



NARAL
Pro-Choice America

Mifepristone: The Impact of Abortion Politics on Women's Health and Scientific Research

Mifepristone is the first and only Food and Drug Administration (FDA)-approved medication providing women with a safe and effective nonsurgical option for early pregnancy termination. Mifepristone has been tested extensively and used safely and effectively worldwide since 1981 and in the United States since 2000. By 2005, about one-fifth of women in the U.S. who received abortion care used mifepristone.¹ Despite its proven safety and its promise for scientific research, continued political attacks on mifepristone provide a prime example of how opposition to a woman's right to privacy and choice impairs medical advances and contradicts scientific research, compromising public health.

Mifepristone is Safe and Effective

Mifepristone, also known by its original name RU 486 and its trade name Mifeprex®, has undergone rigorous testing and has been used safely and effectively for almost 30 years.

- Millions of women worldwide have safely used mifepristone as an early option for nonsurgical abortion.²
- Since the FDA approved mifepristone in 2000, more than one million U.S. women have used the drug for safe and effective nonsurgical abortion care. The rate of reported adverse events for mifepristone is very low: approximately 0.28 percent.³
- Mifepristone is as safe as or safer than other commonly used medications. The number of adverse events associated with mifepristone is less, for example, than for such medications as Viagra and Tylenol.⁴
- Mifepristone was *not* "fast-tracked" through the FDA approval process as anti-choice activists claim; the medication underwent the standard, rigorous review process and clinical trials required for all new medications.⁵
- A 1998 study based on the clinical trials reports very high patient satisfaction with the regimen: 96 percent of women who have used mifepristone would recommend the method to others.⁶ Moreover, a 2000 report revealed that the medication had widespread appeal to a broad range of American women, regardless of race or ethnic background.⁷
- Studies of women using mifepristone suggest that when given a choice between nonsurgical and surgical abortion care, 57 to 70 percent choose the nonsurgical option.⁸

Mifepristone Has Other Potential Uses

Access to mifepristone enhances the ability of researchers to study other beneficial uses of the medication. However, persistent efforts by anti-choice lawmakers to hinder access to the medication will not only block reproductive choices for some women but will also impinge upon the potential advancement of research into its various uses.

- Mifepristone can help to induce labor and treat medical problems such as infertility, endometriosis, and certain types of tumors.⁹
- Mifepristone may be useful for treating certain breast-cancer tumors, with experts estimating that the drug may be an effective treatment for 40 percent of these cases.¹⁰
- Additionally, researchers have suggested that mifepristone may be useful in treating HIV, Cushing's disease, and glaucoma.¹¹

Evidence-Based Use of Mifepristone Is Safe, Effective, and Necessary

Evidence-based, or "off-label," use of mifepristone has come under attack by anti-choice forces in an attempt to scare women and further restrict their access to the medication. Contrary to these unfounded claims, evidence-based use of all drugs — including mifepristone — is common, safe, effective, and appropriate.

- More than one in seven prescriptions for common medications is for off-label use.¹²
- Standard medical practice assumes that in many instances, evidence-based drug use is essential to providing optimal patient care. Indeed, it is standard practice for doctors to use FDA-approved drugs for alternative uses, such as prescribing aspirin for the prevention of heart attacks.¹³ Today, heart and seizure medications are the medications most commonly prescribed for other purposes.¹⁴
- While estimates vary about the total number of prescriptions written for evidence-based use, an American Medical Association (AMA) official has estimated that 40 to 60 percent of all prescriptions in the United States are written for evidence-based uses.¹⁵
- Research with mifepristone has shown that alternatives to the FDA-approved regimen are safe, effective, and in most cases, preferable to the FDA regimen.¹⁶

Telemedicine and Medical Abortion

In 2008, Planned Parenthood of the Heartland in Iowa began using telemedicine to provide medical-abortion care. Using telemedicine for medical abortion can help provide health care to women who would otherwise not be able to receive it.

Telemedicine is the delivery of a health-care service using telecommunications technology. Videoconferencing, transmission of still images, remote monitoring of vital signs, continuing

medical education and nursing call centers are all considered part of telemedicine.¹⁷ Telemedicine is becoming more common practice – many fields of medicine including cardiology, pediatrics, dentistry, and psychiatry are using it to deliver health services. This type of care also holds promise for reproductive-health services.

- The system of telemedicine is especially important for Americans who live in remote or rural areas and do not have access to a nearby doctor, or who need a specialist located across the country. Approximately one-fourth of Americans live in rural areas while only 10 percent of physicians practice in these areas.¹⁸
- Eighty-seven percent of U.S. counties have no abortion provider.¹⁹ It is extremely difficult for some women to travel to a reproductive-health clinic where they can access abortion services directly from a provider.
- According to a 2011 study on the use of telemedicine for medical abortion, there is no major difference in complications between in-person and telemedicine care and telemedicine patients were more likely to report satisfaction with their care.²⁰

Furthermore, anti-choice activists' claims that using telemedicine to dispense mifepristone is dangerous to women because it lacks appropriate care and oversight from medical professionals are false.

- When women go to Planned Parenthood of the Heartland clinics, they undergo a thorough process before receiving abortion services. "Before the video conference begins, a patient in a distant clinic meets (in person) with a nurse. There, blood tests, a medical history, an exam, an ultrasound and counseling on matters like what to expect from the procedure and plans for a follow-up exam are completed. The results are shared (by computer) with a doctor miles away, and the doctor and the patient (at all times accompanied by the nurse, who sits beside her) meet by videoconference over a private network."²¹

Anti-Choice Attacks on Mifepristone

Despite FDA approval and worldwide acceptance of mifepristone, opponents of women's reproductive freedom continue their longstanding efforts to restrict access to the medication. These political assaults threaten to undo the promise of this important scientific and medical advancement.

