What You Need To Know About RU486

By Molly B. Ginty

Mifepristone (a. k. a. RU-486, a. k. a. the "abortion pill") is like no other medication on the market today.

> ...many women's health advocates are applauding mifepristone's arrival. The drug has the potential to improve access to abortion, boosting the number of doctors who offer it and frustrating the efforts of anti-choice militants.

Women who want it may never get to take it, because their doctors are unwilling or unable to provide it. Women who try it may never learn the name of its manufacturer, the address of its distributor, or the identities of government experts who approved it—facts concealed from the public for fear of anti-abortion violence.

The secrecy that surrounds mifepristone may frustrate its many supporters, but it illustrates a crucial point: the decision to take mifepristone—like the decision to try any method of abortion—is as fiercely political as it is personal.

After a decade of successful use in Europe and a protracted tug-of-war in the U.S., mifepristone is at long last available to women in America. On the surface, this option seems straightforward enough: a way to end early pregnancy by taking two drugs over the course of three days. It will provide women and girls with an alternative to surgery for approximately 1.4 million abortions that occur in the U.S. every year.

Nevertheless, mifepristone's arrival in America has fuelled fervour on both sides of the abortion debate. Already fettered by existing laws on waiting periods and parental consent, it has also inspired new anti-choice legislation. Requiring extensive medical protocols, the drug is too expensive for many women to afford.

But despite its drawbacks, many women's health advocates are applauding mifepristone's arrival. The drug has the potential to improve access to abortion, boosting the number of doctors who offer it and frustrating the efforts of anti-choice militants. As Gloria Feldt, president of Planned Parenthood Federation of America, says, "This is the first truly major technological breakthrough for women's reproductive health care since the birth control pill was introduced in 1960."

Abortion Rx

Originally called RU-486 (for Roussel Uclaf, the French company that developed it, and the catalogue number assigned to it), mifepristone was synthesised in 1980 and has been available in Europe since 1988. Since

then, 62,000 women have used the drug in Europe, and it now accounts for 20 percent of all abortions in France. In the U.S. it has been sold since November 2000 under the brand name Mifeprex.

Although it can be used to treat everything from breast cancer to brain tumours, it is prescribed primarily as an abortion drug. Taken fewer than 49 days after the woman's last menstrual period, mifepristone helps terminate a pregnancy in its earliest stages.

To have a "medical abortion," as a non-surgical abortion is sometimes called, a woman visits her healthcare provider and is given three pills totalling 600 milligrams of mifepristone, which blocks the action of the hormone progesterone. This causes the fertilised egg to detach from the uterine wall, and the uterine lining to break down. Two days after taking the first drug, the woman returns and takes 400 micrograms of misoprostol (brandname: Cytotec), which causes uterine contractions and helps expel the fertilised egg. Afterward, bleeding or spotting occurs for nine to 16 days. The patient returns to her doctor 12 days after her second appointment and has an exam to ensure that she is no longer pregnant.

Doctors can make slight variations on these FDA-approved protocols: they can prescribe a slightly lower or higher dosage of mifepristone or misoprostol; they can administer misoprostol orally or vaginally; or they can allow patients to take misoprostol at home, resulting in fewer office visits and a lower cost.

> Physical reactions to the drugs vary with each woman's body chemistry and the length of her pregnancy. And mental reactions vary as well: some patients say medical abortion requires more emotional involvement than traditional surgical abortion, because surgery shields a woman from the sight of the embryo.

Many women who have tried medical abortion say it feels more natural—more like a miscarriage or heavy period than a standard surgical abortion.

"The cramping wasn't worse than anything I'd have with a normal period, which surprised me because I was expecting more pain, says "Sara," a hospital administrative assistant from Maryland who took misoprostol to complete a spontaneous miscarriage. "Having this option gave me a lot more control. I don't like anaesthesia. I don't like not being able to actively participate in what's going on with my body. To be knocked out with legs in stirrups would be absolutely terrifying to me."

Women also say they appreciate the privacy afforded by non-surgical abortion, and the ability to go home and rest while the abortion is still occurring, either alone or with a partner or friend close by.

