NARAL
Pro-Choice America Foundation

MIFEPRISTONE AND THE IMPACT OF ABORTION POLITICS ON SCIENTIFIC RESEARCH & WOMEN'S HEALTH

Opposition to women's reproductive freedom has impaired medical advances and scientific research in the United States. Political attacks on mifepristone, an early option for non-surgical abortion, provide a prime example. Mifepristone, also known by its trade name, Mifeprex®, and its original name RU 486, has been tested extensively and used safely and effectively since 1981. As of January 2004, 29 countries had approved the use of mifepristone for pregnancy termination.[1] Despite this extensive medical use and worldwide acceptance, anti-choice forces in the United States are working to deny women access to the drug, recognizing that mifepristone would expand women's reproductive choices and make it more difficult to target abortion clinics for violence and harassment.

The Fight for Mifepristone 's Approval

During the first Bush administration, the U.S. Food and Drug Administration (FDA) issued an "import alert" which helped ensure that mifepristone would not be available in the United States for any purpose. A U.S. District Court that examined the "import alert" concluded, "[T]he decision to ban the drug was based not from any bona fide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."[2]

In January 1993, President Clinton signed an executive order lifting the import ban on mifepristone.[3] From 1994-1995, the Population Council conducted clinical trials on mifepristone in the United States. In 1996, the FDA Advisory Committee for Reproductive Health Drugs recommended approval of mifepristone as a safe and effective non-surgical method of abortion. In September 1996 and again in February 2000, the FDA issued "approvable letters" for the drug.

As FDA approval became more likely, anti-choice political efforts to block it gained momentum: In 1998 and again in 1999, the House adopted amendments offered by anti-choice Rep. Tom Coburn (R-OK) to bar the FDA from expending any funds to test, develop or approve drugs that could cause an abortion, such as mifepristone. Anti-choice lawmakers were unable to show any precedent for Congress inserting itself into the scientific decision-making process of the FDA to deny Americans access to a safe and effective drug. The Coburn amendments were dropped in each case, and on September 28, 2000, the FDA finally approved mifepristone, for use in combination with misoprostol, as an early option for non-surgical abortion.[4]

Anti-Choice Attacks on Mifepristone

Within days of the FDA's approval of mifepristone, anti-choice forces immediately shifted their focus to restricting women's access to the drug and the attacks continue today:

- In 2000, anti-choice members of the House and Senate introduced legislation severely restricting the number and kind of providers who could prescribe mifepristone. Sen. Tim Hutchinson (R-AR) and Rep. David Vitter (R-LA) reintroduced this legislation, ironically entitled the "RU-486 Patient Health and Safety Act," in 2001, but it never saw committee or floor action.

- 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. Bush's spokesperson later attempted to clarify that there was little he could do with respect to the ruling, but his subsequent appointments of anti-choice opponents of mifepristone to important cabinet and administration positions demonstrate his continued hostility toward the drug and the FDA approval.

    - Prior to his confirmation as secretary of the Department of Health and Human Services (HHS), Tommy Thompson stated an intention, if confirmed, to revisit the FDA's approval of the drug**.** Mifepristone was the only drug already approved by the FDA that Thompson singled out for further investigation.

    - In 2002, Bush appointed W. David Hager to the FDA Advisory Committee for Reproductive Health Drugs, despite widespread opposition from key members of Congress and numerous organizations concerned with women's health. 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. In December 2003, Hager renewed his call to "review' mifepristone.[5] In previous writings, Hager also condemns birth control pills and emergency contraception, and advocates prayer as a treatment for many serious illnesses, as well as PMS, headaches and skin disorders.

- In 2001, Michigan prohibited state-mandated abortion literature from describing any procedure that uses a drug that has not been specifically FDA-approved for abortion. Misoprostol, which must be used in tandem with mifepristone to terminate a pregnancy, is FDA-approved as an ulcer medication, but is also used through an evidence based regimen (also known as "off label") for non-surgical abortion. By prohibiting mention of misoprostol in state-mandated literature – which all women are required to read before obtaining an abortion – anti-choice lawmakers attempted to enact a back-door restriction on mifepristone use. In a settlement reached with pro-choice litigators, the state eventually acknowledged that misoprostol is FDA-approved for use with mifepristone.

The agreement also allows doctors to produce their own literature regarding abortion procedures if state materials aren't available.[6]

- In 2001, an Ohio state representative introduced legislation that would have required women seeking mifepristone to obtain the approval of a psychiatrist before receiving the drug. The sponsor of the bill acknowledged that, if enacted, the law would "make it so difficult to obtain the pill that it would effectively prohibit its use."

