



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

Mifepristone is the first and only 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. 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 25 years.

- Millions of women worldwide have safely used mifepristone as an early option for nonsurgical abortion.¹
- Since the FDA approved mifepristone in 2000, more than 800,000 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.²
- Mifepristone was *not* "fast-tracked" through the FDA approval process as anti-choice activists claim; the drug underwent the standard, rigorous review process and clinical trials required for new medications.³
- A 1998 study based on the clinical trials reports very high patient satisfaction with the regimen: 95.7 percent of women who have used mifepristone would recommend the method to others.⁴
- 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.⁵
- 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 medications as Viagra and Tylenol.⁶

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 drug

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.⁷
- 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.⁸
- Additionally, researchers have suggested that mifepristone may be useful in treating HIV, Cushing's disease, and glaucoma.⁹

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.

- 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.¹⁰
- 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.¹¹
- Many evidence-based uses are widely known and widely studied, and are, as a result, recommended by medical textbooks, research institutions, and professional organizations.¹²
- AMA Vice President M. Roy Schwarz stated that "[i]n some cases, if you didn't use the drug in the off-label way you'd be guilty of malpractice."¹³

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 drug. These political assaults threaten to undo the promise of this important scientific and medical advancement.

Some recent attacks include the following:

- In 2004, Ohio enacted a measure prohibiting evidence-based use of mifepristone.¹⁴ A federal judge has issued an injunction preventing the law from going into effect.¹⁵

- In 2004, four states considered six measures restricting access to mifepristone (KS, NJ, OH & WV).¹⁶ In 2006, two states considered three such measures (NJ & WV).¹⁷ In 2007, two states again considered three such measures (ND & OK).¹⁸ In 2008... [update with new Who Decides info].
- Legislation to restrict access to mifepristone has also been introduced in Congress.
 - 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 drug.¹⁹
 - In 2005, anti-choice Rep. Roscoe Bartlett (R-MD) and Sen. Jim DeMint (R-SC) sponsored the “RU-486 Suspension and Review Act.”²⁰ 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. Rep. Bartlett re-introduced the measure in the 110th Congress.²¹
- In 2002, 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.²² Although Hager is no longer in this position, his biased appointment demonstrates 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 what is a safe and effective drug. The hearing was chaired by Rep. Mark Souder (R-IN), who opposes all legal abortion, not just mifepristone, and states 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.”²³

In addition to these and other recent 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. His subsequent anti-choice appointments to important cabinet and administration positions demonstrate his continued hostility toward the drug 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.”²⁴

- 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 drug. Though Thompson ultimately backed off of his threat, mifepristone was the only drug already approved by the FDA that he singled out for further investigation.²⁵

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.²⁶

- Physicians in all 50 states, the District of Columbia, Puerto Rico, and Guam now offer mifepristone.²⁷
- In 2004, the number of U.S. women choosing mifepristone doubled from the first full year of availability in 2001.
- A 2002 report on mifepristone use in Europe suggests that the number of facilities offering nonsurgical abortion care and the proportion of women choosing the method are likely to increase gradually as physicians become more knowledgeable about the procedure and as more women seeking abortions inquire about mifepristone.²⁸
- 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.²⁹

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Notes:

¹ National Abortion Federation (NAF), *Facts About Mifepristone (RU-486)* (May 2007).

² Email from Abigail Long, Director of Marketing and Public Affairs, Danco Laboratories, to Adam Zimmerman, Legal and Policy Research Associate, Legal Department, NARAL Pro-Choice America (Nov. 2, 2007) (on file with NARAL Pro-Choice America).

³ General Accountability Office (GAO), *Food and Drug Administration Approval and Oversight of the Drug Mifeprex*, GAO-08-751 (August 7, 2006). See also National Abortion Federation (NAF), *Frequently Asked Questions About Mifepristone* (March 6, 2007) at http://www.prochoice.org/pubs_research/publications/downloads/professional_education/medical_abortion/faq_about_mifepristone.pdf (last visited Nov. 7, 2007).

Notes, cont.

