RU-486

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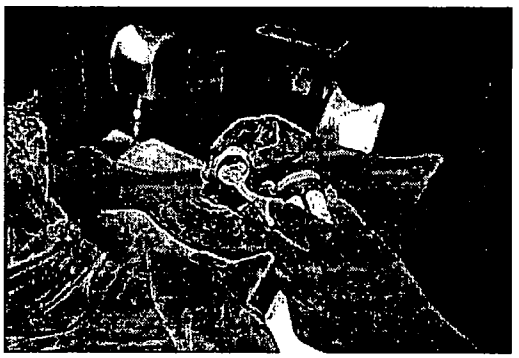

Compiled by Karla Saladino

October 4, 2000

Congress May Limit RU - 486 Use

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By THE ASSOCIATED PRESS

Filed at 3:33 p.m. ET

WASHINGTON (AP) -- Abortion foes in Congress introduced bills on Wednesday that would tighten standards for doctors administering the newly approved abortion pill RU-486.

Rep. Tom Coburn, R-Okla., joined by Sen. Tim Hutchinson, R-Ark., said the legislation was needed because the Food and Drug Administration, in setting rules for prescribing the drug, had ''caved in'' to abortion rights groups seeking easy access to abortion. ''Congress now has the unenviable task of correcting the FDA's mistake.''

Kate Michelman, president of The National Abortion and Reproductive Rights Action League, said the legislation would impose restrictions that would ''in effect negate the ability of doctors to prescribe this option for women.''

Coburn said he hoped to get the bill to the House floor in the final days of this session. Hutchinson was less ambitious, saying he was looking to have a hearing this year and pursue the issue next year.

The FDA approved RU-486 on Sept. 28, ending a 12-year debate in this country. It gives American women a pharmaceutical abortion method already in wide use in France, Britain, China and 10 other countries.

President Clinton praised the decision as ''one of science and medicine,'' but abortion opponents said it would encourage more women to end their pregnancies.

The FDA said that in order to prescribe the drug, doctors must be able to pinpoint the date of the pregnancy, rule out women with ectopic or tubal pregnancy, and be prepared to take surgical steps to complete the abortion or stop the bleeding in the case of problems. Also, women must sign a form agreeing to the necessary three doctor visits.

Coburn, a practicing physician who says he has delivered 3,500 babies and performed abortions to save the lives of mothers, said his aim was to better protect women who take the drug.

He and Hutchinson would require the prescribing physician to be legally empowered and trained to perform an abortion, properly trained in the drug's administration and have admitting privileges at a nearby hospital.

Michelman said the result would be to relegate RU-486 ''to a non-option for women'' because they would in effect only be able to obtain the pill from the declining number of doctors who perform abortions. ''This is exactly the type of bill that George W. Bush would sign into law.''

Hutchinson accused the FDA of bowing to political pressure in adopting what he said were inadequate protections. ''It is extremely disturbing that the FDA would switch gears in a matter of months and water down patient protections for American women just to see the RU-486 pill approved before the end of this administration.''

The pill was taken up in Tuesday night's debate between presidential nominees Vice President Al Gore and Texas Gov. Bush. Bush said he was disappointed in the ruling but didn't think the president could overturn it. Gore said the FDA had concluded the drug was medically safe and he supported its decision.

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Va. Curbs RU-486 Use by Minors

By Jennifer Lenhart
Washington Post Staff Writer
Tuesday, October 10, 2000; Page B01

Virginia officials said yesterday that the state law requiring parental notification before minors have abortions applies to the abortion pill, RU-486, which the Food and Drug Administration approved last month after a decade of study.

Virginia's guidelines for the pill's use appear to be the region's strictest. The District has no parental consent law, and Maryland's law gives physicians wide latitude to decide whether consent is necessary.

The approval of RU-486, a pill that when taken with a second drug can induce a miscarriage, has opened a host of questions for politicians, doctors and activists on both sides of the abortion issue.

In Virginia, where health officials and the attorney general's office have been studying the legal questions surrounding the pill's approval, it is also uncertain whether Medicaid funds will be available for women seeking the drug. Virginia law denies the use of public money for a surgical abortion except in cases of rape, incest or if the woman's life is in danger.

In the District, officials said yesterday that they, too, are unsure whether the prohibition against using public funds for abortion applies to the pill.

"This is a whole new area of

———Also From The Post———
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- **Live Online Transcript:** Eleanor Smeal, co-founder and president of the Feminist Majority Foundation, answered questions about the recent FDA approval of the abortion pill RU486.
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"This is a whole new area of contraception which heretofore has not been available," said D.C. Council member Jim Graham (D-Ward 1). "I'm not sure whether additional action is required or not."

Maryland law allows public funding for abortion "for almost any reason," said David Lam, executive director of Maryland Right to Life.

But given some of the medical issues associated with RU-486--such as bleeding and cramping--Lam said his organization may pursue a so-called informed consent law that would require doctors to inform women of the risks.

Other than that, he said, "I really don't think there's a whole lot states can do. . . . We can't override the FDA."

The Old Dominion appears to be the first among states with parental notification or consent laws to announce that those laws apply to RU-486, abortion rights officials said yesterday. Such laws are on the books in 31 other states.

"They were not written with either surgical or medical [abortion] in mind but rather with the intent to get parents involved and to discourage minors from having abortions," said Betsy Cavendish, legal director of the National Abortion and Reproductive Rights Action League.

Cavendish said she and other abortion rights officials expect virtually all states with such laws to apply them to the pill.

Virginia abortion rights supporters agreed yesterday with state officials that the law does cover RU-486 and that minors who seek an abortion using the pill will be required to notify at least one parent or legal guardian at least 24 hours in advance.

"Virginia's parental notification law on the books specifically references nonsurgical abortion as being covered by the requirement that a minor must demonstrate that she has told a parent of her abortion," said Karen A. Raschke, an attorney in Richmond for the Center for Reproductive Law and Policy.

Laws on whether Medicaid funds can be used to cover abortions vary widely from state to state. Under federal guidelines, women on Medicaid are eligible to use the program for surgical abortion in cases of life endangerment, rape or incest, and some abortion rights activists said yesterday that the same standards, at the very least, should apply to the abortion pill.

"I don't see any reason why . . . at the state level, a woman wouldn't be able to get RU-486 if she's entitled to it" under the federal guidelines, Cavendish said.

Virginia Attorney General Mark L. Earley (R), who sponsored the parental notification law in 1997 when he was a state senator, had his staff evaluate the law in light of the FDA's approval of the abortion pill. The conclusion was that it "remains intact and applies with regards to RU-486," said Earley's spokesman, David Botkins.

Doctors are required to get parental permission before dispensing any

other medication to a minor, said Botkins, so that would also apply to RU-486.

Staff writers Lori Montgomery and Sewell Chan contributed to this report.

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Abortion Foes Want States to Curb RU-486

By William Claiborne
Washington Post Staff Writer
Thursday, October 5, 2000; Page A01

CHICAGO, Oct. 4 — Having failed to prevent the federal government from approving the abortion pill RU-486, antiabortion advocates nationwide are now mobilizing to restrict its use through new state laws.

In interviews this week, legislative directors or heads of nearly two dozen antiabortion groups in states with some of the nation's most restrictive abortion laws said they were examining whether measures could be drawn specifically to include RU-486 in existing laws. Those laws require parental consent and waiting periods for abortions, and prohibit public funding of abortions and abortion counseling by state employees.

Some abortion opponents, noting that numerous states have laws requiring a physician or pathologist to examine the fetal tissue after an abortion, said those states could press for a strict interpretation of the laws to force women to collect the products of their drug-induced miscarriages and take them to their doctor's office. Antiabortion activists said this could deter the use of the drug.

Also mentioned by the advocacy groups were the "conscience-based exemptions" in 45 states that permit health care workers to refuse to participate in abortions because of their moral or religious beliefs.

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Most of the drug's opponents concede there is little likelihood of enacting full-scale bans on the controversial drug, which will be sold under the name Mifeprex, because states lack the authority to override Food and Drug Administration rulings. Also, the U.S. Supreme Court ruled in 1992 in the landmark Planned Parenthood v. Casey case that although states cannot ban abortion, they can regulate the procedure as long as they do not impose an "undue burden" on women's right to choose.

But the antiabortion activists say that when legislatures return to session after the election, they will seek to have bills introduced or existing abortion control laws amended to at least restrict distribution of the drug or impede women's access to it.

"I think the states will first be looking to tweak existing abortion control laws to specifically include [RU-486] and all nonsurgical abortions, and then they'll go from there," said Laura Tobler, senior policy specialist for the National Conference of State Legislatures in Denver.

Last year alone, 439 bills to restrict abortions were introduced in state legislatures, and 70 were enacted in 34 states, according to the New York-based National Abortion and Reproductive Rights Action League (NARAL). Nine states considered but did not adopt measures specifically restricting access to RU-486 or controlling the dispensing of information about it in anticipation of FDA approval, Tobler said.

Betsy Cavendish, NARAL's legal director, said, "We can expect them to continue their onslaught and open up a new front on mifepristone," RU-486's chemical name.

Parental notification and consent laws, in effect in 31 states, can be applied to any abortion situation, including what abortion rights activists call "medical abortions," according to the New York-based Center for Reproductive Law and Policy.

Similarly, "physician only" laws, which in 43 states prohibit non-physicians from performing abortions, could be applied to health care providers who assist with medical abortions. The 14 states that have "targeted regulation of abortion provider" laws could force doctors contemplating offering medical abortions to fulfill requirements that specify things such as how office space must be laid out and how they must be staffed.

"It's not a magic pill that will make the burdensome abortion restrictions on the books in every state in the nation vanish," said the center's president, Janet Benshoof, referring to RU-486's approval. "Despite mifepristone's great potential to improve medical services for women, antiabortion state legislatures have already erected a labyrinth of laws restricting all abortions."

In Washington, Rep. Tom Coburn (R-Okla.), a physician, introduced a bill today requiring that only doctors trained to perform surgical abortions or stop excessive bleeding could prescribe the drug. The FDA requires only that doctors prescribing the drug be able to arrange for a surgical abortion. Sen. Tim Hutchinson (R-Ark.) said that it would be "very, very tough" to win Senate approval before Congress adjourns this month but that he hoped Congress will eventually consider the bill and

other ways to answer RU-486's approval.

Most of the legislative effort against RU-486 on a state level is expected in the Midwest, which traditionally has been most aggressive about regulating abortion.

Michael Fichter, executive director of Indiana Right to Life, said that a proposed "conscience-based exemption" law in his state may be amended to include hospital pharmacists, who he said will be "on the front line" of dispensing the drug to physicians affiliated with the hospitals.

Like most midwestern states, Indiana passed a ban on the controversial late-term procedure opponents call a "partial birth" abortion. In all, 30 states have passed bans on the procedure, although federal courts have blocked most of them. In June, the Supreme Court overturned Nebraska's ban on such abortions because the law was worded too broadly and did not include an exemption when a woman's life was at risk.

Ed Rivet, legislative director of Michigan Right to Life, said his group will seek to include mifepristone in a bill that would remove state-funded health care coverage for surgical abortions. "We'd like to do more, but we assume this is a federally controlled issue, and we are somewhat limited in what we can do," Rivet said. "But we'll do what we can."

Rivet and several other antiabortion advocates said they thought there may be precedents to states counteracting the FDA, including the case of fenfluramine, half of the diet drug combination known as fen-phen, which Tennessee banned in 1991. Several other states imposed strict controls on the drug after reports that patients were abusing it. In 1997, fenfluramine was withdrawn from the market after being linked to heart valve damage.

Rivet noted that the "medical abortion" procedure effectively approved by the FDA last week also involves a combination of two drugs: Mifeprex, which is taken by a pregnant woman within seven weeks of the beginning of her last menstrual period, followed two days later by misoprostol, which previously had been approved by the FDA to prevent ulcers.

FDA officials said they knew of no instances of states successfully overruling an agency decision approving or disapproving a drug. They said that would constitute state "preemption" of federal authority and has never been upheld in this area. Officials also said that the fen-phen case did not involve state preemption because although the FDA approved each of the drugs involved separately, it never approved the specific combination that some states ultimately banned.

Laura Echevarria, spokeswoman for the Washington-based National Right to Life Committee, conceded that the fen-phen case might be tenuous as a precedent and that applying abortion control laws already on the books is probably the best route for state antiabortion groups.

Patty Skain, executive director of Missouri Right to Life, said her group had not developed a strategy against RU-486 but was considering

pressing for the adoption of "safety measures" that would impede access to the drug. However, she said many Missouri antiabortion advocates were making their top priority the education of women about the drug's side effects, including severe bleeding and pain.

Similarly, Nebraska's Right to Life executive director, Julie Schmidt-Albin, said her group was "up to our neck" in pressing the legislature for a ban on the University of Nebraska Medical Center's use of aborted fetuses for research and had not yet considered a strategy for state action against mifepristone.

David Lam, executive director of Maryland Right to Life, also said that legislative priorities for the 2001 session had not been set yet but that the group favored informed consent legislation "so women are fully informed about the risks and dangers of RU-486 and aware of the alternatives that are available."

In Virginia, Robin DeJarnette, government relations director for the Family Foundation, said she hopes a resolution can be passed asking Congress to direct the FDA to rethink its decision.

Virginia Del. Robert G. Marshall (R-Prince William) said he is considering introducing a bill that would hold doctors and medical facilities liable for any complications a woman might experience as a result of being prescribed the drugs.

Staff writers Leef Smith, Christian Davenport and Marc Kaufman contributed to this report.

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Abortion Pill Is Complicated

By Marc Fisher
Thursday, October 5, 2000; Page B01

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Discuss this and other columns on the Marc Fisher Message Boards.

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From all the talk about RU-486, the abortion pill, you would think there'd been another one of those technological breakthroughs that explode age-old assumptions. You'd think that the swallowing of a pill was going to narrow differences between opposing philosophies or eliminate women's anguish or take politics out of health.

None of that is going to happen. Nor should it.

When a debate gets as fierce as the abortion wars have become, there is more than partisanship and political philosophy at work.

The more black and white the abortion argument grew, the more obvious it became that this is a most gray area indeed.

Like those Scottish terrier magnets that kids used to buy from turnpike vending machines, the two sides in the abortion battle repelled each other as a matter of nature. But the public dispute masks the private reality of abortion: It is at once an act of mercy and of horror.

It can be an avalanche of emotional and physical pain that lends itself easily to a polarized political debate because that debate, even in its extreme expressions of blockades and screaming, arrests and violence, is a relatively easy distraction from the act itself.

The advent of a pill--so simple, so small--is the perfect rhetorical device for ratcheting up this distraction to a new level. After all, we live in the age of easy answers; technology is supposed to relieve the tensions in life.

But it rarely lives up to that promise, and this pill is no exception. It is, to start with, hardly a simple medical procedure. It involves multiple visits to the doctor, multiple medications, considerable pain and no relief from the trauma of ending a pregnancy, no matter how justifiable the motivation.

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In the first months after the Berlin Wall fell, I met many East German women who had grown up under a Communist health system in which abortion was the standard form of contraception. It was a commonplace to meet women who had had 8, 10, 12 abortions.

They spoke about what they had experienced with the same frail, teary voices in which I have heard many American women tell of their sole experience with the procedure. No matter what you decide about right and wrong, no matter how deeply you believe you are making the correct decision, there is no getting used to an act that ends a life.

What I learned from the German women I had met, women who were emerging from a society in which "choice" was no choice at all, was that the propaganda terms used in the American abortion wars are simplistic beyond meaning. "Choice" and "life" are slogans, not realities. Keep abortion available, but make it harder, many of the German women said. Push women to think through their decisions; encourage maturity instead of knee-jerk reaction.