- Even though mifepristone is already covered by existing regulations on abortion, anti-choice lawmakers continue their senseless attack on the drug. In 2001, anti-choice state lawmakers introduced 22 measures restricting access to mifepristone; one was enacted. In 2002, 12 state measures were introduced and two were eventually enacted. In 2003, anti-choice lawmakers introduced one measure restricting access to mifepristone. [7]

- On January 29, 2003, Rep. Vitter (R-LA) re-introduced the "RU 486 Patient Health and Safety Act" in the House. Rep. DeMint (R-SC) introduced the "RU 486 Suspension and Review Act" in the House on November 6, followed by Sen. Brownback (R-KS), who introduced the same legislation in the Senate on November 21.

    - The "RU 486 Suspension and Review Act" would legislatively override the FDA's approval of mifepristone and would require an entirely new, additional "review" of the drug's approval. [8]

Despite FDA approval of mifepristone as a safe and effective drug, as well as worldwide acceptance of mifepristone's use for pregnancy termination, opponents of women's reproductive freedom are continuing their efforts to restrict mifepristone in 2003. These political attacks threaten to undo the promise of this important scientific and medical advancement.

Mifepristone is Safe and Effective

- In the three years since FDA approval of mifepristone, more than 200,000 U.S. women have used the drug for safe and effective non-surgical abortions.[9]

- More than 1 million women worldwide have safely used mifepristone as an early option for non-surgical abortion.[10]

- U.S. clinical trials tested a mifepristone/misoprostol combination that has been used safely and successfully in Europe.[11] The U.S. clinical trials involved 2,100 women across America. The *New England Journal of Medicine* reported in 1998 that a regimen of mifepristone and misoprostol was successful in medically terminating a pregnancy of 49 or fewer days duration in 92 percent of cases, and that the regimen was safe, with side effects consisting of heavy bleeding, cramping and nausea.[12]

- 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, and 91.2 percent would choose it again if necessary.[13]

- Studies of women using mifepristone suggest that when given a choice between non-surgical and surgical abortion, 57-70% choose the non-surgical option.[14]

- Protocol for mifepristone/misoprostol includes counseling, a physical examination, and a determination of the length of the pregnancy. At the first visit an initial dose of mifepristone is taken orally. Two days later, a prostaglandin called misoprostol is administered orally or in suppository form. Women return for a final visit, approximately 11 days later, to verify that the abortion is complete. If it is not complete, traditional surgical abortion is strongly recommended.[15]

- Women might prefer to use mifepristone over traditional, surgical abortion for a variety of reasons. Mifepristone does not require an invasive procedure or surgery, requires no anesthesia, and does not carry the risk of uterine perforation or injury to the cervix. In addition, many women feel it gives them greater control over their bodies and increases their privacy.[16] A study released in 2001 found that women perceive non-surgical abortion as a "natural" method – women who choose non-surgical abortion place importance on the method's resemblance to "a natural miscarriage" and the fact that the abortion can occur at home.[17] Another study found that women from diverse sociodemographic backgrounds consider medical abortion "highly acceptable."[18]

- If the mifepristone/prostaglandin regimen became widely available internationally, it could reduce the estimated 20 million unsafe abortions occurring annually worldwide by giving women an alternative to surgical abortions conducted under dangerously unhygienic conditions.[19] The World Health Organization estimates that unsafe abortions result in approximately 80,000 maternal deaths, and hundreds of thousands of disabilities.[20]

Access to Mifepristone May Increase the Number of Abortion Providers

- The U.S. currently suffers from a shortage of abortion providers. Eighty-seven (87) percent of counties have no abortion provider.[21]

- Physicians in all 50 states, the District of Columbia, Puerto Rico, and Guam now offer mifepristone.[22] While a 2001 survey revealed that only six percent of gynecologists and one percent of general practice physicians provided the drug in the first year of its approval,[23] in 2003, the percentage of women choosing Mifeprex® doubled from the first full year of availability in 2001. Over half of Mifeprex® customers are physicians in private practice.[24]

- A 2002 study of mifepristone use in Europe suggests that the number of facilities offering non-surgical abortion 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.[25]

Other Potential Uses of Mifepristone

- Mifepristone is an antiprogestin and works to terminate pregnancies by breaking down the uterine lining necessary to sustain a pregnancy. As an antiprogestin, it may have numerous other beneficial medical uses as well.[26]

    - Antiprogestins such as mifepristone can help to induce labor, prepare the cervix for dilation, and treat medical problems such as infertility, endometriosis, and certain types of tumors, including meningioma and fibroid tumors.[27]

    - Mifepristone may be useful for treating certain progesterone-dependent breast cancer tumors, with experts estimating that the drug may be an effective treatment for 40 percent of breast cancer tumors.[28]

- Additionally, researchers have suggested that mifepristone may be useful in treating HIV.[29]

- Mifepristone also works to some degree as an antiglucocorticoid, meaning it may interfere with certain adrenal gland hormones involved in regulation of tissues throughout the body. Potential applications as an antiglucocorticoid include the treatment of Cushing's disease and glaucoma.[30]

Access to mifepristone enhances the ability of researchers to study other beneficial uses of mifepristone. However, persistent efforts by anti-choice lawmakers to hinder access to the drug will likely impinge upon the potential advancement of research into its various uses.