In a study by associates at the Pacific Institute for Women's Health, 63 percent of patients who took the abortion pill said they wanted to avoid surgery; 56 percent believed it was safer; 41 percent believed it was more natural; 35 percent wanted to lower their risk of infection; and, 27 percent wanted to end their pregnancies as early as possible. Most patients had a positive experience: 94 percent would recommend the procedure to others and 87 percent would choose it again.

But some women have had slightly more negative experiences with medical abortion. "It was painful," says "Lynn," who used the drugs during clinical trials in 1999. "There were sharp, vigorous contractions, and it took three hours to expel most of the clotted tissue."

Physical reactions to the drugs

vary with each woman's body chemistry and the length of her pregnancy. And mental reactions vary as well: some patients say medical abortion requires more emotional involvement than traditional surgical abortion, because surgery shields a woman from the sight of the embryo. And mifepristone also takes a lot longer—two weeks as opposed to a few hours for a standard abortion. "If you want abortion over and done within a short period of time, then medical abortion is not for you," says Amy Allina, programme director for the National Women's Health Network.

The drug is also not appropriate for women who have bleeding disorders or adrenal gland problems, who use IUDs, or take corticosteroids or blood thinners. The most common side effect is cramping, followed by nausea, vomiting, and diarrhoea. In eight percent of cases, bleeding or spotting lasts for 30 days or more. Also in eight percent of cases, surgical intervention is required to complete the abortion, or more rarely, to stop excessive bleeding. Within a month of taking abortion drugs, most women can conceive again. Overall, the earlier a pregnant women uses mifepristone, the gentler and safer it appears to be.

How to get a prescription

Women who want to try mifepristone can turn first to their regular doctors.

Surveys by the Kaiser Family Foundation conducted before approval by the U.S. Food and Drug Administration (FDA) indicated that more than half of obstetricians and gynaecologists would likely prescribe mifepristone at some point in the future—including some who don't already do surgical abortions. About 45 percent of family physicians expressed interest in prescribing the drug regimen, as well. But in a country where seven doctors or other clinic workers have been murdered since 1993, providers have cause to worry about their safety and may decide to steer clear of mifepristone.

FDA protocols that apply to mifepristone may also turn doctors away, especially those who aren't already set up to provide surgical abortions. Before taking the drug, a woman must read a medication guide and sign a "patient agreement" verifying that she has discussed mifepristone with her doctor and decided to terminate her pregnancy. "Doctors say mifepristone is 90 percent counselling, so it takes more time than surgical abortion," says Planned Parenthood's Feldt. Physicians must be able to peg the precise duration of a patient's pregnancy—a protocol that could mean investing in a US$20,000 ultrasound machine. If doctors don't have surgical expertise, they must find a qualified surgeon to help in the event of an emergency.

Because of the extra counselling, malpractice insurance, and staff training that mifepristone can involve, may physicians are now taking a wait-and-see approach. "I don't think many doctors will jump up and say 'I want to do this!'" predicts Allina. "They will watch. They will listen. And as it becomes more common, more of them will include it in their practice."

If a woman discovers that her regular doctor is not willing or able to offer mifepristone, there are still ways to find qualified providers (see Action Alert, page 92). By the end of this year, all of the National Abortion Federation's 360 members—along with Planned Parenthood affiliates—plan to prescribe mifepristone to patients who request it. Doctors can order mifepristone from Danco Laboratories, the pharmaceutical company that distributes it in the U.S. Danco will ship mifepristone only to licensed MDs who sign and return a prescriber's agreement. It will not sell the drug in pharmacies or on the Internet. Danco is charging physicians US$270 for each dose of mifepristone—bringing the cost for women to anywhere from US$300 to $700 or more.

As of March 2001, the nation's major insurers have pledged to cover mifepristone. Health maintenance organisations will likely cover it in two-thirds of cases, as they do for surgical abortions. For women who must rely

on public health care, some government assistance may be available: the federal Medicaid programme covers abortion in cases of rape, incest, or threats to a woman's life, and 16 states cover abortion for poor women in all cases. Planned Parenthood will likely offer the regimen on a sliding scale as it does for surgical abortion.

The Maelstrom

Some patients who choose mifepristone over surgery do so partly because of politics. "If my doctor gives me a pill and I am taking that pill, my doctor is less likely to be putting his or her life on the line," says Lynn. "It brings the pro-choice argument right back where it belongs, which is with me. I'm taking full responsibility for my actions by not putting somebody else in jeopardy."