But thinking maturely about abortion is much harder than hurling slogans. So the Vatican's newspaper condemns this medication as "the pill of Cain--the monster that cynically kills its brothers."

And abortion rights advocates react with their usual flood of soothing, numbing rhetoric about how the expelled embryo "has no sensory organs, no developed brain and is unable to feel hunger or any other form of pain."

The pro- people are pro-pill. The anti- people are anti-pill. But somewhere in between the activists stand the people over whom they are fighting, people who make individual decisions that are not political in the least but cut to the soul and force men and women to sit together and finally face realities of who they are and what they believe. And for the people who must make those decisions, the pill neither adds nor subtracts anything but atmospherics.

Because the pill is not about "choice" or "life." It's about death, and that is what we fear most, and that is what abortion requires us to face. And sometimes that decision is right, and sometimes that is wrong. And no pill makes it any more or less so.

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Mifepristone: More Than an Abortion Pill

By Judy Mann
Wednesday, October 4, 2000; Page C13

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Doris Marley Laird, a professor of humanities at Florida A&M University, suffered terrible headaches for five years, until one night she had a nocturnal seizure. She woke with the overhead light on, and she was leaning on her elbow. Her husband asked her how she felt, she said she felt all right, and he told her to try to go back to sleep.

The next morning he was on the phone with a doctor, she was hospitalized, and a CAT scan showed a tumor the size of an orange. Her neurosurgeon was blunt. He told her that if he didn't operate immediately, she would become demented and die. The operation, performed on Dec. 7, 1982, lasted 23 hours, and during that time, the surgeon removed a benign meningioma that had wrapped itself around both optic nerves. She was in the hospital more than three weeks. She had to learn to walk again, and she lost her sense of smell. But the surgeon had saved her eyesight and her life.

Four years later, the tumor was back. She had a second craniotomy. But this time, the frontal lobe of the brain was damaged, and she ended up in a deep clinical depression that lasted until she was put on different medication.

Four years later, the tumor had returned again, and she had a third brain surgery in 1992. Her second and third operations lasted 12 hours. For all three, she had to have her head completely shaved. She wore wigs for years.

Finally, she contacted a friend in Atlanta who had the same condition and was being treated with a drug. She met with his doctor, neurosurgeon Nettleton Payne, who got together a battery of tests and filed a request for compassionate use of a French-manufactured drug, mifepristone, with the Food and Drug Administration. Laird has been taking a 200-milligram tablet of the drug daily since 1993.

Mifepristone is also known as RU-486. Because it is used for early-stage chemical abortions, it has been caught up in the abortion war for more than a decade. Few people have had access to it, and few doctors have

than a decade. Few people have had access to it, and few doctors have had enough of the drug to conduct clinical trials to determine its effectiveness against a number of diseases. The Feminist Majority Foundation has been a leader in the effort to allow Americans access to RU-486, and it was awarded the sole responsibility for administering the compassionate-use program under which Laird has been getting the drug.

Last week, the FDA approved the use of mifepristone for abortions, giving women another option for terminating a pregnancy in the embryonic stages. Restrictions that states have applied to abortions, such as waiting periods and parental consent, will still apply. But a survey has shown that more doctors will be willing to use the abortion pill than are willing to perform surgical abortions, which means there is likely to be an increase in abortion providers, says Eleanor Smeal, head of the Feminist Majority Foundation.

The Population Council, a research agency for family planning, has licensed Danco Laboratories to produce the drug for use in this country. Now that the abortion hurdle has been overcome, Smeal believes that the supply of the drug will increase and that more and more doctors will want to use it in clinical trials. "Having this approved will further tumor research," she says.

Research being conducted at the University of Rochester is showing that mifepristone can reduce fibroid uterine tumors by 50 percent, Smeal says. Fibroid tumors, which can become large enough to adhere to other organs such as the bladder, are the leading cause of the more than 500,000 hysterectomies performed on American women each year. "If you can make it through menopause, the tumors shrink, and you don't need a hysterectomy," Smeal says. "So reducing them by 50 percent could save a great many women from getting a hysterectomy."

A small study released in June showed that 200 milligrams of mifepristone administered daily was effective against ovarian cancers that had become resistant to chemotherapy. Three of 34 patients had a complete response, and six had a partial response, meaning that the drug was able to shrink the tumors and prolong life.

Other small studies suggest that mifepristone--a synthetic hormone antagonist that binds to progesterone receptors--also may be effective against breast and prostate cancers. The drug tamoxifen, which binds to estrogen receptors, is routinely prescribed to women who have estrogen-positive breast cancer. Smeal says mifepristone might be similarly useful against progestin-dependent cancer. Forty percent of breast cancers are progestin-dependent, says Smeal, which means mifepristone might reduce breast cancer recurrences.

"I think when there is more supply and more clinical trials, we will find it useful" for controlling a number of tumors, Smeal says.

The drug also has properties that can help treat Cushing's disease, an endocrine disorder, and certain types of depression.

The foundation plans to ask the National Institutes of Health to increase funding for clinical trials of the drug. "The cancer studies take longer, and they are expensive," says Smeal. "A study for [fibroid tumors] would go much faster. You know if they've shrunk. I think we'll have

results from something like that soon."

Mifepristone has been shamefully politicized. Had Laird had access to it after her first brain surgery, she might not have had to have two other major, invasive, life-threatening operations.

As Smeal points out, one in every two men and one in every three women will get cancer in their lifetimes. "We should use every hunch everybody can think of, and this is more than a hunch."

What NIH needs to do now is to make up for the lost time by directing money into research that will tell us about the efficacy of a drug that holds promise for reducing suffering and death. That is pro-life.

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Doctors' Fears May Limit Use Of Abortion Pill

By Serge F. Kovaleski and Susan Okie
Washington Post Staff Writers
Sunday, October 1, 2000; Page A01

While the approval of RU-486 promises to transform the abortion debate, advocates and opponents say the abortion pill's impact could be muted by trepidation among doctors about prescribing the controversial drug.

Although the drug's availability through private doctors' offices is expected to make it much harder for antiabortion activists to target abortion providers, some medical professionals may remain fearful of protesters or even violence, experts say.

Some states, including Virginia, already have abortion reporting requirements that would apply to RU-486 and make it difficult for doctors who use it to remain anonymous. And antiabortion activists already have begun looking for ways to use such fears to their advantage, including seeking similar laws in other states.

"I think the big concern for doctors is security. They do not want to . . . be intimidated or subject to violence or have their staff and families subject to the actions of anti-choice people," said Maxine Klane, a registered nurse and vice president for patient services at Planned Parenthood of Metropolitan Washington. "Physicians have been killed in this country over abortion."

Doctors also may shun the pill

The controversial abortion pill RU-486, also known as mifepristone. (AFP)

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Doctors also may shun the pill because they are not familiar with administering it or dealing with the complications that could arise, or with the counseling that would be required of them, some observers said.

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"The predictions for the whole thing may be a little optimistic in terms of people thinking that doctors who are not performing abortions are going to come out of the woodwork and start prescribing the pill," said Ron Fitzsimmons, executive director of the National Coalition of Abortion Providers.

At a meeting last week at Washington Hospital Center of doctors training to be obstetricians-gynecologists, for example, news of the drug's approval did not prompt any more residents to voice a willingness to perform abortions, according to David Downing, director of the hospital's residency program.

"Roughly half will not do abortions and do not want to learn abortions. About half have some interest," said Downing.

"My experience with up-and-coming doctors is that they make decisions very early on whether they will or will not perform abortions," he added. "The mode of the abortion usually does not play a role."

Doctors who have religious objections to abortion, for example, are no more likely to use the drug, which will be on the market as Mifeprex within a month.

"I will not be prescribing it myself," said Jeremy Janssen, a chief resident in George Washington University's family practice program. "I feel that the Constitution is pretty clear that the right to life is before the right to liberty, and I don't think it's going to change my viewpoint."

Obstetrician-gynecologists and family practitioners, who care for pregnant women, are the specialists most likely to offer RU-486.

Fewer than 10 percent of obstetrician-gynecologists perform the surgical procedure, and among those who do not, a recent survey by the Kaiser Family Foundation suggested that 45 percent might prescribe the abortion drug. The study also reported that about half of family practice physicians, nurse practitioners and physicians' assistants said they would be willing to prescribe the drug.

Observers contended that in states such as Virginia, for instance, where an estimated 80 percent of the counties have no abortion providers, RU-486 could have a major impact.

"This will make a significant difference for women who now have to travel hours to reach a clinic where surgical abortions are provided," said Ben Greenberg, director of government relations for Planned Parenthood Advocates of Virginia. "The other major issue is that this will truly become a decision between a woman and her physician, as opposed to a woman having to go to a clinic where abortions are provided."

Many of the obstetrician-gynecologists who decide to provide RU-486 are likely to be practitioners who previously gave up doing surgical abortions because of concerns about antiabortion activists, said Thomas

F. Purdon of the University of Arizona in Tucson, president-elect of the American College of Obstetrics and Gynecology. "I think some of those physicians will start up now with this medical treatment," he said.

Most doctors, however, have not had a chance to learn about the newly approved drug or the provisions under which the Food and Drug Administration will allow them to provide it. The FDA requires detailed counseling and three office visits and mandates that doctors be able to do a surgical abortion, or arrange for one, in the small percentage of cases where RU-486 fails.

Training in how to use RU-486 is being offered in half-day sessions across the country by doctors working with the National Abortion Federation, an organization of abortion providers. So far, 1,800 doctors, nurses and counselors have attended such training, including about 300 from clinics or medical practices that don't offer surgical abortions.

"Initially, it's going to be offered by current abortion providers," predicted Vicki Saporta, the NAF's executive director. "Over time . . . I think a wide variety of physicians will be expanding their practices to include this option."

But it remains unknown how many doctors will eventually embrace RU-486.

"There are so many ancillary issues surrounding abortion that it could be discouraging to someone thinking about prescribing RU-486, and many of them could back away," Fitzsimmons said. "This is more than a pill. . . . The politics is colliding with the medical reality."

Staff researcher Madonna Lebling contributed to this report.

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CORRECTIONS

Saturday, September 30, 2000; Page A02

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A Sept. 29 article incorrectly described counseling that women receive before taking the abortion pill RU-486. Counselors tell women that it would threaten their health if they failed to also take a second drug, misoprostol, which causes contractions to expel the embryo.

A Sept. 29 obituary on former Canadian prime minister Pierre Elliott Trudeau incorrectly reported the age of his youngest son, Michel, at the time of his death. He was 23. In some editions, the article incorrectly reported when Mr. Trudeau regained a majority government; it was 1974.

An article in the Sept. 28 Style section misstated the distance traveled by Olympic 100-meter sprinters in one-hundredth of a second. The distance is about four inches.

A Sept. 24 article on the books President Clinton is reading or has read incorrectly identified the authors of two books: "Saving the Soul of Medicine," by Margaret A. Mahony, and "The Hunting of the President: The Ten-Year Campaign to Destroy Bill and Hillary Clinton," by Joe Conason and Gene Lyons.

GOP Bid to Restrict Use of Abortion Pill Gains on Hill

By Marc Kaufman
Washington Post Staff Writer
Saturday, September 30, 2000; Page A04

Efforts by congressional Republicans to overturn the approval of the abortion drug RU-486 or restrict its availability gained momentum yesterday on Capitol Hill.

At the same time, antiabortion activists accused the Food and Drug Administration of caving in to political pressure in failing to put tighter restrictions on the drug's use. They pressed the agency to release more details about the drug.

Rep. Tom Coburn (R-Okla.) said he will offer legislation early next week that would restrict the distribution of the drug. An aide said the measure likely will be offered as an amendment to one of the spending bills remaining before Congress.

House Majority Leader Richard K. Armey (R-Tex.) sharply criticized the Clinton administration's decision to approve the drug and said he will support efforts by lawmakers to find a way to curtail its use.

Michele Davis, a spokesman for the majority leader, said Armey will be "amenable" to legislation seeking to counter the Food and Drug Administration's ruling Thursday, but added: "I don't know if it's doable" so late in the session.

Vice President Gore reiterated his support of the FDA's decision during

Also From The Post
• GOP Bid to Restrict Use of Abortion Pill Gains on Hill (The Washington Post, Sept. 30, 2000)
• For an Abortion Opponent, RU-486 Is a Bitter Pill (The Washington Post, Sept. 30, 2000)
• Abortion Pill Gets Approval From FDA (The Washington Post, Sept. 29, 2000)
• For One Woman, Drug Was the Right Choice (The Washington Post, Sept. 29, 2000)
• Area Activists, Residents Face New Era on Abortion (The Washington Post, Sept. 29, 2000)
• Decision Forces Foes To Revamp Strategy (The Washington Post, Sept. 29, 2000)

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• How the Pill Works

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• FDA News Release on Approval
• FDA Approval Letter
• FDA Q & A on Mifepristone (RU 486)
• FDA Medication Guide on Mifepristone

Live Online
• Live Online Transcript: Eleanor Smeal, co-founder and president of the Feminist Majority Foundation, answered questions about the recent FDA approval of the abortion pill RU486.
• Live Online Transcript: Susan Willis, assistant director of programs for the National Conference of Catholic Bishops shared the pro-life view on the abortion pill.

What's Your Opinion?
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Vice President Gore reiterated his support of the FDA's decision during an appearance Thursday night on CNN's "Larry King Live" show. But Gore seemed eager to broaden the subject to abortion in general, arguing that Bush would seek to overturn Roe v. Wade by appointing antiabortion judges to the Supreme Court.

"You know, this is really a major issue that will be decided on Nov. 7 this year," Gore said. "I support a woman's right to choose; my opponent does not."

Bush did not expand yesterday on his earlier comments stating strong opposition to the FDA ruling. But his spokesman, Ari Fleischer, said Bush might sign a bill that would ban the drug if one is passed by Congress.

"He'd review it, and I think it would depend on what it says," Fleischer said. "But make no mistake, he thinks that decision is wrong."

Bush would not make opposition to RU-486 a requirement for a new FDA commissioner, Fleischer said, but he would ask his commissioner to "review the decision to make sure all of the health and safety aspects have been thoroughly looked into."

While international studies have shown that RU-486 has not increased the number of abortions in Europe, Fleischer said Bush remains convinced that the drug will increase abortions in this country.

"His fear is that if you make a pill so easily available, that instead of making abortion more rare, it will make it more common," Fleischer said.

Coburn's bill would limit distribution and use of the drug to licensed physicians qualified to handle complications resulting from an incomplete abortion or ectopic pregnancy. Under his approach, the physician must be trained and authorized by law to provide surgical abortion and must have certification for the ultrasound dating of pregnancy.

Another provision under consideration by Coburn and his aides would require the creation of a registry of providers--a list of doctors who may prescribe the abortion drug. In the past, antiabortion groups have posted on the Internet the names of physicians and clinics performing abortions.

"The registry is intended to give the government knowledge of providers," said John Hart, an aide to Coburn. "There may be a way to do it and avoid some of the obvious problems."

Many of those restrictions were proposed by the FDA in June and prompted protests from abortion rights advocates. The advocates said the restrictions were designed to make mifepristone use difficult and to limit its availability by making doctors reluctant to use it, rather than to address any bona fide safety concerns.

Abortion rights advocates said yesterday that they are also studying how state abortion regulations might affect the sale and use of RU-486, which will be sold as Mifeprex.

"We're sure there will be efforts to ban [RU-486] in some states," said

Gloria Feldt, president of Planned Parenthood of America. "But we worry less about extreme legislation like that which can be easily challenged in court. It's the death from a thousand cuts--all kinds of state rules governing abortion--that could keep women from getting access to it."