January 1, 2004

Notes

[1] Danco Laboratories, LLC, "Mifeprex® Fact Sheet," *at* http://www.earlyoptionpill.com/m_kit.php3 (last visited December 8, 2003). In the late 1980s/early 1990s, mifepristone was approved for use in China, France, Great Britain, and Sweden following extensive clinical trials that demonstrated its safety and effectiveness. Austria, Belgium, Denmark, Finland, Germany, Greece, Israel, the Netherlands, and Spain followed suit, approving mifepristone in 1999.

[2] *Benten v. Kessler*, slip op. at 12, No. CV-92-3161 (E.D.N.Y. July 14, 1992).

[3] The White House, Office of the Press Secretary, "Memorandum for the Secretary of Health and Human Services, Subject: Importation of RU-486" (Jan. 22, 1993); The White House, Office of the Press Secretary, "Remarks by the President During Signing of Presidential Memoranda" (Jan. 22, 1993).

[4] Press Release, U.S. Food and Drug Administration (FDA), FDA Approves Mifepristone for the Termination of Early Pregnancy (Sept. 28, 2000) (on file with NARAL Pro-Choice America). For a more detailed chronology of the fight for the approval of mifepristone, please see NARAL's factsheet, "The Fight for Mifepristone," (January 1, 2004) *available at* http://www.prochoiceamerica.org/facts/fight_for_ru486.cfm.

[5] Paul Nowak, *FDA Advisory Committee Member Backs Review of RU 486 Abortion Drug*, Lifenews.com, December 3, 2003, *at* www.lifenews.com/nat234.html (last visited December 9, 2003).

[6] Center for Reproductive Rights (CRR), *Medical Abortion: An Alternative for Women* (May 2001), *at* http://www.crr.org/pub_fac_medabor.html (last visited January 18, 2003); CRR *Laws and Regulations Affecting Medical Abortion*, June 2003, *at* http://www.crlp.org/pub_fac_medabor2.html (last visited December 31, 2003).

[7] In 2001, 22 measures restricting mifepristone were introduced in 13 states (AR, HI, IN, IA, KS, KY, MO, NC, OH, OK, RI, SC, WI, WY); one measure was enacted in Iowa. In 2002, eleven measures restricting mifepristone were introduced in ten states (IN, IA, KS, KY, MI, NJ, RI, SD, VA, WV); two measures were enacted in Iowa and South Dakota. NARAL Pro-Choice America, 2001 & 2002 *State Legislative Charts: Medical Abortion* (information on file with NARAL Pro-Choice America). In 2003 Ohio was the only state to introduce a measure to specifically restrict access to mife this session.

[8] H.R 3453, 108th Cong. (2003).

[9] Danco Laboratories, *supra* note 1.

[10] *Id*.

[11] National Abortion Federation (NAF), *Clinical Trials Using the Standard Regimen* (2002) *at* http://www.earlyoptions.org/online_cme/m1clinical.asp (last visited December 9, 2003).

[12] Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 NEW ENG. J. MED 1241 (Apr. 30, 1998). According to recent research, mifepristone may be effective later in pregnancy. In a report of 2000 consecutive cases treated with mifepristone up to 63 days' duration, the complete abortion rate was 98 percent. Helena Von Hertzen, *Research on Regimens for Early Medical Abortion*, 55 J. AM. WOMEN'S MED. ASSOC. 136 (Supplement 2000), *citing* P.W. Ashok, et al., *An Effective Regimen for Early Medical Abortion: A Report of 2000 Consecutive Cases*, 13 HUMAN REPRODUCTION 2962-65 (1998). Another study of 313 women found mifepristone to be 94.5 percent effective in terminating pregnancies of 63 to 83 days' duration. D.E. Judge, *Medical Abortion Works up to 83 Days from LMP*, 4 J. WATCH WOMEN'S HEALTH 58 (Aug. 1999), *citing* E.V. Gouk, *Medical Termination of Pregnancy at 63 to 83 Days Gestation*, 106 BRITISH J. OBSTETRICS & GYNAECOLOGY 535-39 (June 1999).