Politics and mifepristone have been all but inseparable since French researchers first used the drug in 1982 to induce abortion. It took 18 years, a string of lawsuits, and a reported US$50 million in non-profit funding to bring it to America. But now that drug has arrived, it seems that the uproar is only beginning.

First there is the flap over mifepristone's price: it will be as expensive, if not more, than a standard surgical abortion. "We priced this drug to be a viable option in the market place," says Heather O'Neill, a spokesperson for Danco. "We also

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have to recoup the costs associated with bringing it to the U.S."

The high price of the drug came as a surprise to health activists who hoped the drug would cost at least US$100 less than it does. "There is nothing we would love more than for the price of this drug to be lower," says Planned Parenthood's Feldt. "But we have to recognise the reality that bringing mifepristone here took more than the usual amount of time, money, and courage."

While some activists are shrugging off the high cost as inevitable, others are seething. "They should justify this or explain it," says Barbara Seaman, vice president of Abortion Rights Mobilisation and a contributing editor for Ms. "They should also be able to do this for much less."

The FDA's handling of the drug is just as controversial as mifepristone's price. Some health advocates claim the agency dragged its feet by taking four years to review mifepristone's application, making its approval agonisingly slow compared to that of other medications reviewed simultaneously. Activists also claim extra protocols were slapped on the drug for political reasons. These protocols, while safeguarding patients, make mifepristone more time-consuming for doctors and thus boost its price.

Countering activists' criticisms of the FDA are spokespeople from Danco and the Population Council, the health research firm that ran the clinical trials of mifepristone in the U.S. Both insist that the FDA acted in a timely manner. "We don't believe it was politics that held it up at the FDA," says Sandra Waldman, director of public information at the Population Council.

But neither side can deny that the FDA took special precautions with mifepristone, carefully hiding the names of its executives and investors. "We're not exactly handing out our

address on street corners," says O'Neill. But safety measures didn't stop vandals from locating the car of Danco's medical director, Dr. Richard Hausknecht, and doing US$2,000 worth of damage to it. "At least they didn't shoot me," Hausknecht shrugs.

To avoid the controversy and violence that often surround abortion, other health professionals are distancing themselves from mifepristone. Several colleges across the country (including Boston University, Emory University, and the entire Florida public university system) have announced they will not offer it at their campus health centres. Searle, the pharmaceutical company that makes misoprostol, the second drug used in medical abortion, has fired off a strongly worded letter to health care providers saying misoprostol (normally prescribed to gastrointestinal ulcers) is "not approved for the induction of labour or abortion" and that its maker promotes it "only for its approved indication." The letter doesn't mention that misoprostol's use in abortion is perfectly legal because the FDA has approved its use in other regimens. And of course hospitals affiliated with the Roman Catholic Church (currently 10 percent of all hospitals and increasing, thanks to recent mergers) have proclaimed they will not carry the drug.

Then there are the anti-abortion militants, who call mifepristone "baby poison" and are already threatening the doctors who provide it. One anti-choice group has even created an "RU-486 Registry," a website that proclaims itself to be a "database of baby-butchering doctors and their closest blood cohorts." Before being temporarily shut down in December 2000, the site listed the names and states of nearly 500 abortion providers, politicians, and others who support a woman's right to choose. The names of those wounded by militants were printed in grey typeface. The names of those murdered had black lines slashed through them.

Scariest for most activists are the legal assaults on mifepristone. Though surveys indicate that 55 to 65 percent of people in the U.S. believe the government should not bar a woman's access to abortion, government as it stands today may not support the majority. In recent years, state legislatures have passed a barrage of restrictions that speak of abortion in general terms and will thus apply to mifepristone. "These laws could put women [who want to try mifepristone] past the 49-day cut-off," says Bebe Anderson, staff attorney for the Centre for Reproductive Law and Policy (CRLP). "Waiting periods enforced in 13 states require women to consult their doctors, then return 48 hours later to have an abortion. In areas where abortion doctors are only available one day a week, women may have to wait a full week between appointments. Parental involvement laws enforced in 32 states could make the delay even longer. It can take a minor several weeks to get permission to have an abortion without her parents' knowledge or consent."