The National Right to Life Committee said yesterday that the FDA should be required to answer questions about how it made its decision.

According to legislative director Douglas Johnson, the committee wants to know whether the drug will be manufactured in China, which the Wall Street Journal reported was likely, and whether the FDA dropped some tough restrictions it had proposed over the summer because of a "political pressure campaign against them"--a charge denied by FDA officials.

"We think these are questions the American public deserve to have answered." Johnson said.

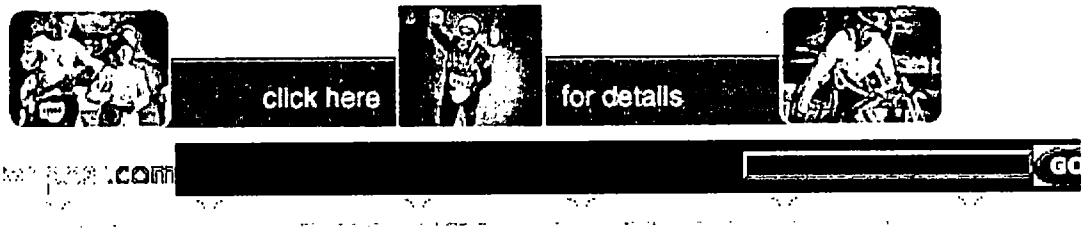
The FDA took the unprecedented step of not naming the company that will produce the drug, citing security concerns.

Ken Connor, president of the Family Research Council, a conservative advocacy group, plans to press for information on where the drug will be made. The group also said it will encourage people to elect people to Congress and state legislatures who will "respect life" and "to support a president who has the power to replace the head of the FDA."

A number of pollsters and political consultants said yesterday that while the FDA's decision could thrust the issue of abortion into the presidential race, abortion is not likely to become a dominant issue.

"It just might raise the profile of this issue that voters haven't focused about very much, and that candidates don't want to talk about very much," said pollster Andrew Kohut of the nonpartisan Pew Research Center.

Staff writers Terry M. Neal, Eric Pianin, Thomas B. Edsall and Juliet Eilperin contributed to this report.



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For an Abortion Opponent, RU-486 Is a Bitter Pill

By Libby Copeland
Washington Post Staff Writer
Saturday, September 30, 2000; Page C01

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This, then, is how the decision plays out: not yet in the bedrooms of America, where the new abortion pill will allow women to end their pregnancies in privacy and solitude; but here, at the dining table with Mary Ann Kreitzer.

Mary Ann Kreitzer, who has been protesting abortion since Roe v. Wade.

Who has charged abortion clinics and chained herself to operating tables; who has been arrested "maybe a dozen, 15" times.

Who uses a bullhorn when she plays "sidewalk counselor," and shouts to pregnant women outside abortion clinics, "You don't want to do this."

She mourns a lot these days, for hers is a crusade measured in increments, and for every woman who swallows RU-486 in the privacy of her own home--far away from picketers--that is one less soul Kreitzer can save.

"I'm a crier," she confesses, and true to her word, her green eyes turn glassy when she talks about the FDA's approval of the controversial abortion pill on Thursday. She grieves, she says, "for the women, for the babies, for the country." Opposite the many women who see in RU-486 more freedom-- of choice, of control--there are those like Kreitzer, 53-year-old Alexandria resident, staunch Catholic, wife of 31 years and mother of five, for whom the pill represents a lost battle in an interminable war.

Ours is a "culture of death," she says over and over, as if the ominous phrase had some power. Now, Kreitzer warns, abortions will be more "hidden." Now, she worries, taking the abortion pill may be viewed as easy and meaningless as "popping an aspirin."

Dinner in the Kreitzer household: meatloaf and mashed potatoes. Larry and Mary Ann take the head and foot of the table, respectively, flanked by two daughters, a son-in-law and a granddaughter. Mary Ann leads the discussion on this new abortion pill. The family is antiabortion, but she is the crusader; it is she who spends most Saturdays outside the Annandale Women and Family Center on Duke Street, who counsels alternatives to abortion at a crisis pregnancy center in Manassas, who publishes a newsletter for Catholic women.

This is a mission, she says, and she accepts its rewards and its backlash. She says the back window on her car has been smashed three times in as

She says the back window on her car has been smashed three times in as many years--the back window above the bumper sticker, "I love babies born and unborn." (Only later did she add the one that says, "Lorena Bobbitt for White House intern.")

And she has had numerous run-ins with the police. Alice Kreitzer Doyle, Mary Ann Kreitzer's 30-year-old daughter, remembers visiting her mother in jail when she was young. It "was actually kind of an exciting thing," says Alice, who has always considered her mother to be morally righteous.

"I went to jail three different times," for nonviolent tactics of blocking clinics and staging sit-ins, Kreitzer says.

"Oh, poor grandma," says Alice's 5-year-old, Madeleine Doyle.

The grandmother takes the granddaughter's tiny wrist in her palm.

"If you were around," she asks the child, "you would have prayed for me, wouldn't you?"

On a poster that Kreitzer will carry with her to an antiabortion rally this weekend, there are pictures of the infants she says she and others have saved: Gloria, Maryam, Fatima, Amy. And in the center, there is the pope, and there is Mother Teresa. Kreitzer was reared in a family of 10 children. She survived breast cancer in 1986. She is a stay-at-home mom. Her hair is gray, cut into a nondescript it'll-do bob; her cheeks are broad and expressive.

There will be no talk of lesser evils in the Kreitzer household; no credence given to the idea that if abortion is a fact of American life--which it is--perhaps more options are better than fewer. Some call the option of RU-486 "empowering." Kreitzer cannot fathom this.

"A mother killing her child no matter what method she uses is never empowering," she says. And that is that.

So what will the pill represent? Kreitzer wonders. Will it make women more comfortable with the concept of abortion, as she fears? Or, as her husband Larry muses, will going through abortion at home--and dealing with its aftermath--act instead as a deterrent? Ingesting RU-486, the FDA reports, causes cramping and weeks of bleeding. So what will be the outcome of this tiny pill on the landscape of America?

"No one really knows what the impact will be," she says.

On that, at least, she and supporters of RU-486 agree. But the supporters of the pill, which will be sold generically as mifepristone, make a crucial distinction.

"The impact of mifepristone will be understood only when women have full access to the medication--without fear of harassment or intimidation," says Jatrice Martel Gaiter, president and CEO of Planned Parenthood of Metropolitan Washington, through a spokesman. She adds, "the availability of mifepristone does not make the decision to have an abortion any easier."

In the meantime, Mary Ann Kreitzer will continue with her bullhorn and her counseling and her newsletter. Some tactics will have to change, she says, as they always have, to adapt to new threats. She and fellow abortion opponents will have no choice but to publicize which doctors are dispensing RU-486.

"Those who are willing to kill children need to be exposed," she says.

She holds firm to her cause. When friends called Thursday morning, after the pill was approved, she tried to reassure them. "I said to them what Mother Teresa always said, which is God doesn't call us to be successful, he calls us to be faithful."

FDA Approves Abortion Pill

By Marc Kaufman
Washington Post Staff Writer
Friday, September 29, 2000; Page A01

The controversial abortion drug RU-486 won long-sought approval from the federal government yesterday for sale in the United States, launching what opponents and advocates agree will be a new era in the nation's rancorous abortion debate.

Undated file photo shows the controversial abortion pill RU-486, or mifepristone. (AFP/File Photo)

Also in PM Extra
• Woman Recounts Experience With RU 486

Abortion Pill
• FDA News Release on Approval
• FDA Approval Letter
• FDA Q & A on Mifepristone (RU 486)
• FDA Medication Guide on Mifepristone

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The Food and Drug Administration's decision for the first time gives American women an alternative to surgical abortion: a pill that will be widely available and will allow them to abort a pregnancy in the privacy of their homes.

The drug is expected to be available within a month and to cost about the same as a standard abortion. It will be administered first at clinics that have received special training but eventually by any doctor who can ensure that a standard abortion will be available in the rare instances that the pill fails.

As a result, the pill is expected to fundamentally transform the abortion experience for millions of American women. Instead of facing the prospect of a potentially hostile environment outside a clinic, they will be able to abort their pregnancies much more discreetly, much earlier and with what many women describe as a greater sense of control.

The announcement was hailed by abortion rights supporters as a breakthrough for American women and condemned by abortion opponents as a travesty for endangering human life.

Gloria Feldt, president of Planned Parenthood of America, called the approval "an historic moment, comparable to the arrival of the birth control bill 40 years ago." Kate Michelman of the National Abortion and Reproductive Rights Action League called it a "milestone on the long road to women's reproductive freedom and equality in this country."

But Laura Echevarria, spokeswoman for the National Right to Life

But Laura Echevarria, spokeswoman for the National Right to Life Committee, said approval marks an unfortunate turning point for the country. "In the past, the FDA has approved drugs to save lives and prolong lives," she said. "Now they are approving a drug designed to take human life."

The decision quickly became part of the presidential campaign. Vice President Gore said the decision "is not about politics, but the health and safety of American women and a woman's fundamental right to choose." Texas Gov. George W. Bush called it "wrong" and said he fears it will make abortions "more and more common rather than more and more rare."

Republican leaders have made clear they want to overturn the decision, and House Republican Conference Chairman J.C. Watts (Okla.) said that "a new administration, I am certain, with moral leadership and a commitment to the family will reverse this Clinton-Gore decision."

President Clinton criticized as political the Republican attack on yesterday's decision. "This administration treated that issue as purely one of science and medicine," he said. "And the decision to be made under our law is whether the drug should be approved by the FDA on grounds of safety."

The intense feelings about the pill--and the fear of potential violence by opponents--were manifested in two aspects of yesterday's decision. FDA Commissioner Jane E. Henney said the agency for the first time did not publish the names of the experts who reviewed RU-486 for the agency. In addition, it broke precedent by not publishing the name or location of the company that will manufacture the drug.

RU-486, which will be sold as Mifeprex, will allow American women to use an abortion technique first approved in France in 1988 and available now across Europe and in countries from Israel to China. The FDA said that 620,000 European women have used it.

Based on the drug's impact in other countries, the pill is not expected to increase the number of abortions in the United States, which has been dropping significantly for the past decade, to about 1.3 million annually. Surgical abortions are expected to remain more common because RU-486 can be used only during the first 49 days after a woman's most recent menstrual period.

Advocates predict, however, that the drug will increase the number of women who undergo early abortions, because it can be used earlier than surgical abortions generally are performed.

The FDA dropped restrictions on how RU-486 might be used that it proposed last summer. There will be, for instance, no registry of doctors prescribing the drug or women who use it, and prescribing doctors will not be required to be licensed to perform surgical abortions. Advocates of the drug had feared such restrictions would severely limit the drug's availability.

The drug will not be available through pharmacies, however, and will be distributed to patients with a detailed pamphlet outlining all possible complications. In addition, the sponsor of the drug, the Population Council, will be required to conduct post-marketing studies of the drug's

effects and of whether doctors are using it properly. If problems are found, Henney said, individual doctors could lose their right to prescribe the drug and its overall approval could be reassessed. That unusual requirement could make the drug more easily withdrawn under a new administration, observers said.

Dropping the proposed restrictions sparked an outcry from Rep. Tom Coburn (R-Okla.), who has twice led successful efforts in the House to deny FDA funds for the testing of RU-486. (The efforts died in the Senate.) Coburn said he would offer a bill limiting distribution of the drug to include most of those proposed restrictions.

Under the FDA protocol, women will visit their doctors three times for an RU-486-induced abortion and will take two sets of drugs. The first drug is RU-486, which softens the uterus and loosens its connection with the embryo. The second is misoprostol, which triggers the contractions that expel the embryo.

Researchers have been experimenting with different dosages and reduced doctor visits since the initial application was made to the FDA in 1996. But Henney said that the agency would not allow divergences from the approved protocol and that doctors who use different protocols could lose their ability to order the drug.

Officials said there has been no final decision on how much the medical abortion will cost. But abortion rights advocates have said the cost is expected to be similar to that of a surgical abortion--about $300.

The French pharmaceutical company that first developed the drug decided against seeking FDA approval because of antiabortion opposition, and rights to the drug were transferred to the Population Council, a New York-based reproductive rights group.

The Population Council ultimately gave the rights to manufacture and distribute the drug to a start-up company named Danco Laboratories LLC, which has been financed directly or indirectly by foundations set up by, among others, George Soros, Warren Buffett and David Packard.

The FDA first ruled that the drug was safe, effective and "approvable" in 1996. But in addition to abortion politics, including boycott threats against potential drugmakers, the drug's approval was slowed by business blunders by the American sponsor.

One issue that delayed the drug's approval was the sponsor's difficulty finding a company that would manufacture it and assuring the FDA that the product would be pure. Danco finally found a manufacturer but has been unwilling to publicly disclose any information about it because of concerns it will be targeted by antiabortion activists. The manufacturer is believed to be overseas, and speculation has focused on China or India.

Staff writers Ellen Nakashima, Ben White and Juliet Eilperin and special correspondent Christine Haughney contributed to this report.

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For One Woman, Drug Was the Right Choice

By Marc Kaufman
Washington Post Staff Writer
Friday, September 29, 2000; Page A18

When Amy found out she was pregnant a year ago, she went to a clinic near her home in the Seattle area and asked if she could get an abortion using the controversial drug RU-486, even though it had not yet received U.S. government approval.

The 36-year-old mother and university laboratory worker thought RU-486 would give her a greater sense of control, allowing her to be home with her husband instead of at an abortion clinic. And Amy, who had terminated a pregnancy when she was 16, also found the idea of a drug-induced abortion more appealing than a surgical procedure.

With the FDA's announcement yesterday that the drug had been approved in the United States after years of bitter debate, Amy's experience provides a glimpse into what many American women will likely be going through. Using the abortion pill was more difficult than Amy had anticipated, but she nonetheless is glad she did it.

"It's not an easy experience, and it seems very important to have good support around you," said Amy, who asked that her last name be withheld. "But I'm comfortable with the decisions I made, and am glad that I had a medical abortion."

Since clinical trials for RU-486 began in the United States in 1994, more than 10,000 American women like Amy have used the drug for their abortions. Surveys have found that 88 percent of those women felt their abortions were very or moderately satisfactory, and 95 percent who used the drug in trials said they would recommend it to others.

Also in The Post
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The clinic Amy went to referred her to another in the area that was testing the drug. Amy met the requirements for mifepristone use: She was less than 49 days from her last menstrual period, did not have an ectopic pregnancy, had no bleeding problems, and did not have an inserted IUD or certain kidney or liver conditions. The drug is not believed to be as safe or effective for women more than 49 days from their last period.

The exact dosages that have been used in U.S. tests have varied, and some of the women aborted in hospitals or doctor's offices and some at home. But the basic regimen has been the same:

During her first visit, a doctor counseled Amy about how the abortion would work and what to expect. One of the strongest messages was that she could take the first of two different pills and then decide not to take the second. The first pill ends the pregnancy, but Amy's health would be threatened if she didn't take the second pill to expel the embryo.

Amy underwent an ultrasound test to determine the exact age of the embryo, and then she was given RU-486, or mifepristone, and sent home. The FDA has approved a protocol calling for 600 milligrams of the drug, but in studies such as Amy's, women have typically received a lower dosage of 200 milligrams.

The mifepristone blocks progesterone, a hormone needed to maintain a pregnancy. Without it, the lining of the uterus softens and begins to break down, and bleeding can begin. That part was easy, Amy said. In fact, she did not feel much of anything from taking the RU-486 alone.