- Since 2003, at least 17 states have considered measures restricting access to mifepristone.
 - In October 2011, an Oklahoma district court judge granted a temporary injunction against a law that prohibits the use of mifepristone. The injunction was granted in a suit challenging the law brought by the Oklahoma Coalition for Reproductive Justice and Nova Health Systems, which operates a reproductive-

health clinic in Tulsa.²² The anti-choice measure²³ was passed by the anti-choice Oklahoma state legislature earlier this year and signed into law by anti-choice Gov. Mary Fallin (R) in May.

- In 2004, Ohio passed a law prohibiting evidence-based use of mifepristone.²⁴ A federal judge at first issued an injunction preventing the law from going into effect,²⁵ but in July 2009 the court ruled that physicians are prohibited from prescribing mifepristone for off-label use and that doctors must prescribe the medication in accordance with FDA-approved labeling.²⁶
- In 2011, state legislatures around the country witnessed a wave of attacks on the use of telemedicine for medical-abortion care.
 - Eleven states introduced legislation and seven states enacted measures that prohibit the use or dispensing of mifepristone through telemedicine networks: AZ, KS, ND, NE, OH, OK, TN.²⁷

There have also been anti-choice attacks in Congress:

- In June 2011, Rep. Steve King (R-IA) offered a surprise-attack amendment to the FY'12 Agriculture appropriations bill that was intended to forbid use of the nation's telemedicine system for delivery or discussion of mifepristone. The amendment passed 240-176. In October, Sen. Jim DeMint (R-SC) filed a similar amendment to the FY'12 Agriculture, Commerce-Justice-Science and Transportation-HUD "minibus" appropriations bill. Because time for debate was limited, he did not bring the amendment up for consideration.
- In 2010, Sen. Tom Coburn (R-OK) tried to ban mifepristone from the new health-care system. The effort failed.²⁸
- In 2006, Sen. David Vitter (R-LA) introduced the "RU-486 Patient Health and Safety Act," which would impose a number of onerous and medically unnecessary restrictions on mifepristone's availability — making it virtually impossible for any doctor to prescribe the medication.²⁹
- In 2005 and 2007, anti-choice Rep. Roscoe Bartlett (R-MD) and Sen. Jim DeMint (R-SC) introduced the "RU-486 Suspension and Review Act."³⁰ The bill would legislatively override the FDA's approval of mifepristone, and would pull the drug off the market while an entirely new, additional "review" is conducted on the drug.
- In 2002, then-President Bush appointed W. David Hager, an avowed anti-choice proponent, to the FDA Advisory Committee for Reproductive Health Drugs, despite widespread public outcry and opposition from key members of Congress and numerous organizations concerned with women's health. Before his appointment, Hager authored the Christian Medical Association's "citizen's petition" calling upon the FDA to reverse its approval of mifepristone, claiming it has endangered the lives and health of women.³¹

Although Hager is no longer in this position, his biased appointment demonstrated the Bush administration's comfort with improperly mixing politics and science.

- In May 2006, anti-choice lawmakers held a congressional hearing to attack mifepristone and unjustly undermine public confidence in the medication. The hearing was chaired by then-Rep. Mark Souder (R-IN), who opposed all legal abortion, not just mifepristone, and stated publicly on his official website that "hopefully we will be able to accumulate enough evidence to make the FDA overturn their approval of the drug."³²

In addition to these and other attacks, anti-choice forces have been battling mifepristone for years, both before and after its approval:

- During the 2000 presidential campaign, George W. Bush stated his opposition to mifepristone and said that he would be "inclined not to accept" the FDA's approval ruling.³³ His subsequent anti-choice appointments to important cabinet and administration positions demonstrated his continued hostility toward the medication and the FDA approval.
- During the George H.W. Bush administration, the FDA issued an import alert that banned mifepristone in the United States for personal use. A federal district court that examined the import alert concluded, "[T]he decision to ban the drug was based not from any bonafide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."³⁴
- In 2001, prior to his confirmation as secretary of the Department of Health and Human Services, Tommy Thompson stated an intention, if confirmed, to revisit the FDA's approval of the medication. Though Thompson ultimately backed off of his threat, mifepristone was the only medication already approved by the FDA that he singled out for further investigation.³⁵

Access to Mifepristone Improves Reproductive-Health Options

Women might prefer to use mifepristone over traditional, surgical abortion care for a variety of reasons. Mifepristone does not require surgery and requires no anesthesia. In addition, many women feel it gives them greater control over their bodies and increases their privacy.³⁶

- Physicians in all 50 states, the District of Columbia, Puerto Rico, and Guam now offer mifepristone.³⁷
- In 2008, 59 percent of abortion providers in 1,066 facilities provided medical-abortion care. At least nine percent of providers only offer medical-abortion care.³⁸
- By 2005, the number of U.S. women choosing mifepristone more than doubled from the first full year of availability in 2001.³⁹
- In 2004, registered nurse-practitioners in Washington state were granted authority to prescribe mifepristone to patients, allowing women greater access to safe, reproductive-health options.⁴⁰

January 1, 2012

Notes:

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