Like conservative state legislatures, the U.S. federal government also contains a significant anti-abortion element. Between 1998 and 2000, Oklahoma Representative Tom Coburn introduced measures to block access to the drug. None of this legislation passed, and Coburn retired in December, but his cohorts are still in Congress. "And every time anti-choice legislation is introduced, it gives [anti-abortion activists] a chance to spread false propaganda about this drug."

The current House is 50 percent anti-choice, 32 percent pro-choice, and 18 percent mixed, while the Senate is 47 percent anti-choice, 35 percent pro-choice and 18 percent mixed. On the Supreme Court, three justices consistently support *Roe v. Wade*, three consistently oppose it, and three support more restrictive abortion laws. It is crucial that abortion rights supporters keep the pressure on their senators and representatives to make sure that conservative justices are not placed on the high court, and that anti-choice laws do not make it to President George W. Bush's desk.

Mifepristone: A Chronology

1980
Researchers at Roussel Uclaf in France develop mifepristone, a drug that blocks the action of stress hormones. While testing it, they discover that it also blocks hormones needed to sustain pregnancy.

1982
Clinic trials of mifepristone as an abortion drug begin in France and, a year later, in the U.S.

1985
The National Institute of Health begins research on other uses of mifepristone.

1988
Women in France and China gain access to mifepristone.

1989
Roussel Uclaf announces it will not market or distribute mifepristone outside of France, and the FDA bans importation for "for personal use".

1990
Feminist Majority Foundation members travel to France to urge Roussel Uclaf to bring the drug to the U.S.

1991-1992
The United Kingdom and Sweden approve mifepristone.

1992-1993
U.S. customs officials seize mifepristone from a woman who tries to enter the country with it. The New England Journal of Medicine publishes studies showing it is effective, and the National Institute of Medicine reports that it can help fight a range of diseases. President Clinton asks the FDA to lift the ban and urges the Department of Health and Human Services to promote mifepristone.

1994-95
Roussel Uclaf gives U.S. patent rights to the Population Council, which conducts clinical trials of mifepristone on 2,121 women. Abortion Rights Mobilisation, an activist group, produces a copy of the drug and distributes it to the researchers and patients seeking abortions.

1996
The FDA determines that mifepristone is "approvable" but requests additional information.

1997
Gedeon Richter, the Hungarian company that pledged to produce mifepristone in the U.S., backs out of its agreement to do so.

1999
The Feminist Majority Foundation begins distributing the drug for "compassionate use" in treating diseases like breast cancer. Mifepristone becomes available in ten more countries.

2000
The FDA approves the use of mifepristone for abortion on 28 September.

If mifepristone can weather the political maelstrom, it could potentially change the scope, scale and nature of abortion in America. If more doctors begin administering the drug, it could boost abortion access in the U.S. where the number of abortion providers has dropped to 30 percent since 1982, and 86 percent of counties have no provider at all. Since mifepristone could hypothetically be administered by almost any physician with prescription-writing privileges, it could frustrate the efforts of anti-choice protestors and spare women the pain of being called "baby-killer" as they enter a clinic to carry out a decision that was already agonising for many of them. If abortion moves into private offices, where will the militants stand with their placards, rosaries, and megaphones?

Gaining new ground

As they roll up their sleeves for the battles ahead, mifepristone's supporters take heart in the victories they've already won. They know that unlike many "new" drugs, this medication has been safely used by millions of women and has been researched by scientists for nearly two decades.

They also know that mifepristone is gaining new ground everyday. Planned Parenthood and the National Abortion Federation are training doctors to use it. Danco and the Population Council are conducting follow-up studies, as are independent

scientists, in order to refine the medical abortion regimen. Proponents are preparing to bring mifepristone to new countries, where it could reduce the number of unsafe abortions—now estimated at 20 million world-wide each year.

The decision to terminate an unwanted pregnancy is one that more than a million American women make annually. Statistics show that 43 percent of us will have an abortion by the time we are 45. For women who don't want surgery, "mifepristone may make abortion physically easier," says "Sharon," a housewife and mother in Rochester, New York, who took the drug in January 2000. "But emotionally, I don't think anything can make the decision to terminate pregnancy easier. This is a gut-wrenching decision and not one that women make lightly."