Amy took a second drug, called misoprostol, two days later to trigger contractions designed to expel the developing embryo. Most women will return to their doctors for the second pill; Amy got hers at the first visit. While the protocol the FDA approved yesterday calls for women to take misoprostol pills, Amy's study called for vaginal insertion of the hormone.

Amy started cramping after about 30 minutes and had two to three hours of sharp, menstrual-like cramps that kept her lying down with her knees up or running to the bathroom, she said. The contractions were close and constant as the embryo was expelled along with numerous blood clots. (Amy said that she saw nothing that appeared to be the embryo.) She also had heavy blood flow for the five days that followed.

Most women experience cramps that range from moderate to severe, said Paul Blumenthal, medical director of Maryland Planned Parenthood. As a result, most women are given some pain relief, such as ibuprofen with codeine, though many find they don't need it, he said.

In studies, about 6 percent of women expelled the embryo with mifepristone alone, 44 percent within four hours of taking misoprostol and 63 percent within 24 hours.

Several weeks later, Amy returned to the clinic to make sure the abortion had been successful. A small percentage of women--between 2 percent and 8 percent--experience excessive bleeding or do not abort successfully with the drug regimen and must undergo a surgical

abortion. As a result, the FDA regulations require doctors dispensing RU-486 to be either trained in surgical abortions or have a referring relationship with a trained doctor.

Amy had another ultrasound test and was asked questions to determine if she was physically and emotionally well. Everything had gone smoothly for her.

Despite the pain and discomfort, Amy remains convinced she made the right choice.

"I felt like I was carrying it out myself. It probably was more uncomfortable [than a surgical abortion] but then someone else is doing that to me, and I didn't want that," she said.

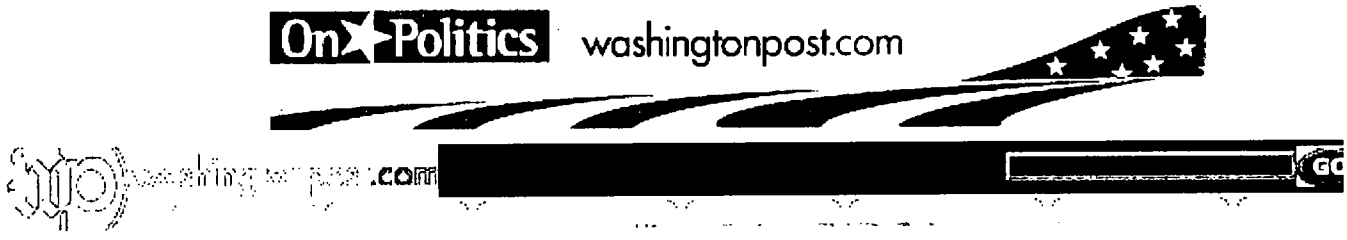
"It felt morally right," added Amy, who has a 5-year-old son. "I think all women should have that same option."

More than 620,000 abortions have been triggered by RU-486 worldwide, and studies generally find similar success and satisfaction. In France, which legalized RU-486 first in 1988, about 30 percent of abortions are now drug-induced.

In the past year, the National Abortion Federation has trained 1,800 doctors, nurses and clinic counselors nationwide in how to use mifepristone. Most have been associated with abortion clinics or women's reproductive health centers so far, officials said.

Reproductive health experts predict that RU-486 will increase the number of early abortions. Pregnancy detection technology has advanced greatly in recent years, enabling women to learn much earlier whether they are pregnant. Doctors have traditionally waited until after the eighth week of pregnancy to perform a surgical abortion, but that wait is not necessary with RU-486.

"After you've made up your mind that you need an abortion, it's physologically and physically difficult to continue with the pregnancy," Amy said. "When you've said that goodbye, then there's no reason to wait. It's time for goodbye."



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Area Activists, Residents Face New Era on Abortion

By Susan Levine and Leef Smith
Washington Post Staff Writers
Friday, September 29, 2000; Page A19

Maxine Klane started her morning yesterday with a meeting at the Planned Parenthood clinic in Falls Church, and so was there when the fax machine started humming shortly before noon and the announcement--long awaited, deeply contested--arrived at last.

"FDA Approves Mifepristone," declared the single page from headquarters in New York, using the generic name for the abortion pill RU-486.

"The staff was waving it in the air and saying, 'They approved it! They approved it!' " said Klane, who oversees patient services at Planned Parenthood's six Washington area clinics. "There was a great deal of elation."

With the Food and Drug Administration's move yesterday to allow the abortion pill on the market, many abortion rights advocates exulted, but other reactions were more nuanced, even uncertain. Numerous area doctors refused to comment, reflecting the emotion and violence that have surrounded abortion in the United States.

"This is an issue of personal safety and preference," said Lisa Saisselin, a spokeswoman for George Washington University Hospital, conveying the decision of its OB-GYN staff to remain mum. "They choose not to comment."

Elisabeth Van Der Woude, owner of the Prince William Women's Clinic in Manassas, who has been targeted by protesters, said her office will offer mifepristone. But she cautioned that it likely will be more expensive than a surgical abortion and, according to the clinical trials she's read, more painful. For those reasons and the fact that women must

From The Post
• Abortion Pill Gets Approval From FDA (The Washington Post, Sept. 29, 2000)
• For One Woman, Drug Was the Right Choice (The Washington Post, Sept. 29, 2000)
• Decision Forces Foes To Revamp Strategy (The Washington Post, Sept. 29, 2000)

Graphics
• How the Pill Works

Abortion Pill
• FDA News Release on Approval
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• Live Online Transcript: Eleanor Smeal, co-founder and president of the Feminist Majority Foundation, answered questions about the recent FDA approval of the abortion pill RU486.
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she's read, more painful. For those reasons and the fact that women must make two trips to a doctor's office before the abortion is complete, she will hesitate to recommend the pill.

It "will be more traumatic than [the usual surgical abortion] done in the office," Van Der Woude said.

Still, she described the drug as a "milestone" in the history of abortion in this country, offering women greater access to the procedure through their gynecologists and general practitioners. "Some women may like the privacy of [having an abortion] in their home, with their husband or significant other or parents there," she said.

That is one of the drug's major selling points. Rather than possibly having to cross a protest line outside a clinic, a woman who has decided to end a pregnancy can swallow mifepristone in her doctor's office or at home. Two days later, she must return to the office for a second medication that causes her body to expel the aborted embryo.

"Now people won't have to fear right-wing extremists. They won't have to deal with harassment," said Nell Till, 55, who works at Anne Arundel County Circuit Court as an administrative assistant. "It will stop a lot of demonstrations. I think it will take away the need for the clinics and therefore the venue for the protesters."

The protesters agreed. "There's no doubt that one advantage in the abortion debate was the abortion clinic," said the Rev. Patrick Mahoney, of the Washington-based Christian Defense Coalition. "It was an address, a rallying point. It was the focal point for demonstrators and dissent."

And if opponents no longer have that, "it totally changes our approach and tactics," he said. "The pro-life movement has not moved quickly enough to deal with the new abortion. . . . The pro-life movement can't be an anachronistic movement stuck back in the '70s."

Although the FDA says that complications have proved rare, some people worried yesterday about the what-ifs. Fairfax legal assistant Terry Guy, 23, questioned the health risks when a woman takes the abortion process home.

Recalling the near-fatal hemorrhage of a girlfriend who had an abortion two years ago at a clinic, she asked: "Who's going to be responsible if someone bleeds to death at home? It's really scary."

Colleague Kathi Mulholland criticized mifepristone as an advancement that may make abortion too easy. "When a woman has a surgical abortion, she's going to remember it," Mulholland said. "This is like getting a gum ball out of a gum ball machine. It's too easy. It's a quick fix."

The pill will not make its way immediately into the marketplace. Officials at Planned Parenthood of Metropolitan Washington, whose clinics perform 6,000 surgical abortions annually, said they must complete guidelines on how to inform patients about the drug and how it will be distributed.

"We get calls all the time asking for it," Klane said. "I think now we're

going to have to really go into high gear."

Although this kind of abortion can take place within weeks of conception--and several weeks earlier than a surgical procedure is usually done--its timing likely will not change minds on either side of the debate.

"I don't think abortion should be used as a family planning tool," said Phil Dunn, 55, an Annapolis developer, "but a drug like [the] birth control [pill] that performs anti-conception is no different than an abortion pill for the early stages."

Just as opposed was housekeeper Ida Jones, 56, who works at Anne Arundel Medical Center: "I don't believe in abortion. It's for weak-minded people. I think it's bad because it kills."

Staff writers Avram Goldstein and Ira Shapira contributed to this report.

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BRITANNICA.COM

EDITORIAL

Approval for RU-486

Friday, September 29, 2000; Page A32

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THE FOOD AND Drug Administration has, at long last, approved domestic use of the abortion drug mifepristone--better known as RU-486. The approval was 12 years in coming. Importation was initially banned, and the French patent holder--fearing antiabortion sentiment in this country--then declined to market it here. The patent was turned over to an American nonprofit group and the drug was found safe and effective, but manufacturing and marketing hurdles persisted. Now the drug will be available--albeit with some reasonable restrictions.

The FDA's move could inject a welcome measure of privacy into abortion access. Women will be able to get the drug without crossing picket lines at abortion clinics and perhaps in areas of the country, too widespread, where abortion access is difficult or nonexistent. According to the FDA, some 620,000 women in Europe have taken mifepristone. Those who believe abortion should be legal hope, and opponents fear, that the drug may help move the controversy out of the public eye.

But RU-486 won't put an end to the controversy, nor to the need for surgical abortion clinics. The drug is approved for use only during the first 49 days of pregnancy. It in no way lessens the moral complexities of the abortion debate, and taking it isn't the trivial, pop-a-pill medical procedure its enthusiasts have sometimes imagined. Medical abortion requires an oral dose of mifepristone and then, two days later, a dose of another drug. The full procedure requires a few trips to a doctor; side effects include cramping and bleeding; one in a hundred women will have bleeding severe enough to require surgery. That is why the FDA wants RU-486 administered only by doctors with expertise and the capability to arrange surgical interventions if necessary. Women will be given detailed pamphlets on the drug and its potential complications.

All of this may lessen the attractiveness of mifepristone as compared with surgical abortions and so diminish the impact of yesterday's decision. But given that the drug's utility has long been known, its availability was overdue.

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BRITANNICA.COM

Abortion Pill Gets Approval From FDA

By Marc Kaufman
Washington Post Staff Writer
Friday, September 29, 2000

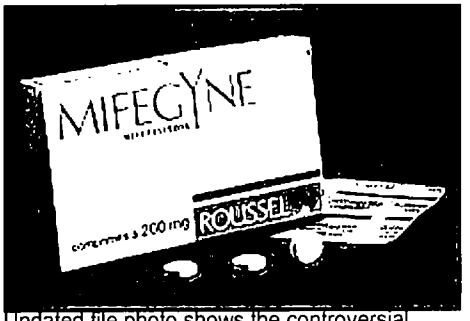
The controversial abortion drug RU-486 won long-sought approval from the federal government yesterday for sale in the United States, launching what opponents and advocates agree will be a new era in the nation's rancorous abortion debate.

The Food and Drug Administration's decision for the first time gives American women an alternative to surgical abortion: a pill that will be widely available and will allow them to abort a pregnancy in the privacy of their homes.

The drug is expected to be available within a month and to cost about the same as a standard abortion. It will be administered first at clinics that have received special training but eventually by any doctor who can ensure that a standard abortion will be available in the rare instances that the pill fails.

As a result, the pill is expected to fundamentally transform the abortion experience for millions of American women. Instead of facing the prospect of a potentially hostile environment outside a clinic, they will be able to abort their pregnancies much more discreetly, much earlier and with what many women describe as a greater sense of control.

The announcement was hailed by abortion rights supporters as a breakthrough for American women and condemned by



Undated file photo shows the controversial abortion pill RU-486, or mifepristone. (AFP/File Photo)

———Also in The Post———
• For One Woman, Drug Was the Right Choice (The Washington Post, Sept. 29, 2000)
• Area Activists, Residents Face New Era on Abortion (The Washington Post, Sept. 29, 2000)
• Decision Forces Foes To Revamp Strategy (The Washington Post, Sept. 29, 2000)

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• Live Online Transcript: Susan Willis, assistant director of programs for the National Conference of Catholic Bishops shared the pro-life view on the abortion pill.

What's Your Opinion?

women and condemned by abortion opponents as a travesty for endangering human life.

What's Your Opinion?
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Gloria Feldt, president of Planned Parenthood of America, called the approval "an historic moment, comparable to the arrival of the birth control bill 40 years ago." Kate Michelman of the National Abortion and Reproductive Rights Action League called it a "milestone on the long road to women's reproductive freedom and equality in this country."

But Laura Echevarria, spokeswoman for the National Right to Life Committee, said approval marks an unfortunate turning point for the country. "In the past, the FDA has approved drugs to save lives and prolong lives," she said. "Now they are approving a drug designed to take human life."

The decision quickly became part of the presidential campaign. Vice President Gore said the decision "is not about politics, but the health and safety of American women and a woman's fundamental right to choose." Texas Gov. George W. Bush called it "wrong" and said he fears it will make abortions "more and more common rather than more and more rare."

Republican leaders have made clear they want to overturn the decision, and House Republican Conference Chairman J.C. Watts (Okla.) said that "a new administration, I am certain, with moral leadership and a commitment to the family will reverse this Clinton-Gore decision."

President Clinton criticized as political the Republican attack on yesterday's decision. "This administration treated that issue as purely one of science and medicine," he said. "And the decision to be made under our law is whether the drug should be approved by the FDA on grounds of safety."

The intense feelings about the pill – and the fear of potential violence by opponents – were manifested in two aspects of yesterday's decision. FDA Commissioner Jane E. Henney said the agency for the first time did not publish the names of the experts who reviewed RU-486 for the agency. In addition, it broke precedent by not publishing the name or location of the company that will manufacture the drug.

RU-486, which will be sold as Mifeprex, will allow American women to use an abortion technique first approved in France in 1988 and available now across Europe and in countries from Israel to China. The FDA said that 620,000 European women have used it.

Based on the drug's impact in other countries, the pill is not expected to increase the number of abortions in the United States, which has been dropping significantly for the past decade, to about 1.3 million annually. Surgical abortions are expected to remain more common because RU-486 can be used only during the first 49 days after a woman's most recent menstrual period.

Advocates predict, however, that the drug will increase the number of women who undergo early abortions, because it can be used earlier than surgical abortions generally are performed.

The FDA dropped restrictions on how RU-486 might be used that it

proposed last summer. There will be, for instance, no registry of doctors prescribing the drug or women who use it, and prescribing doctors will not be required to be licensed to perform surgical abortions. Advocates of the drug had feared such restrictions would severely limit the drug's availability.

The drug will not be available through pharmacies, however, and will be distributed to patients with a detailed pamphlet outlining all possible complications. In addition, the sponsor of the drug, the Population Council, will be required to conduct post-marketing studies of the drug's effects and of whether doctors are using it properly. If problems are found, Henney said, individual doctors could lose their right to prescribe the drug and its overall approval could be reassessed. That unusual requirement could make the drug more easily withdrawn under a new administration, observers said.

Dropping the proposed restrictions sparked an outcry from Rep. Tom Coburn (R-Okla.), who has twice led successful efforts in the House to deny FDA funds for the testing of RU-486. (The efforts died in the Senate.) Coburn said he would offer a bill limiting distribution of the drug to include most of those proposed restrictions.

Under the FDA protocol, women will visit their doctors three times for an RU-486-induced abortion and will take two sets of drugs. The first drug is RU-486, which softens the uterus and loosens its connection with the embryo. The second is misoprostol, which triggers the contractions that expel the embryo.

