAL Pro-Choice America in supporting policies that will help women prevent unintended pregnancy.

Anti-choice lawmakers claim that further limitations regarding who may prescribe mifepristone are needed.

Fact: Experts at the FDA, not Congress, should resolve questions relating to a drug's approval; by FDA criteria, mifepristone has already been proven safe and effective. Legislating even stricter constraints on its availability will not make the drug safer or more effective; it will only make mifepristone harder for women to access.

Under the FDA's conditions of approval, mifepristone must be provided by (or under the supervision of) a physician who can:

- assess the duration of a pregnancy correctly;
- diagnose an ectopic pregnancy;
- provide surgical intervention if necessary, or has made plans in advance to provide such care through another qualified physician;

- assure patient access to medical facilities if necessary.

The FDA has approved almost 900 new drugs since 1995, yet Congress has never imposed such onerous and burdensome distribution requirements on any drug, much less one that has proven to be as safe and effective as mifepristone.

Anti-choice lawmakers claim that the FDA's mifepristone approval regimen is much more lenient than other countries', and that for this reason, American women will not be adequately protected under the FDA's approval criteria.

Fact: Our hard-fought freedoms cannot depend upon a country-by-country analysis of medical regimens. Physicians must in all instances be guided by what is best for women. Countries have adopted different conditions under which women use mifepristone. When the FDA approved the drug for use in the United States, it determined it was safe and effective. Below is a list of just a few examples of other countries' varying regimens:

- In Sweden, the United Kingdom, and Russia, mifepristone may be used with a prostaglandin up to 63 days of pregnancy, contrasted with the FDA's approving it for use up to 49 days for American women.
- Various prostaglandins, taken in at least three different forms (injectable, oral, and suppository), have been used with mifepristone in different countries.
- France allows a physician to date a pregnancy using a method other than ultrasound, as does the FDA.
- Mifepristone's dosage varies by country, and at least one other country's regimen involves a mifepristone dosage that is less than half of that the FDA approved for use in the United States.
- The United Kingdom allows doctors other than the prescribing physician to handle any rare complication that might arise from the drug's use, a standard that is comparable to what the FDA approved for the United States.

In sum, one cannot possibly draw any broad conclusion about the relative leniency or strictness of the FDA's approval criteria by comparing the prescription regimens of one country against another – they are simply too widely varying, and often depend on other countries' abortion laws, their own unique systems of health care (which in many cases are nationalized), and their own independent drug-approval authorities. Anti-choice lawmakers' call for further restrictions on mifepristone is disingenuous and unjustified by an examination of other countries' regimens of use. Theirs is a political goal: to reduce access to a very early, safe abortion option. Their campaign, if successful, will come at the expense of women's health.

Anti-choice lawmakers claim that prescribing physicians should have admitting privileges at hospitals within one hour of their offices.

Fact: Mifepristone is safe; there is no need for such scare tactics designed to restrict women's access to the drug. By the same logic, should Viagra patients be within five minutes of cardiac resuscitation devices, in case they have a heart attack?

Requiring physicians to have hospital admitting privileges is unnecessary in light of existing federal law. The Emergency Medical Treatment and Active Labor Act (EMTALA) requires that hospitals stabilize individuals who arrive at emergency rooms with emergency medical conditions. Moreover, the FDA already requires that mifepristone providers be able to perform surgical intervention themselves, or have made plans to do so with other qualified doctors.

The purpose behind this restriction seems clear, and is not based on concerns for women's health: bill sponsors hope to make mifepristone as difficult as possible for women to access. Imposing a geographical restriction on the drug's use would clearly disqualify many women who live or whose doctors' offices are not located within the arbitrary range of an emergency room that the bill requires.

Anti-choice lawmakers claim that mifepristone providers should be certified for ultrasound dating of pregnancy and detecting ectopic pregnancy.

Response: The FDA regulations already require that the drug be provided by or under the supervision of a physician who has the ability to assess the duration of the pregnancy accurately and to detect ectopic pregnancies.

- Ultrasound is not necessary to date and detect pregnancy. Medical providers and patients can accurately detect and date pregnancy based on the woman's last menstrual period, and blood and urine tests.
- The American Institute of Ultrasound in Medicine and the American College of Radiology, which are the only certifying bodies for ultrasound in the United States, do not certify physicians to provide specific ultrasound procedures, such as dating pregnancies and detecting ectopic pregnancies.
- Such a requirement would be yet another deterrent to physicians who might otherwise offer patients this service.

January 1, 2008