But it must be a choice that women make, not legislators or anti-choice crusaders. To help keep this choice in women's hands, activists must make their voices heard. "Women need to vocalise that they want their physicians and insurance providers to both offer and cover mifepristone," says Vicki Saporta, executive director of the National Abortion Federation.

The battle is simple and straightforward. Talk to your friends about medical abortion. Join organisations that support it. Write letters to the editor of your local newspaper. Lobby your federal and state representatives. Urge the National Institutes of Health to fund more studies on mifepristone. Put pressure on the FDA to approve taking misoprostol at home.

As Elizabeth Cavendish, legal director of the National Abortion and Reproductive Rights Action League, says, "This is a tremendously important development for women's reproductive health. It is also a fight that we can win."

Emergency Contraception

Medical abortion should not be confused with emergency contraception (EC), which prevents a pregnancy before it starts, instead of terminating one already in progress. The most common methods of EC involve taking a series of birth control pills, as prescribed by a health care provider. There are two FDA-approved EC kits available: Preven (progestin and estrogen) and Plan B (progestin only). These methods are 75 to 90 percent effective at preventing pregnancy if used within 72 hours of unprotected intercourse. A woman can also be fitted with IUD within five days after intercourse, a method that is 99 percent effective. For more information, visit the Website: <http://www.not-2-late.com>.

Other Methods of Abortion

Dilation and curettage (D & C)
The cervix is dilated, and the contents of the uterus are removed with forceps and curette (a surgical instrument with scoop, ring, or loop at the tip). Timing: 4 to 12 weeks, after a woman's last menstrual period (LMP) Cost: US$250 to US$1,000. Although it is the procedure that many people associate with abortion, it is considered outdated by many gynaecologists and is rarely used today.

Dilation and evacuation (D & E)
The cervix is dilated, and a combination of suction and forceps are used to remove the foetus and the placenta. Timing: 14 to 24 weeks after LMP. Cost: US$400 to US$5,000. Considered the safest way to terminate second-trimester pregnancy, this method is used for later abortion in the event of an emergency.

Electrical Vacuum Aspiration (suction curettage) The cervix is dilated if necessary, and an electric vacuum aspirator removes the contents of the uterus. Often a curette is used to complete the abortion. Timing: four to 14 weeks after LMP. Cost: US$250 to US$1,000. The first-trimester period is the most common type of abortion performed in the U.S. and is 97 to 99 percent effective. It is sometimes referred to as a D & C.

Hysterectomy In this surgical procedure, the foetus and the placenta are removed though an incision in the uterus, similar to caesarean section. Timing: 16 to 30 weeks after LMP. Cost: US$1,000 to US$ 4,000. Generally used only in cases where the mother's health is endangered and no other method is possible. This procedure carries a higher-than-average risk of complication but is very rare.

Manual Vacuum Aspiration (MVA or menstrual extraction) The cervix is dilated if necessary, and the contents of the uterus are removed through a tube into a handheld vacuum syringe. Timing: 4 to 12 weeks after LMP. Cost: US$250 to US$1,000. Performed by pioneering feminists before abortion was legal in the U.S., this procedure is still popular in countries where electrical vacuum methods are not yet available. It is 97 to 99 percent effective.

Prostaglandins (induction) Drugs are administered orally or vaginally to induce contractions that eventually expel the foetus. Timing: 12 to 26 weeks after LMP. Cost: US$500 to US$2,000. Misoprostol, the second drug in the mifepristone regimen, is used this way. Although not as effective as other methods used in the first trimester, prostaglandins are very effective in the second trimester.

Methotrexate An alternate form of medical abortion, also used in combination with misoprostol. It detaches the foetus from the uterine wall by interfering with the ability of cells to multiply and divide, thus halting embryonic development. Timing: 4 to 7 weeks after LMP. Cost: US$250 to US$500. Methotrexate is approved in the U.S. to treat cancer and arthritis, and is prescribed "off-label" as an abortion drug, particularly in ectopic pregnancies. But methotrexate has several drawbacks: it takes longer to work than mifepristone and it triggers bleeding that is less predictable.