Researchers have been experimenting with different dosages and reduced doctor visits since the initial application was made to the FDA in 1996. But Henney said that the agency would not allow divergences from the approved protocol and that doctors who use different protocols could lose their ability to order the drug.

Officials said there has been no final decision on how much the medical abortion will cost. But abortion rights advocates have said the cost is expected to be similar to that of a surgical abortion – about $300.

The French pharmaceutical company that first developed the drug decided against seeking FDA approval because of antiabortion opposition, and rights to the drug were transferred to the Population Council, a New York-based reproductive rights group.

The Population Council ultimately gave the rights to manufacture and distribute the drug to a start-up company named Danco Laboratories LLC, which has been financed directly or indirectly by foundations set up by, among others, George Soros, Warren Buffett and David Packard.

The FDA first ruled that the drug was safe, effective and "approvable" in 1996. But in addition to abortion politics, including boycott threats against potential drugmakers, the drug's approval was slowed by business blunders by the American sponsor.

One issue that delayed the drug's approval was the sponsor's difficulty finding a company that would manufacture it and assuring the FDA that the product would be pure. Danco finally found a manufacturer but has been unwilling to publicly disclose any information about it because of

concerns it will be targeted by antiabortion activists. The manufacturer is believed to be overseas, and speculation has focused on China or India.

Staff writers Ellen Nakashima, Ben White and Juliet Eilperin and special correspondent Christine Haughney contributed to this report.

Lifestyle & Family

The Abortion Pill

Americans will soon be able to get Mifeprex, the pills that may take abortion services out of the clinics and into the doctor's office. The FDA's approval of the drug is opening a new medical and legal front of the battle over abortion.

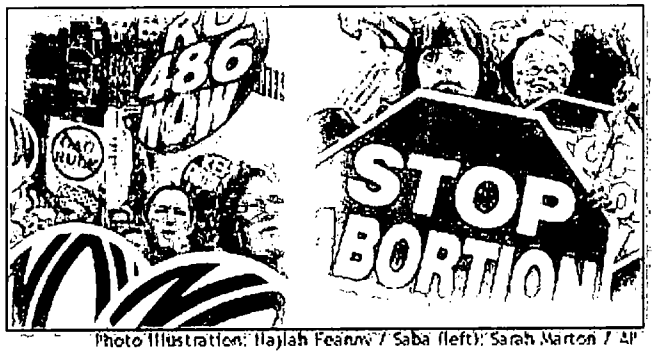

Photo Illustration: Hajlah Feanny / Saba (left); Sarah Marton / AP

Standing firm: The FDA's decision to approve RU-486 will only fuel the debate over abortion

By David France and Debra Rosenberg
NEWSWEEK

October 9 issue— On the afternoon last week that the Food and Drug Administration gave its approval to mifepristone, the abortion pill known as RU-486, Emily Green was calling it "weird good news." Good news because she is pro-choice. Weird because it came just a few weeks too late.

COMPLETE STORY

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Newsweek

David France
SENIOR EDITOR

Newsweek

Debra Rosenberg
CORRESPONDENT

JUST OUT OF COLLEGE and beginning a new job in San Francisco, the 22-year-old felt unready for a baby. But then a home pregnancy test brought unwelcome news. A doctor subsequently confirmed that she was almost four weeks pregnant, much too soon for a traditional surgical abortion. Mifepristone, on the other hand, can be used at any time before the eighth week. By the time she was cleared for the surgical procedure two weeks ago, she felt emotionally devastated by the delay. "Look, no one wants to have an abortion," she says, "but I think I could have reduced the psychological ramifications by not waiting." She's pleased other women won't have to share her experience now: "I was just happy that another barrier to access has been struck down."

Only half of America is celebrating. Though 50 percent of Americans are pro-choice, an additional 47 percent opposed making the pills available, according to Gallup polls. Conservative lawmakers are already proposing strict regulations for the new drug and calling for an investigation of the FDA's approval process. And pro-life activists are warning they'll discover who is prescribing it and expose them "doctor by doctor," says the Rev. Flip Benham, director of Operation Save America (formerly Operation Rescue). "If there's any doctor in any city that thinks he can prescribe this and have any degree of anonymity, he is mistaken," Benham shouted into a cell phone while picketing a Dallas abortion clinic Friday morning. "They want to put their practice in jeopardy, they can start prescribing this pill."

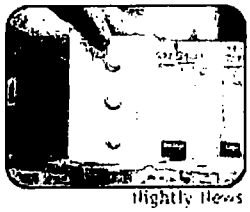
Facts about mifepristone

How does it work?

Mifepristone interrupts pregnancy in its early stages by blocking the action of progesterone, the natural hormone that prepares the lining of the uterus for a fertilized egg and then maintains the pregnancy. Without the effects of progesterone, the lining of the uterus softens and breaks down, and bleeding begins.

Al Gore welcomed the FDA's decision; George W. Bush called the approval "a mistake," but—with an eye on moderate swing voters—did not try to exploit the issue.

And so it goes in America's long-running debate over abortion rights. Al Gore welcomed the FDA's decision; George W. Bush called the approval "a mistake," but—with an eye on moderate swing voters—did not try to exploit the issue. That does not mean, however, that mifepristone is likely to "end the abortion war," as its proponents once predicted. In fact, the questions RU-486 raises about the future delivery of abortion services suggest that, three decades after Roe v. Wade , the nation's anguished battle over the issue is entering a new, even more complicated phase.



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September 28, 2000
After 12 years of poltical and regulatory debate, the FDA announced today a decision about the controversial abortion pill RU-486. NBC's Robert Hager reports.

The pill's opponents have few options now that the FDA has spoken. Bush has vowed to oppose abortion if elected in November, but there is little he can do to block mifepristone short of appointing Supreme Court justices who would restrict abortion. The law gives the president only indirect authority over drug approvals, through his appointments at the FDA and Health and Human Services. Richard Merrill, a former chief counsel at the FDA, says a new anti-abortion FDA head could launch new studies, but the pills would stay on the market unless new data showed they were harmful.

Meanwhile, Danco Laboratories, a small New York City-based pharmaceutical company formed expressly to market mifepristone under the brand name Mifeprex, expects the pills will reach their first patients later this month. The implications are enormous. Of the 1.4 million abortions in the United States each year, nine of 10 are performed in specialized clinics by a dwindling number of physicians—2,000 at last count, 14 percent fewer than four years earlier. Most of them are in cities. These trends have made it increasingly easy for abortion foes to target doctors in a campaign that's included protests, intimidation and even violence.

At first, beginning in late October, the pills will be available through traditional abortion networks—in clinics and family-planning centers. The National Abortion Federation says two thirds of its 360 member clinics are prepared to offer mifepristone immediately, and Planned Parenthood, which currently performs traditional, or surgical, abortions at 148 affiliates, expects the advent of nonsurgical abortions will increase that number to 165 within a year. Already this year 1,800 physicians have attended official training sessions.

AUDIO Newsweek On AirRU-486: Changing the Abortion Landscape?

Those doctors will presumably be among the first to take mifepristone out of the clinics to physicians' offices. The FDA attached only light restrictions to how the pill can be dispensed, though there are myriad state laws already governing abortions which still apply and there could be more coming. In theory, any doctor qualified to determine the length of a pregnancy (and who can refer a patient to a traditional abortion as a backup) can prescribe it. A 2000 survey by the Kaiser Family Foundation found that 44 percent of women's health-care doctors are at least "somewhat likely" to do just that.

Mifepristone first entered clinical trials in Geneva in 1981, and France approved the pill in 1988. But in America it immediately hit snags, many of them political. First the French manufacturer, Roussel-Uclaf (the "RU" in RU-486), announced it wouldn't attempt to distribute it here in 1988 after boycott threats. A year later, the then President George Bush signaled his opposition by banning imports of the pill, which anti-abortion-rights activists called "human pesticide" or a "chemical coat hanger." The nonprofit Population Council, which had been granted U.S. distribution rights, stumbled, too, getting itself embroiled in financial partnership (and then litigation) with a convicted criminal, and then failing for several years to find a willing manufacturer.

RU-486 Timeline

1988
· RU-486 becomes available in France.

1989
· Bush administration bans it in the United States.

1993
· Clinton administration begins working to bring RU-486 to the United States.

1994
· French manufacturer Roussel-Uclaf gives U.S. rights to the medication to the nonprofit Population Council in New York. Clinical trials begin.

1996
· FDA declares RU-486 a safe and effective means of early abortion, but it withholds final approval pending final manufacturing and labeling requirements.

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· New England Journal publishes study saying RU-486 successfully ended pregnancies in 92 percent of American women who tested the drug.

2000
· On Sept. 28, FDA gives final approval for the U.S use of RU-486.

SOURCE: Associated Press.

- The Abortion Pill
- A Doctor's View
- Anna Quindlen: RU-486 And The Right To Choose
- Questions and Answers: Caught in the Middle
- The Bases Gird for Battle

Since then 10,000 women have participated in FDA trials of mifepristone. The drug works by blocking progesterone, a natural hormone needed for sustaining pregnancy. According to the protocol approved last week, a pregnant woman can elect a pharmacological abortion if no more than 49 days have passed since the start of her last menstrual cycle (a third of all U.S. abortions take place within this time-frame) and if she does not have one of several restricting conditions, like chronic adrenal failure or bleeding disorders.

RELATED NEWS Web exclusive: A Doctor's View

If the patient decides to proceed, her doctor will hand her three mifepristone pills to be taken in the office, and 48 hours later, two different pills—a wholly

separate drug called misoprostol, made by the pharmaceutical company Searle for treating ulcers. The misoprostol causes contractions that lead to a miscarriage, typically within four hours. The patient must pay a third visit to a doctor to confirm successful completion. Studies show the technique is 92 percent to 97 percent effective. The remaining women, who don't abort successfully on the pills, must follow with a traditional surgical abortion. In all, the procedure is less swift and more complicated than the method it replaces. And opponents worry about the drug's safety. In 1 percent of women, severe bleeding can require surgical intervention, and perhaps 2 percent will need a blood transfusion. Though it involves less immediate risk than surgical abortions, because no instruments are inserted through the cervix, there are no hard data from the estimated 500,000 European women who have taken mifepristone to prove their long- term health.

"The pills seem like a more natural procedure, more like having a menstrual period."
— **LEEANN**

Half of all American pregnancies are not planned, and Leeann's was one of them. The 29-year-old Ohio office worker already had three children and thought she could not care for another when she found herself four weeks pregnant last year. She had heard about a local mifepristone drug trial and decided that was the best choice for her. "The pills seem like a more natural procedure, more like having a menstrual period," she said. She took the mifepristone at the clinic and the misoprostol at home two days later. While some women report extremely painful contractions, she was not plagued by them. She miscarried the following morning, at home.

This sort of story has anti-abortion groups gearing up for the new battle. Oklahoma Rep. Tom Coburn, who twice won House approval for his bill against RU-486, is readying a new bill. He says that President Clinton subordinated the FDA to politics, a charge Commissioner Jane Henney rejects. "Absolutely not," she says. "We use science to ground our decisions. That's the most important matter here." Still, she took heat from all sides, including extensive letter-writing campaigns, beginning with the day of Henney's confirmation hearing, which was punctuated by talk of abortion pills.

RELATED NEWS The Bases Gird for Battle

Rollback won't be easy. In theory, Congress could pass a law instructing the DEA to classify the drug as a dangerous substance, as it did with methadone. But efforts by pro-life legislators have proved fruitless so far. An anti-abortion-rights secretary of Health and Human Services could conceivably declare the pills an "imminent hazard to health," Merrill says. But this has happened only once since 1962.

And so the struggle, as usual, may go to the states. Already, mifepristone will be subject to the regional vagaries of abortion laws: 13 states have mandatory waiting periods and 31 require parental notification. Lars Noah, a visiting professor at the University of Texas Law School who's an expert on FDA law, says state legislatures could decide who can dispense the drug and under what conditions without violating the constitutional right to abortion, because other methods are available.

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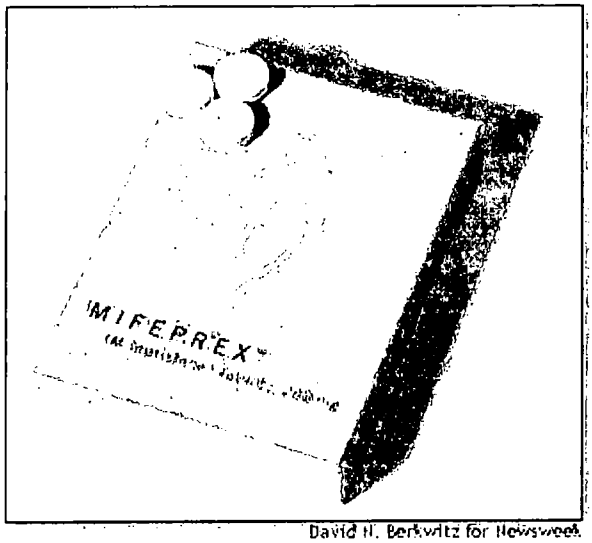
Speaking before a cabinet meeting last week, President Clinton hoped to put a clear message on the nation's medicine cabinet by calling on Americans to respect the FDA's ruling on mifepristone "as the scientific and medical decision it was." But that misses the bedrock fact about abortion: it's never just about science.

With Pat Wingert in Washington and Heather Won Tesoriero in New York

A Doctor's View



David H. Berkvitz for Newsweek

How RU486 could change the abortion landscape

The controversial pill

By Dr. Eric Schaff
NEWSWEEK WEB EXCLUSIVE

October 1 — The Food and Drug Administration's decision on Sept. 28 to approve Mifepristone, or RU-486, as a method of non-surgical abortion is nothing short of a major milestone in health care for women in America.

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MSNBC Live Vote

Do you support the FDA's decision to approve RU-486?

○ Yes

○ No

VOTE

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Vote to see results

FOR THE FIRST TIME, American women with a pregnancy no older than 49 days from their last menstrual period, have the opportunity to go to their gynecologist or family physician and receive the two-medication regimen that will bring on their menses and induce an abortion more than 95% of the time.

- The Abortion Pill
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- The Bases Gird for Battle

Mifepristone is not likely to end the abortion debate or the anti-abortion harassment or violence. But it may diffuse the situation. It will allow more physicians to provide this service in their office settings, which are less likely to be targeted for anti-abortion harassment. Early abortion is also more acceptable to the majority of Americans (though not to those who will not accept abortion at any level) because it is more abstract than abortions that take place later in the pregnancy.

AUDIO Newsweek On AirRU-486: Changing the Abortion Landscape?

Indeed, the major advantage of mifepristone is that we will see a shift toward earlier abortions in the United States, and earlier abortions means safer abortions. Legal use of Mifepristone has another advantage: it will now be available for researchers to explore a whole new class of anti-progesterone drugs. The drug holds great promise as an emergency contraceptive, a weekly or monthly contraceptive and in the treatment of fibroids, endometriosis and certain cancers, such as meningiomas of the brain, prostate and breast.

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SOURCE: Associated Press.

Mifepristone's safety has been well documented since it first came into use. More than 500,000 women in Europe have had early abortions with mifepristone, and millions of women have used it in China as well. In the United States, almost 9,000 women have had mifepristone abortions during clinical trials. The vast majority of women in those trials reported a high satisfaction rate with the drug. And there have been no reports of deaths associated with the current treatment regimen of mifepristone followed by a second drug, misoprostol.

Essentially, mifepristone works by blocking progesterone-a hormone naturally produced by the ovary and necessary to maintain an early pregnancy. Blocking progesterone causes a small embryo to detach from the endometrium, (the inside of the uterine lining.) A second medication of misoprostol, taken two days later, causes uterine contractions, which expel a pregnancy.