- ⁴ Beverly Winikoff et al., *Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol*, 7 ARCHIVES FAM. MED. 360 (July/Aug. 1998).
- ⁵ Rachel K. Jones & Stanley K. Henshaw, *Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden*, 34 PERSP. ON SEXUAL & REPROD. HEALTH 154, 159 (2002).
- ⁶ Danco Laboratories, *Mifeprex® (mifepristone) Background Information*, December 15, 2004; Association of Reproductive Health Professionals, *What You Need to Know: Mifepristone Safety Overview*, at <http://www.arhp.org/factsheets/mifepristonessafetyoverview.cfm> (last visited Jan. 3, 2008).
- ⁷ Institute of Medicine, COMMITTEE ON ANTIPROGESTINS, CLINICAL APPLICATIONS OF MIFEPRISTONE (RU 486) AND OTHER ANTIPROGESTINS 1, 8-13 (Molla S. Donaldson et al. eds., 1993).
- ⁸ Feminist Majority Foundation, *The Medical Uses of Mifepristone* (2005), at <http://www.feminist.org/action/action120f.htm> (last visited Jan. 3, 2008).
- ⁹ Feminist Majority Foundation, *The Medical Uses of Mifepristone* (2005), at <http://www.feminist.org/action/action120f.htm> (last visited Jan. 3, 2008); *Mifepristone: Emergency Contraception and Other Uses*, 11 THE CONTRACEPTION REP. 13 (Dec. 2000), at <http://www.contraceptiononline.org/contrareport/article01.cfm?art=109> (last visited Jan. 3, 2008).
- ¹⁰ Marvin M. Lipman, *Using Approved Drugs for Unapproved Purposes*, CONSUMER REP. HEALTH, Feb. 1998, at 10.
- ¹¹ Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. LEGAL MED. 365 (1999); Fran Kritz, *FDA Seeks to Add Drugs' New Uses to Labels*, WASH. POST, at Z11 (Mar. 29, 1994); see also James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 80 (1998) (reporting that off-label/evidence-based prescriptions may account for more than 25 percent of the 1.6 billion prescriptions each year, with some estimates running as high as 60 percent); National Abortion Federation (NAF), *Pharmacological Approaches to Early Abortion* (2002) at http://www.earlyoptions.org/online_cme/m1pharma.asp (last visited Jan. 3, 2008).
- ¹² Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. LEGAL MED. 365 (1999).
- ¹³ Fran Kritz, *FDA Seeks to Add Drugs' New Uses to Labels*, WASH. POST at Z11 (Mar. 29, 1994).
- ¹⁴ OHIO R.C. § 2919.123.
- ¹⁵ *Planned Parenthood Cincinnati Reg. v. Taft*, 337 F. Supp. 2d 1040 (S.D. Ohio 2004), notice of appeal filed, No. 04-4371 (6th Cir. Oct. 22, 2004).
- ¹⁶ H.R.6019, 2004 Reg. Sess. (Kan. 2004); H.C.R. 5023, 2004 Reg. Sess. (Kan. 2004); A.B. 1406, 2004 Leg., 211th Sess. (N.J. 2004); H.B. 126, 125th Gen. Assem., Reg. Sess. (Ohio 2003); H.B. 4636, 2004 Leg., 79th Sess. (W. Va. 2004); H.B. 4296, 2004 Leg., 79th Sess. (W. Va. 2004).
- ¹⁷ A.B. 2740, 2006 Leg., 213th Sess. (N.J. 2006); H.B. 2091, 2006 Leg., 81st Sess. (W. Va. 2006); H.B. 4082, 2006 Leg., 81st Sess. (W. Va. 2006).
- ¹⁸ H.B. 1464, 2007 Leg., 60th Sess. (ND 2007); H.B. 2181, 2007 Leg., 51st Sess. (OK 2007); S.B. 715, 2007 Leg., 51st Sess. (OK 2007).
- ¹⁹ S. 3939, 109th Cong. (2006).
- ²⁰ H.R.1079, 109th Cong. (2005); S. 511, 109th Cong. (2005).

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²¹ H.R.63, 110th Cong. (2007).

²² American Association of Pro Life Obstetricians and Gynecologists, "Petition Filed with FDA Regarding Seriously Flawed Mifeprex (RU-486) Approval Process," Aug. 20, 2002.

²³ United States Congressman Mark Souder: Issues and Legislation, at <http://souder.house.gov/index.cfm?FuseAction=Issues.Home> (Jan. 3, 2008).

²⁴ *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992).

²⁵ Laura Meckler, *Thompson Would Review Abortion Pill*, ASSOCIATED PRESS ONLINE, Jan. 19, 2001.

²⁵ Population Council, *Mifepristone, At Last* (Jan. 2001), at http://www.popcouncil.org/publications/momentum/momentum1200_1.html (last visited Oct. 12, 2005).

²⁵ Telephone Interview by Sara N. Love with Heather O'Neill, Director of Public Affairs, Danco Laboratories, LLC, (Dec. 8, 2003).

²⁵ Rachel K. Jones & Stanley K. Henshaw, *Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden* 34 PERSP. ON SEXUAL & REPROD. HEALTH 154, 159 (2002).

²⁵ Wash. Op. Att'y Gen. No. 1 (Jan. 5, 2004).

²⁵ Institute of Medicine, COMMITTEE ON ANTIPROGESTINS, CLINICAL APPLICATIONS OF MIFEPRISTONE (RU 486) AND OTHER ANTIPROGESTINS 1, 8-13 (Molla S. Donaldson et al. eds., 1993).

²⁵ Feminist Majority Foundation, *The Medical Uses of Mifepristone* (2005), at <http://www.feminist.org/action/action120f.htm> (last visited Jan. 3, 2008).

²⁵ Feminist Majority Foundation, *The Medical Uses of Mifepristone* (2005), at <http://www.feminist.org/action/action120f.htm> (last visited Jan. 3, 2008); *Mifepristone: Emergency Contraception and Other Uses*, 11 THE CONTRACEPTION REP. 13 (Dec. 2000), at <http://www.contraceptiononline.org/contrareport/article01.cfm?art=109> (last visited Jan. 3, 2008).