[13] Beverly Winikoff et al., *Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol*, 7 ARCHIVES OF FAMILY MEDICINE 360 (July/Aug. 1998).

[14] Rachel K. Jones and Stanley K. Henshaw, *Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden*, 34 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 159 (May/June 2002), *citing* Cameron et al., *Impact of the Introduction of New Medical Methods on Therapeutic Abortions at the Royal Infirmary in Edinburgh*, BRITISH J. OF OBSTETRICS & GYNAECOLOGY, 1996 103(12): 1222-1229 and Winikoff B., *Acceptability of Medical Abortion in Early Pregnancy, 1995* 27 FAMILY PLANNING PERSPECTIVES 142-48, 185 (1995).

[15] Hazem El-Refaey et al., Induction of Abortion with Mifepristone (RU 486) and Oral or Vaginal Misoprostol, 332 NEW ENG. J. MED. 983-84 (Apr. 13, 1995); Population Council, *Frequently Asked Questions*; Population Council, "Medication Guide for Mifeprex™ Users," *at* http://www.popcouncil.org/mifeprex/medication_guide.html (last visited Jan. 21, 2003); National Abortion Federation (NAF), *Protocol Recommendations for Use of Mifepristone and Misoprostol in Early Abortion*, Early Medical Abortion with Mifepristone and Other Agents: Overview and Protocol Recommendations (NAF Curriculum Module) (October 2002).

[16] Population Council, *supra* note 1.

[17] S. Marie Harvey, Linda J. Beckman & Sarah J. Satre, *Choice and Satisfaction with Methods of Medical and Surgical Abortion Among U.S. Clinic Patients*, 33 FAMILY PLANNING PERSPECTIVES 212 (Sept./Oct. 2001).

[18] Shelley Clark, Charlotte Ellertson & Beverly Winikoff, *Is Medical Abortion Acceptable to All American Women: The Impact of Sociodemographic Characteristics on the Acceptability of Mifepristone-Misoprostol Abortion*, 55 J. AM. MED. WOMEN'S ASSOC. 177, 181 (supplement 2000).

[19] World Health Organization, *Address Unsafe Abortion,* (1998), *at* http://www.who.int/archives/whday/en/pages1998/whd98_10.html (last visited December 31, 2003).

[20] *Id*.

[21] Lawrence B. Finer & Stanley K. Henshaw, *Abortion Incidence and Services in the United States in 2000*, 35 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 6 (2003); The Alan Guttmacher Institute (AGI), *Facts in Brief, Induced Abortion, at* http://www.agi-usa.org/pubs/fb_induced_abortion.html (last visited December 9, 2003).

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

[23] Kaiser Family Foundation, *National Survey of Women's Health Care Providers and Reproductive Health: Medical Abortion Results* (Sept. 24, 2001) (toplines); Kaiser Family Foundation, "Chart 3: Who is Providing Medical Abortion? And Who Will Provide it in the Next Year?," *National Surveys of Women's Health Care Providers and the Public: Views and Practices on Medical Abortion* (Sept. 24, 2001) (chartpack).

[24] Telephone interview with Heather O'Neill, *supra* note 22.

[25] Rachel K. Jones & Stanley K. Henshaw, *Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden* 34 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 159 (May/June 2002).

[26] INSTITUTE OF MEDICINE COMMITTEE ON ANTIPROGESTINS: ASSESSING THE SCIENCE, CLINICAL APPLICATIONS OF MIFEPRISTONE (RU 486) AND OTHER ANTIPROGESTINS: ASSESSING THE SCIENCE AND RECOMMENDING A RESEARCH AGENDA, 28-29 (Molla S. Donaldson et al. eds., National Academy Press 1993); Population Council, *Frequently Asked Questions: Medical Abortion*.

[27] INSTITUTE OF MEDICINE COMMITTEE ON ANTIPROGESTINS, *supra* note 26, at 1, 8-13; Population Council, *supra* note 26; Marja-Liisa Swahn, Marc Bygdeman & Kristina Gemzell Danielsson, *Various Uses of Mifepristone in Gynecology and Obstetrics*, 8 REPRODUCTIVE HEALTH MATTERS 122,124 (Nov. 1996).

[28] Feminist Majority Foundation, *Feminist Majority Foundation Reports on Mifepristone, at* http://www.feminist.org/gateway/ru486one.html (last visited December 31, 2003).

[29] *Id.*

[30] INSTITUTE OF MEDICINE COMMITTEE ON ANTIPROGESTINS, *supra* note 26, at 1, 13; *Mifepristone: Emergency Contraception and Other Uses*, 11 THE CONTRACEPTION REPORT (December 2000), *at* http://www.contraceptiononline.org/contrareport/article01.cfm?art=109 (last visited December 31, 2003).