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As with any medical procedure, side effects and complications may occur. Approximately 5 percent of women using this method to abort will need a surgical completion to finish the process; 1% for continuing pregnancies, 2% for heavy or persistent bleeding and 2% for an assortment of other medical and non-medical reasons.

Yet nearly all women will experience some side effects during a medical abortion. For this reason, women must be counseled about expected side effects when using mifepristone. The most common side effects of mifepristone are pain, bleeding, nausea, vomiting and diarrhea, mild fever or chills and headaches and dizziness. But these side effects tend to be minor and short lived with reassurance and medications to relieve the symptoms. The next major hurdle is to provide clinicians adequate training in the procedure and ensure that women and doctors receive reimbursement from insurers. If those challenges can be met, all women will finally have access to an early, non-surgical, safe and private abortion.

Eric Schaff, MD, a University of Rochester associate professor and practicing physician, is a member of the National Medical Committee of the Planned

Parenthood Federation of America and sits on the board of the National Abortion Federation.

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Opinion

Anna Quindlen: RU-486 And The Right To Choose

Cheering, wailing, hailing, damning—the abortion pill is important but no panacea

By Anna Quindlen
NEWSDAY

October 9 issue— The legal right to choose to have an abortion in America has always been a kind of mirage. On Jan. 22, 1973, when the Supreme Court handed down one of its best-known decisions, Roe v. Wade, its supporters hailed it in simple and eloquent terms. The back alleys and coat hangers of the past would give way to safety and privacy, a new age in which a woman could examine her conscience and decide without terror or desperation whether to carry a child to term.

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BUT IT HAS NOT BEEN THAT SIMPLE. The right to choose became the right to convince a judge that you should have an abortion because you couldn't dare tell your parents. It became the right to walk through keening demonstrators, strangers begging you not to kill your baby. It became the right to be treated by a doctor who the next day could end up dead, murdered because of his work.

Newsweek
Anna Quindlen
CONTRIBUTING EDITOR

It was supposed to be private and intimate. But in the glare of politics privacy morphed into secrecy, and intimacy became shame. "A century of criminality had laid down too thick a patina to be stripped away by a sudden rewording of the law," Cynthia Gorney wrote of the reluctance of doctors to perform the procedure in her authoritative history of the abortion wars, "Articles of Faith." That patina was thick, too, for the women involved.

Above all, a pregnancy was still ending—sometimes a pregnancy that had produced happiness, then heartbreak; sometimes a pregnancy that had produced denial, then panic. It was a momentous thing. The people who hated abortion talked one way about it, and the people who wanted it to be legal talked another way, and neither group really spoke the words that were in the hearts of women who simply wanted the custody of their own bodies back.

Last week the Food and Drug Administration made a decision that was hailed or vilified, depending on party and point of view, as a landmark moment in the history of this struggle. After an exhaustive review, the FDA approved a pill that induces abortion. No surgical procedure, no clinic, just a doctor giving a woman three pills one day, two pills two days later. For 20 years, longer than some of the women who will use it have been alive, RU-486 has been part of the mirage, too, the long-delayed promise of greater self-determination.

But even abortion-rights activists conceded that the pill, which must be used within seven weeks of a woman's last menstrual period and results in considerable and sustained cramping and bleeding, has limited use. This will not do for 16-year-olds who convince themselves they are late because of a cold, the flu, inaccurate counting, the phases of the moon. This will not do for the poor woman with a couple of kids who just wants to get the thing over with.

RU-486 provides an earlier, safer abortion rather than a later, riskier one. And it may lead women to the offices of obstetricians and family practitioners rather than to abortion clinics. That was another early mirage, the vision of clinics outside the traditional hospital orbit that would be better for both women and health-care providers. No one anticipated that the clinics and their staff members would become the too-easy targets of vandalism and violence, that one day an abortion provider would need both a speculum and a bulletproof vest.

Opponents of abortion have made much recently of the horror of late-term procedures. You would hope that they would therefore react to the abortion pill, which ends a pregnancy before an embryo becomes a fetus, in a measured way. But you would hope too much. RU-486 has been described as an unspeakable evil, as easy as taking an aspirin (if aspirin caused you to miscarry and vomit). It evokes that mythic antiabortion bogeywoman, the party girl who has her fifth abortion

without a second thought, then goes clubbing with friends.

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And it speaks to a deeper fear, too. J. C. Watts Jr., a Republican member of Congress, revealed it in his response to the FDA approval: "Do-it-yourself abortion has no place in a civilized society." That is what enrages opponents about RU-486, that it is an exercise in self-determination for the woman who chooses to use it. She is in charge of the decision, the mechanism and the process, not a dupe and not a victim; the choice is quite literally in her hands. This is the reverse of those laws that seek to prosecute doctors who perform abortions but not their patients, as though the practitioner was the evil genius and the woman on the table present but not participating. Doubtless the congressman would be horrified by Margaret Sanger's famous quotation "No woman can call herself free who does not own and control her own body."

The abortion pill increases that control. But it is unlikely to be revolutionary in the way either its friends or its foes suggest. France has had great success with RU-486, but even there surgical abortions far outnumber the pharmaceutical variety. Perhaps we should look slightly farther north, where the Netherlands has an abortion rate per thousand women less than half that in the United States, largely because contraceptives are widely available and covered by health insurance. The pill that would best serve all our interests is the one that prevents conception, not causes abortion, which is why birth-control services should be covered by all health-care plans.

It all comes down to this: America does not face a choice between legal abortion and no abortion. It faces a choice between legal abortion, which is usually safe, and illegal abortion, which often maims or kills. RU-486 may well make legal abortion safer, and that is a good thing for many women. Not potential women, not theoretical women, but real live women with homes, husbands, gardens, families, friends, children, jobs and consciences. They have waited in vain for the ideal, but in the meantime they do the best they can under difficult circumstances. You don't know them. You don't know what's in their hearts or their minds or their wombs. And, frankly, it's none of your business. The biggest mirage of all is that it is.

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Mike Theiler / Reuters

The FDA's Henney

Questions and Answers: Caught in the Middle

Jane Henney, commissioner of the FDA, on the agency's controversial decision to approve the abortion pill

NEWSWEEK WEB EXCLUSIVE

September 29 — On Thursday, the Food and Drug Administration approved the abortion pill RU-486 for use in the United States.

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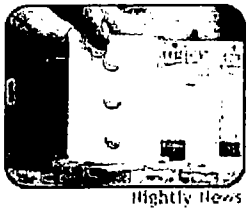
THIS METHOD, which is actually a combination of two drugs, mifepristone and misoprostol, allows women to abort at home. Pro-choice advocates and abortion

opponents are bitterly divided on its approval. FDA commissioner Dr. Jane Henney spoke to NEWSWEEK's Debra Rosenberg about the decision.



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September 28, 2000
After 12 years of poltical and regulatory debate, the FDA announced today a decision about the controversial abortion pill RU-486. NBC's Robert Hager reports.

Does this pill end the abortion wars?
I think that what this means is that we now have a medical alternative available for women who choose to seek early termination of their pregnancy. That, in essence, is what this approval means for American women.

Do you think this will end some of the conflict over abortion?
I wouldn't even want to speculate on that. I would have no way of knowing.

So far, you've kept a low profile as FDA commissioner. What's your view on abortion? Are you pro-choice?
As commissioner, what I'm expected to do is see that products are reviewed in an objective and scientific fashion and my personal views on any matter are not really to play in those decisions.

So you don't want to say?
No.

This decision makes you a hero to a lot of people. It makes you a villain to a lot of people. What does it feel like to be the one to approve this controversial drug? Do you have any misgivings?
[I think] the agency has worked very hard using its routine processes that it uses for all approvals, using science to ground its decision to make sure that the standard is high here.

It doesn't feel any different than any other decision?
It feels different in that all [the media] are calling today, but I think that many of our product decisions are very meaningful for the populations that they would appear to serve...from AIDS drugs, to cancer drugs to drugs for children. So this is perhaps an important decision for women who want to make this choice. What we do as a public health agency when we make review decisions is to make sure that when patients have choices or products available to them, they [have] a very high standard for safety and efficacy.

It appeared earlier that there might be some substantial restrictions on the drug's availability. Can you describe how those restrictions arose and what happened to keep them out of the final approval?

RU-486 Timeline

1988
· RU-486 becomes available in France.

1989
· Bush administration bans it in the United States.

1993
· Clinton administration begins working to bring RU-486 to the United States.

1994
· French manufacturer Roussel-Uclaf gives U.S. rights to the medication to the nonprofit Population Council in New York. Clinical trials begin.

1996
· FDA declares RU-486 a safe and effective means of early abortion, but it withholds final approval pending final manufacturing and labeling requirements.

1998
· New England Journal publishes study saying RU-486 successfully ended pregnancies in 92 percent of American women who tested the drug.

2000
· On Sept. 28, FDA gives final approval for the U.S use of RU-486.

SOURCE: Associated Press.

...Many of the requirements of [the] clinical trials started the baseline for our discussions ... some of them became less stringent because we felt that they could be well-managed and still have the product be safe and efficacious for the patient...There still is a need to make sure that the physicians who use this are well-qualified [in such areas] as dating a pregnancy, diagnosing of ectopic pregnancy and in terms of getting the kind of information so that women who are choosing this can make very informed decisions...It's not just one pill on one day. It is really a plan of almost two weeks that one has to commit to...two weeks later you need to come back to your physician for a clinical exam to make sure that your pregnancy has been terminated. So it's with some of those things in mind that we look at how this will be used in actual clinical practice versus how it was studied in the clinical trial.

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- WashPost: A woman's story
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- Newsweek: Q&A with FDA chief Jane Henney

But there were some restrictions mentioned earlier this year that did not end up in the final approval.

Again, those were some of the requirements of the clinical trial.

Were there political pressures to add or remove the restrictions?

No.

Several congressmen today charged that your agency speeded up its process to approve mifepristone before President Clinton leaves office. What's your response?

I would say absolutely not. What drives the review clock here—and I would say review clock, not approval clock...are the performance goals we're expected to meet...So any time we were in a review cycle with mifepristone, we were on a six-month clock. Last February, we had to restart the clock after we had not received adequate information from the company. So our deadline for decision-making here was actually September 30...We were at a point during this review cycle when all of the standards have been met, all of the questions have been answered to our satisfaction and so we have made an approval decision.

Do charges that the FDA plays politics damage the agency's credibility? What can you say to convince the American people that the agency is immune to politics?

There was a [Pew] survey conducted earlier this spring of all the regulatory bodies of the federal government, or some of the most prominent. And it's very clear from those surveys that...[people] have extraordinarily high confidence in what this agency does. When they were also [asked] 'Do you believe the agency makes its decisions based in science and objective fact?' again, the level was very high. There was a very strong correlation to how the public and many of its constituencies view this agency, because we base our decisions in science and we are objective in our decision-making.

Do you think the introduction of RU-486 will go down as the most contentious in FDA history?

No. We make controversial decisions almost every single day here. It certainly is one that has had high visibility. But I think if you look at many of the issues we are expected to deal with, many of them are extremely controversial and so we do believe we are comfortable and confident of what we do. We do find our decision-making gets driven by a scientific process and an evidence-based process rather than just whim.

Were there any threats or efforts to intimidate the advisory panel or other FDA officials?

Actually I wasn't at the agency at the time of the advisory committee so I don't know the answer to that.

Do you have any security concerns now for yourself or the agency?

I really can't comment on security matters.

There have been some reports that you have strengthened security. Can you comment on that?

I really can't comment on security matters.

Do you worry that Congress will retaliate against the FDA or against you personally for this decision?

I think that the issue—when it is looked at in terms of the process that was used for this product—will be seen as no different than any other product that we have had under review...We are very confident and comfortable with this decision for anyone who would call it into question.

Do you think that an anti-abortion president could change the availability of RU-486?

It would be absolutely unprecedented for a president to reverse a product review decision made by this agency.

But not absolutely impossible?

I said that it would be unprecedented.

There have been some reports that the drug will

be manufactured overseas. Can you tell us where the drug is being made and whether you have any concerns about quality control?

No. At the request of the company, because of their concerns that if the manufacturing site becomes known, there may be physical security issues there—not only for their ability to keep manufacturing the drug, but also for their personnel that might work in that site, their own personal security—we have determined that we will keep that information confidential.

Isn't it a matter of public record that people should be able to know?

This is a matter that is provided to us in terms of commercial confidentiality. When or if any harm would come to this company, they would essentially be out of business.

Can you confirm whether the drug is being manufactured overseas?

No.

Mifepristone will be used in conjunction with another drug, misoprostol, also called Cytotec. But its maker, Searle, just issued a letter warning that Cytotec is not approved for the induction of labor or abortion. Does that mean the FDA is sanctioning off-label use of that drug?

What we have approved is really a treatment plan that includes both mifepristone and misoprostol. We will be working with the company, Searle, in terms of the information that they're now providing on their label.

Then you'll work with them to relabel it?

Yes.

Some opponents of mifepristone say we don't know much about the long-term effects of the drug, that women who took the drug years ago in Europe, for example, aren't being monitored. Is that the case?

We know much more about the European experience, clearly, than those women who were treated in the U.S. clinical trial. But quite frankly, I don't know how long those women were monitored or if anything significant has been found. I just don't have the answer to your question.

Do you think that this decision will have any effect on the FDA itself?

I think it demonstrates that when we receive applications, we regard them knowing our statutory obligations to review them for safety and efficacy for their intended use, and we use science to ground our decisions. That's the most important matter here.

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Washington Post

News Week

The Bases Gird for Battle

In the trenches, Robertson's troops prep for Election Day

By Howard Fineman
NEWSWEEK

October 9 issue— The morning after the FDA approved RU-486, ban the abortion pill placards popped up at the Christian Coalition convention in Washington. Pro-life activists were buzzing about the decision in the hallways. But when Pat Robertson gave the welcoming address, he didn't mention abortion, let alone the pill, even though he's ardently pro-life. "It's a distraction," he told NEWSWEEK, "and a complex problem of medical research."

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Newsweek
Howard Fineman
SENIOR EDITOR

HAS ROBERTSON MELLOWED? Hardly. In recent years he has retreated somewhat from politics, focusing instead on business deals and soul- saving missions while the coalition sank in a sea of red ink. But now the group is back in the black, and Robertson has returned—a sophisticated player who could be a crucial force in a close election. As a shrewd political veteran, he knows that the "pill issue" works best on its own, without inflammatory rhetoric that could complicate George W. Bush's effort to win the votes of secular suburban women. "The pill can help energize our base," said Warren Tompkins, a leading Bush adviser in the Bible belt, "and we don't have to mention it."

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The candidates and their campaigns used to be the centerpiece of a presidential election. But this year is less akin to hand-to-hand combat than world war, with vast, richly funded alliances battling issue by issue. In the new NEWSWEEK Poll, Al Gore and Bush are in a statistical dead heat (44-45 among likely voters), reflecting a contest in which every phone call could be decisive. Labor unions, trial lawyers, abortion-rights supporters, Roman Catholic priests, evangelical Christians—to name a few—are all working hard to reach their rank and file.

No skirmish is more pivotal than the one between those who view the makeup of the Supreme Court—and especially its rulings on abortion—as the most compelling concern. The big battleground states (Pennsylvania, Ohio, Michigan, Wisconsin and Missouri) contain vast suburbs, large union contingents—and high percentages of "religious conservative" voters. Pro-life Reform candidate Pat Buchanan could be a factor everywhere except Michigan, where he's not on the ballot. Labor's effort in those states is unprecedented. So is that of the National Abortion Rights Action League, which is targeting calls and mail at women, primarily independents and moderate Republicans.