More than an Abortion Drug

In addition to terminating early pregnancy, mifepristone can help treat a host of health problems. Developed to block stress hormones, it has been used to treat brain tumours called meningiomas and a glandular condition called Cushing's syndrome. Is also able to fight endometriosis, uterine fibroids, and breast and ovarian cancers.

Scientists began investigating these applications in the mid-1990s, before politics and distribution delays intervened. "There has been some very basic work, but we haven't had access to this medication before," says Dr. Eric Schaff, a professor at the University of Rochester School of Medicine and a leading researcher on mifepristone. "Now that we do, we've very excited. This drug has tremendous potential for treating some very serious diseases."

Action Alert

To find a health care provider who prescribes mifepristone contact:
National Abortion Federation (US): Website: http://www.earlyoptions.org
Abortion Clinics Online: Website: http://www.gynpages.com
National Coalition of Abortion Providers: Website: http//www.ncap.com

To send a free fax about mifepristone to your government representatives:
Visit the ACLU website at http://www.aclu.org/action/ru486ban107.html

To get the latest news about mifepristone turn to:
Alan Guttmacher Institute: Website: www.agi-usa.org
Kaiser Family Foundation: Website: http://www.kff.org
National Women's Health Network: Website:http://www.womenshealthnetwork.org
Population Council: Website: http://www.popcouncil.org
Planned Parenthood: Website: http://www.plannedparenthood.org

Molly B. Ginty is a writer in New York City. A former abortion clinic escort, she hopes to write a book about women's personal experiences with abortion.

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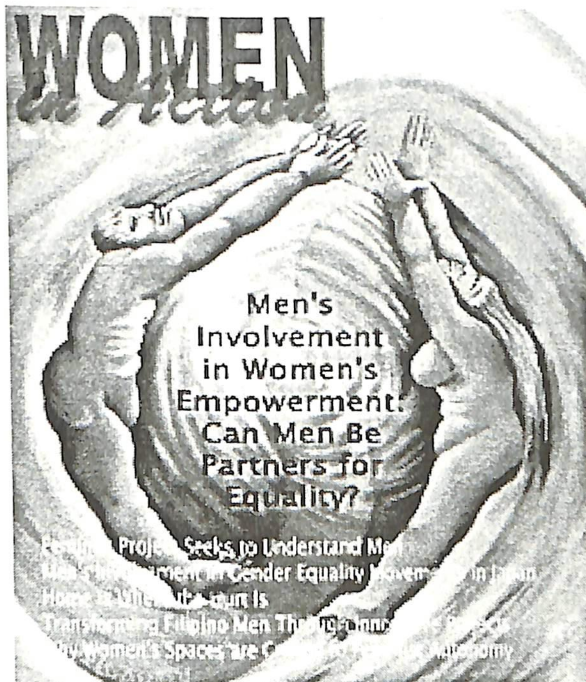

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We!

Isis International

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Inhumane Treatment of Women with Mental Disabilities

Amnesty International (AI) is appealing to concerned organisations and individuals to help in the campaign to protest the cruel, inhuman and degrading treatment of mentally disabled women held at a state institution in the village of Sanadinovo, Bulgaria.

Health experts described the women's conditions as "far worse than we have documented anywhere in the region," amounting to cruel, inhuman and degrading treatment. Others have called it "a slow death."

The Bulgarian Helsinki Committee, Mental Disability Rights International (MDRI) and AI visited the Sanadinovo Social Home for Mentally Disabled Women and found around 20 of the most severely disabled women being housed in a two-room, single-story building, separated from the rest of the facility by a high wire fence. Some suffer from mental illness.

MDRI and AI reported that the 20 women were found "sitting on the ground in the small, paved yard, with no chairs or benches, wearing dirty, ill-fitting, tattered clothes." Several women with amputated limbs or other physical disabilities moved about without any help from the staff.

"During milder, warm weather these women spend most of the day outside the building in the small yard. Conditions inside were appallingly filthy, smelly and unhygienic," according to the report. "The floors of the rooms were wet and there was an overpowering smell of urine and feces even though all the barred windows and doors had been open. There were feces on the floor, particularly under the beds, and traces of feces all over the walls."

Near the women's quarters is a small cage, which holds six women. Women are

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