Bush is relying on the religious right to make up the difference—but it's a complicated effort. Leaders of the "movement" were upset by the GOP convention's placidly non-Bible-thumping tone, and the Bush team's refusal to give them leading roles. "The convention was a joke," Robertson told NEWSWEEK. "I called it 'Democrat Lite'." The campaign annoyed Robertson by declining to send Bush or Dick Cheney to the coalition's convention. But in the last two weeks the campaign has privately wooed the same people it dissed in Philly. While in Washington, Bush-campaign guru Karl Rove soothed conservative leaders. Then he told Robertson that Cheney's wife, Lynne, would attend the meeting and that Bush would address it on videotape.

Robertson seemed mollified, barely. "We're not being consulted," he groused in an interview. Still, he said, the coalition would distribute 70 million election-eve presidential "voter guides" to churches. "We'll execute because we execute," he said. It didn't sound like a heartfelt sermon, but for Bush it could be an answered prayer.

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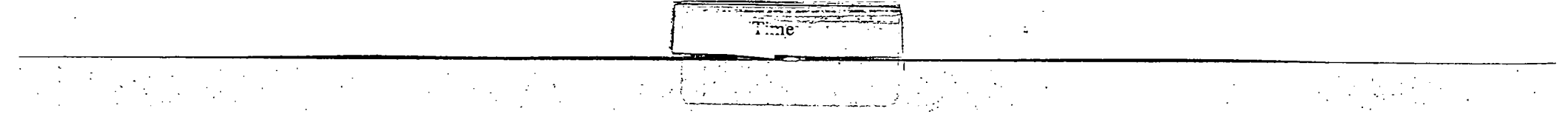
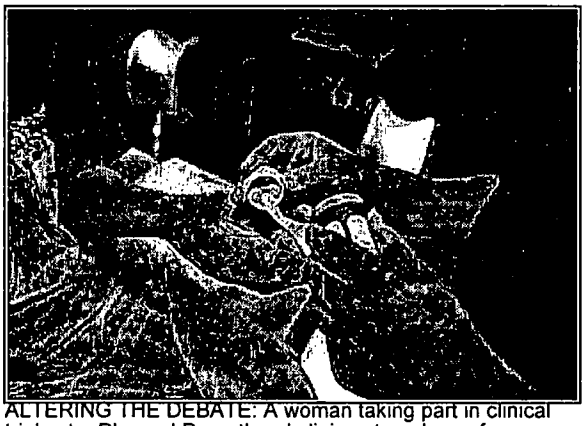

Time

THE ABORTION PILL
OCTOBER 9, 2000 VOL. 156 NO. 15

The Pill Arrives

The FDA gives women a new abortion choice. But will they choose it? And will doctors be willing to take the heat?

BY NANCY GIBBS



ALTERING THE DEBATE: A woman taking part in clinical trials at a Planned Parenthood clinic gets a dose of mifepristone

Did the landscape of abortion in America really change forever last week? Come take a tour. Dr. Stephen Grillot practices family medicine in Colby, Kans. In his town, a woman looking to end a pregnancy would need to drive 300 miles to Wichita to find the nearest abortion clinic. That's if she had the time and means to get away and was willing to pass the protesters to enter a building that has been bombed out and fired upon.

Last Thursday, when the Food and Drug Administration approved the sale of the abortion pill mifepristone--long known as RU 486--it put fewer restrictions on its use than anyone had expected. Virtually any family doctor or ob-gyn can now prescribe the two-drug regimen, provided he or she has some surgical backup arrangement if it fails to end the pregnancy or there are side effects. No more clinics; no more waiting until pregnancy is far enough along for surgical abortion. Just a series of pills taken over a period of days to induce a miscarriage. Advocates hailed it as the greatest breakthrough in women's health since the Pill and vowed to have mifepristone in doctors' hands within a month.

Grillot supports a woman's right to decide whether and how to end a crisis pregnancy. But

Did Abortion Just Get Easier?: The Food and Drug Administration approves RU 486, giving women a new and simpler abortion choice. But will they use it? And are doctors willing to take the heat?

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Coverage of the abortion debate

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Historical background
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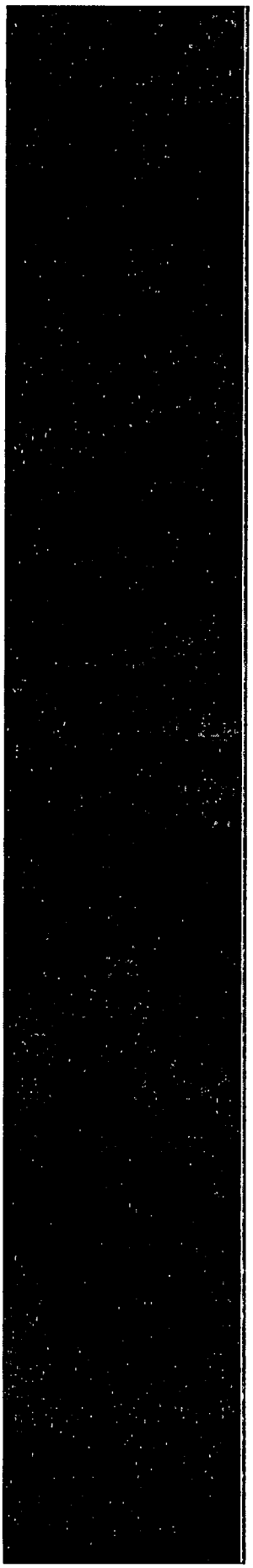
Abortion Pills on Trial
Testing background
DECEMBER 5, 1994

WEB RESOURCES
Planned Parenthood's page on RU-486
Includes history and bibliography

The Population Council
Nonprofit reproductive rights organization

The American College of Obstetricians and Gynecologists

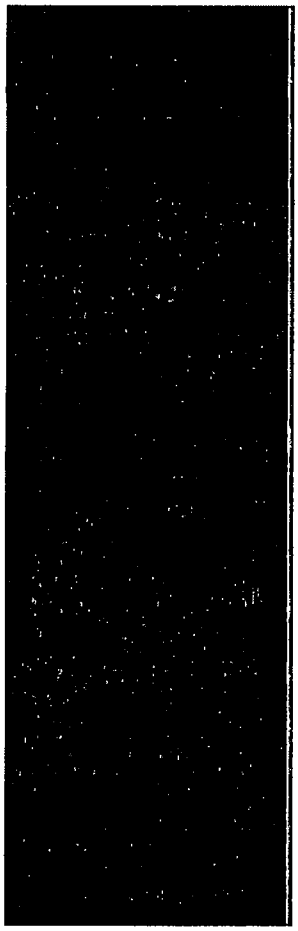


whether and how to end a crisis pregnancy. But he will not be offering this drug. Pro-life sentiment runs strong in his town. "My partners would have a fit if I used it in my practice," he says. "It will be used in the bigger cities. But in a small town like this, it would be hard. Everybody would know about it."

If only doctors in the big cities use it, what will really have changed? Last week's much heralded FDA decision--the denouement of years of controversy over a pill developed in France two decades ago--was not hailed as a triumph just for urban women who already have choices. Mifepristone proponents predicted that when it finally reached the market, it would privatize the whole experience of abortion, take it out of the streets and the courts and the Congress and into the privacy of the home and the doctor's office, enabling women to end a pregnancy before the embryo even resembles a fetus, much less a child. It would change medicine by offering a less invasive procedure; change politics by moving abortion earlier in pregnancy, when fewer people have moral qualms; change, above all, the access, since protesters wouldn't know where to set up a picket line if abortion became part of mainstream family practice.

Maybe the doctors who fell so silent last week in the face of such dramatic medical news were just waiting to learn more themselves, study the legal and financial implications, weigh the ethical ones, of offering a new kind of abortion to their patients. But for all the cheering of abortion-rights activists, it could be a long time before we really know what difference the marketing of mifepristone will make. Opponents vow to take to the streets in force, target the doctors who agree to prescribe it, gouge the conscience of anyone willing to wage chemical warfare on women and children. They call the drug baby poison and are enlisting allies in Congress to try to ban it, threatening boycotts of whoever makes it. As for the doctors faced with a decision, the greater the heat, the greater the fear. It's understandable that they could take a while to make up their mind--which means that what really changed last week may be more the promise of abortion in America than the reality of it.

Most people stay in the balcony of the abortion debate, looking down on the drama from the crowded middle seats. Their feelings tip and tilt according to circumstance and conditions: Was there a waiting period, counseling? If it's a teenager, do her parents know? Surveys find that 65% of people accept first-trimester abortion, but 69% oppose anything later than that. The laws reflect the public ambivalence of a country that wants abortion to be available but not easy. And pro-life forces have done everything in their power to make it harder, by focusing on the unimaginably hard cases. How can you abort a fetus developed enough to have fingernails, they ask?



In fact, for all the moral and legal wrangling, science has been the pro-life camp's best ally over the past decade, as doctors steadily moved up the point of viability, saving premature babies as young as 25 weeks, 24, 23. Sonograms as clear as Christmas cards let parents see their babies suck their thumbs in utero. Better prenatal testing has built greater awareness of how, and how quickly, a fetus develops--all of which may have fueled the discomfort with abortions that occur when a pregnancy is well along.

You could argue that the most important thing that happened last week was that science changed sides and put its power to work for the pro-choice team as well. The abortion pill shifts the focus from the latest stage of pregnancy to the earliest, when the entire embryo is the size of a grain of rice. For abortion-rights activists scarred by five years of fighting over "partial birth" abortions, that is where they prefer the public debate to take place. MORE>>

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TIME

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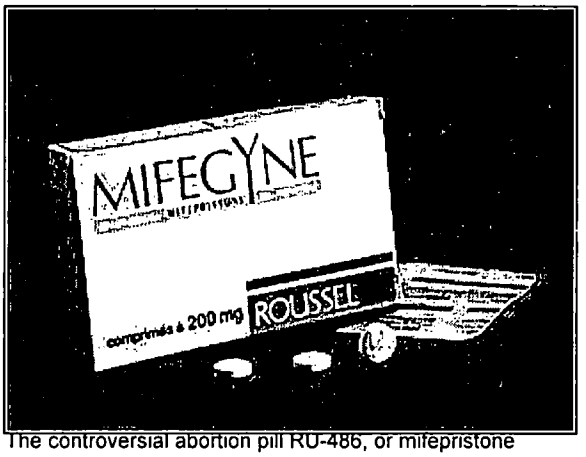
Tuesday, Oct. 10, 2000

The White House and RU-486: Don't Ask, Don't Tell

'Hands off' was the byword as the administration doggedly insulated itself from political fallout, reports TIME's Ann Blackman from behind the scenes



The controversial abortion pill RU-486, or mifepristone

It has not been your usual drug approval process. At the White House, where information is power and officials pride themselves on having the inside scoop, virtually everyone learned that the Food and Drug administration approved the revolutionary abortion pill called mifepristone from — of all places — CNN. President Clinton learned about it only moments earlier from Health and Human Services Secretary Donna Shalala. And Shalala got the news by telephone from FDA commissioner Jane Henney — after the FDA made the announcement public.

TIME has learned that Shalala was so concerned about the administration being accused of ramrodding the abortion pill through the FDA for political reasons in the middle of a tight election that she made it clear to the White House that she did not want anyone there at all involved in the process at all. Message: Butt out. "She's smart," says a key HHS official. "She knew the press was going to ask whether any of this was done for political reasons, and she wanted to answer to be no." Shalala issued strict instructions to her staff to respond to any White House queries with a single sentence: "The FDA is going through its usual approval process."

But it wasn't exactly business at usual. For security reasons, the FDA has taken the unusual step of not disclosing the name or site of the mifepristone drug manufacturer or the names of employees working on it. Nor did they name the doctors and scientists on the FDA advisory committee that made the

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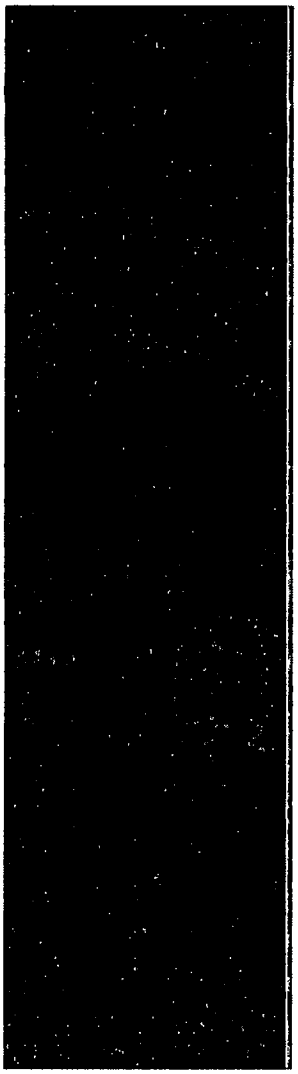

on the FDA advisory committee that made the decision to approve the abortion pills. An HHS official said this precaution has never been taken before in connection with approval of a drug.

Why? Because there are heightened concerns for security every time abortion is in the headlines. Plus, no one is sure sure how the abortion pill decision will play with the general public. Women's rights organizations are thrilled. Right-to-lifers hate it. But there is a large middle group of Americans who have strong views on abortion, and no one can predict if they will approve of making abortion easier, even if medical data shows the drug is safer than surgical abortion. "If we had our choice, this would not have come in election season," says one official.

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Tuesday, Oct. 10, 2000

RU-486 Nod Ushers New Era of Abortion Debate

French professor Emile-Etienne Beaulieu, inventor of the RU-486 abortion drug

By approving the drug, the FDA becomes even further embroiled in the nation's most contentious issue...

Let the protests begin. On Thursday, under extraordinary scrutiny, the Food and Drug Administration approved RU-486, otherwise known as "the French abortion pill," for marketing in the United States under the name Mifeprex. The drug, which is actually two pills taken under a physician's supervision over the course of two days, has been proven extremely effective in ending pregnancies up to the 50th day following conception. These pills are different from the "morning after pill," or emergency contraceptive, which is administered in the 72 hours following intercourse. The FDA, which has been hemming and hawing over final approval for RU-486 for almost four years, made its decision under enormous pressure — from both political and medical organizations.

Pro-life groups responded to the announcement immediately, deploring the FDA's action and citing their concern for the health of women who will take the drug. "This is a sad day for women," said a spokesperson for the Family Research Council. Pro-choice groups, longtime supporters of the drug, expressed gratification at the decision, calling the approval an advance in women's health on par with the introduction of the birth control pill.

This moment has been a long time coming: European women have had access to RU-486 for 12 years, but attempts to import the drug to the United States have been stymied internally by contentious debate. And even when the Clinton administration lifted a ban on importing the controversial drug in 1993, the French manufacturer declined to distribute the pill here, citing the explosive political undercurrents in the U.S.

Instead, Roussel-UCLAF, which holds the pill's 20-year-old patent, granted sole American distribution rights to the Population Council, a nonprofit organization specializing in reproductive issues, with the understanding the group would conduct clinical trials and find a manufacturer for

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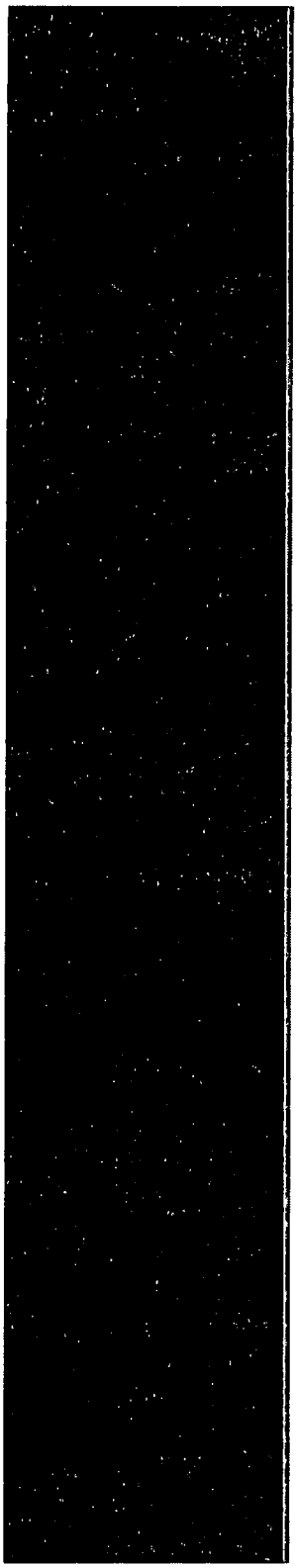

conduct clinical trials and find a manufacturer for the drug. And after six years of research and more than a few last-minute panic attacks from would-be manufacturing companies, the moment has arrived. The Population Council concluded a hugely successful drug trial in which 92 percent of the participants achieved successful medical abortions — the remaining 8 percent required surgical intervention to complete the procedure. Within the study, two thirds of women who'd previously had a surgical abortion rated their experience with RU-486 as far preferable, particularly citing privacy and the absence of invasive measures. The pills must be taken in the presence of a surgically qualified doctor, who must be capable of performing a surgical abortion if the medical abortion fails. Ironically, this restriction means accessibility, which had been one of the drug's major selling points among pro-choice groups, is not likely to be affected by the approval. The guidelines mean the growing number of women who do not have access to surgical abortion will likewise not have access to medical abortion.

Barring any major political upheaval — like the appointment of a new, anti-choice FDA commissioner — the door to the American drug marketplace now stands wide open: After several false starts, a marketing group (the New York–based Danco Laboratories) and manufacturer (the name of which remains anonymous) have signed on. The drug is expected to become available in about a month.

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Tuesday, Oct. 10, 2000

Ready for Battle: The FDA Considers the Fate of RU-486

The 'French abortion pill' has been taboo on American soil for years. That could all change on Friday

This week, the Food and Drug Administration is ground zero in the American debate over abortion. The administration faces a Friday deadline to determine whether the so-called "French abortion pill," or RU-486, should be marketed in the United States. The drug, which is actually two separate pills taken under a physician's supervision over the course of two days, has been proven extremely effective in ending pregnancies up to the 50th day following conception. The drug is very different from the "morning-after pill," or emergency contraceptive, which is administered in the 24 hours following intercourse.

This moment has been a long time coming: When the Clinton administration lifted a ban on importing the controversial drug in 1993, the French manufacturer declined to distribute the pill here, citing the explosive political undercurrents of the U.S. marketplace.

Instead, Roussel-UCLAF, the patent holder of the 20-year-old pill, granted sole American distribution rights to the Population Council, a nonprofit organization specializing in reproductive issues, with the understanding that the group would conduct clinical trials and find a manufacturer for the drug. After six years of research and more than a few last-minute panic attacks from would-be manufacturing companies, the moment of reckoning has arrived: The Population Council has concluded a hugely successful drug trial in which 92 percent of the participants achieved a "favorable" outcome and a marketing group, Banco Laboratories, and manufacturer (the name of which remains anonymous) have been pinpointed.

Now all that stands in between American women and non-surgical abortion is the FDA's stamp of approval. And the agency, which has been hemming and hawing over final approval for RU-486 for almost four years, is under enormous pressure — from both the medical and political worlds. Anti-abortion activists are predictably opposed to the pill, while abortion rights groups argue RU-486 offers women a more private, less invasive and ultimately safer way to terminate unwanted pregnancies.

The FDA is no doubt steeling itself for the rash of phone calls, protests and editorials that will accompany any decision they make. But come

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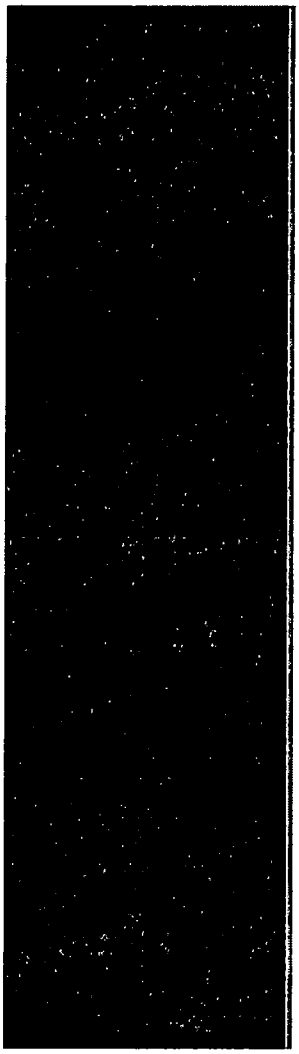

accompany any decision they make. But come Friday, there may be no movement at all. Political observers speculate it's quite possible the agency will hedge its bets and ask for more time to consider the issue, in an effort to divert attention from the pill — and its purpose — until after the November 7 election. And Al Gore isn't likely to protest that line of logic.

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Abortion Pill's Fate Is Linked to Election

Campaign: Gore backs the distribution of the drug found to be safe by the FDA. The GOP ticket has expressed disapproval of the agency's decision.

By AARON ZITNER, SCOTT MARTELLE, Times Staff Writers

WASHINGTON--Although the issue has been lightly mentioned on the campaign trail, whoever wins next month's presidential election could play a significant role in whether and how U.S. women have access to RU-486, the abortion pill.

The drug was approved by the Food and Drug Administration on Sept. 28 after four years of study, including a review of clinical trial data involving more than 2,000 women. It could reach doctors in about a month.

The drug has been available in much of Western Europe for a decade. But the next president could try to limit its U.S. distribution or reverse the FDA's decision altogether.

That is unlikely to happen if Vice President Al Gore, the Democratic nominee, is elected. A supporter of abortion rights, Gore has said he backs distribution of the drug now that the FDA has found it to be safe and effective.

The Republican ticket, by contrast, has expressed disapproval of the FDA decision. However, both Texas Gov. George W. Bush, the presidential nominee, and his running mate, former Defense Secretary Dick Cheney, have turned aside questions about what they might do to limit distribution of the drug.

Specialists in administrative law say that a president cannot unilaterally overturn an FDA decision. But the FDA commissioner, who is a presidential nominee, can order a review of a drug approval based on how it is affecting consumers. And where reports of patient problems may seem minor to one FDA commissioner, another might see those reports as significant enough to warrant limitations on the drug or its removal from the market.

On the day of the FDA approval, a spokesman for the Bush campaign said that the governor, if elected president, would order a "careful review" of the FDA decision.

Bush himself said something different about the drug approval during his debate Tuesday with Gore.

Moderator Jim Lehrer of PBS asked: "You wouldn't, through appointments to the FDA, ask them to reappraise it?"

"No," answered Bush. "I think once the decision's been made, it's been made. Now--unless it's proven to be unsafe to women." He did not elaborate on that comment.

The issue also arose Thursday in the vice presidential debate between Cheney and his Democratic counterpart, Sen. Joseph I. Lieberman of Connecticut. Moderator Bernard Shaw of CNN asked whether the candidates would support legislation filed by Republicans in Congress last week that would limit the distribution of RU-486.

Lieberman said he did not support the bill. Cheney said he had not seen the legislation, and he offered no opinion.

Under that legislation, introduced by Sen. Tim Hutchinson (R-Ark.) and Rep. Tom A. Coburn (R-Okla.), doctors who offer the pill would have to know how to perform surgical abortions, hold admitting privileges at a hospital no more than an hour from their offices and meet other conditions. In contrast, the FDA said almost any doctor could offer RU-486, which is known as mifepristone.

The lawmakers say their aim is to protect women and make sure doctors are prepared to handle any emergencies that may arise from the use of the drug. Abortion rights groups say the legislation would unnecessarily limit the pill only to those clinics where abortion is provided today.

In a conference call with reporters Friday, organized by the Gore campaign, former FDA Commissioner Dr. David A. Kessler said that the Bush-Cheney ticket is being "evasive and contradictory" in its position on RU-486.

"When you listen to both Gov. Bush and Secretary Cheney, they were very evasive on the central question: Would they be willing to veto legislation passed by a Congress that would overrule FDA's decisions?" said Kessler, who was named FDA chief in 1990 by President Bush, the father of the Texas governor, and who continued to serve under President Clinton.

Kessler, now dean of Yale's medical school, said that the most likely attack on the FDA's decision would come in the form of congressional legislation to block the pill's distribution. "I think George Bush and Dick Cheney owe it to the women of this country as to whether they would back this overturning of RU-486," Kessler said.

* * *

Martelle reported from Los Angeles. Times researcher Massie Ritsch contributed to this story.

Armstrong Williams on Abortion Pill

* It's hard to imagine reading more illogical and preposterous statements than found in Armstrong Williams' argument about poisoning babies with RU-486 (Commentary, Oct. 4). I wonder if Williams thinks he's eating chickens when he has eggs in the morning. To a normal adult mind the blocking of hormones (how RU-486 works) to stem fetal development can hardly be construed as "baby poisoning." It's also difficult to accept Williams' argument that the production of RU-486 is tied to the producer of poisons used in the Nazi gas chambers because the manufacturer is an offshoot of a company that produced those poisons in WWII. Using that logic we can tie our entire space program to the Nazis through manufacturers like Siemens and German scientists like Wernher von Braun.

Williams belongs to a group of pious, ever-appalled conservatives who live in an eternal state of disgust with the rest of the human race. It's their livelihood to judge and condemn most of humankind. Just don't look for logic in their arguments.

DAVID FREDERICKS
Huntington Beach

* * *

I applaud Williams' discernment in exposing the abortion pill for what it is--a sickening chemical reminiscent of the Nazi regime. Tell me, what is there to celebrate about the advent of a drug whose sole purpose is the termination of defenseless human life? How can society justify its condemnation of the Holocaust when it expands its assault on countless innocents, whose only "crime" is that they are unwanted? Shame on us!

ARLENE H. PLATTEN
Redondo Beach

Rogan under fire for abortion remarks

'The Ku Klux Klan couldn't do a better job on committing genocide on African-Americans,' congressman says.

By PAUL CLINTON

GLENDALE -- Rep. James Rogan's (R-Glendale) comparison of abortions among African-Americans in the past 27 years to the tactics of the Ku Klux Klan has ruffled some feathers on Capitol Hill and in his own district.

In the Oct. 5, issue of Roll Call, a twice-weekly publication aimed at federal legislators, Rogan was discussed his views about the recent approval of abortion pill RU-486 by the Federal Drug Administration.

"There have been 30 million abortions since Roe v. Wade (1973) and 12 million of those have been African-American." Rogan was quoted as saying in the article. "This has become a Holocaust on the African-American community ... The Ku Klux Klan couldn't do a better job on committing genocide on African-Americans."

In response to the comments, 24 Democratic congressional representatives blasted Rogan's remarks.

"Your comments reflect an insensitivity that leaves us speechless," the members wrote in an open letter to Rogan on Friday. "We find it inappropriate to compare a woman's right to choose to the agenda of the Ku Klux Klan."

The letter was signed by the 14 members of the Congressional Black Caucus, an ad-hoc group led by Rep. James Clyburn (D-Charleston, South Carolina). Five California representatives signed the letter.

In the letter, the legislators demanded an apology from Rogan. On Friday, Rogan stood by his remarks.

"Abortion extremists who have promoted policies that have deprived our community of some 12 million African-American babies are not in a position to lecture me or anyone else about sensitivity," Rogan said. "Instead, they should explain to the nation why they defend the holocaust of minority children."

Rogan's comments come a month prior to an election to determine who will represent his district for the next four years. State Sen. Adam Schiff (D-Glendale) is running against Rogan. Schiff is a pro-choice candidate.

Gwen Flynn, a board member of the

Burbank Human Relations Council, said she was also upset by Rogan's comments.

"On the face of it, I think it's pretty presumptuous of him to make a statement like that and think that he's speaking for African-Americans," Flynn, who is black, said. "I don't know where that comes from. (It is) totally inappropriate, offensive to me."

Sharon Washington, an African-American Pasadena resident who attended a Sept. 30 event where Rogan spoke, said Rogan was on point with his remarks.

"I agree with what he says," Washington said. "He spoke my sentiments exactly."

Lawmakers Propose Higher Standards for Abortion Pill

From Associated Press

WASHINGTON--Abortion foes in Congress introduced bills Wednesday to tighten standards for doctors administering the newly approved abortion pill RU-486.

Rep. Tom A. Coburn (R-Okla.), joined by Sen. Tim Hutchinson (R-Ark.), said the legislation is needed because the Food and Drug Administration, in setting rules for prescribing the drug, had "caved in" to abortion rights groups seeking easier access to abortion. "Congress now has the unenviable task of correcting the FDA's mistake."

Kate Michelman, president of the National Abortion and Reproductive Rights Action League, said the legislation would impose restrictions that would "in effect negate the ability of doctors to prescribe this option for women."

Coburn said he hopes to get the bill to the House floor in the final days of this session. Hutchinson was less ambitious, saying he wants to have a hearing this year and pursue the issue next year.

The FDA approved RU-486 on Sept. 28, ending a 12-year debate in this country. It gives American women a pharmaceutical abortion method already in wide use in France, Britain, China and 10 other countries.

President Clinton praised the decision as "one of science and medicine," but abortion opponents said it will encourage more women to end their pregnancies.

The FDA said that to prescribe the drug, doctors must be able to pinpoint the date of conception, rule out women with ectopic or tubal pregnancy, and be prepared to take surgical steps to complete the abortion or stop the bleeding in case of problems.

Abortion Pill Safety Questioned

By PAULINE JELINEK, Associated Press Writer

WASHINGTON--Abortion opponents contended Sunday that the new abortion pill may be unsafe and raised the possibility of government action to limit its use.

Reform Party presidential candidate Patrick Buchanan called RU/486, the early-abortion method approved Thursday by the Food and Drug Administration for use in the United States, "a human pesticide."

As president, "I would use all the power of my office, including appointments at the FDA, to prevent its being put on the market," Buchanan said on NBC's "Meet the Press."

Green Party candidate Ralph Nader, also on NBC, countered that use of the drug is "up to the woman, not the government."

"This is a pill that's been shown to be safe in Europe for numerous years," Nader said. "And it's preferable to surgical procedure."

Sen. Tim Hutchinson, R-Ark., said on ABC's "This Week" that there are "a lot of questions" surrounding the safety of the pill -and that the outcome of next month's election will determine whether Congress has enough votes next year to put limits on its use.

Eleanor Smeal, president of the Feminist Majority Foundation, also on ABC, said the drug had undergone "tremendous review" by the FDA.

"They can protest as much as they want," she said of abortion foes. "This is a safe, effective method."

One lawmaker, Rep. Tom Coburn, R-Okla., said after the FDA's decision that he would promote legislation calling for severe limits on which doctors could administer mifepristone, the pill's chemical name.

The Christian Coalition's Pat Robertson said on CBS's "Face the Nation" that the drug's approval was a "political ploy" by Democrats to corner Republican presidential nominee George W. Bush on the subject.

Bush, whose father's administration banned RU/486 imports in 1989, opposes abortion. Vice President Gore supports the pill option.

Robertson said the pill should be reviewed to determine if it's a "danger to women."

The pill blocks action of a hormone essential for maintaining pregnancy. It has been used by millions of European women since it was approved nearly a decade ago. Anti-abortion advocates have fought hard to keep the drug out of the United States since it first appeared in France.

FDA Commissioner Jane Henney approved mifepristone based on studies that found it 92 percent to 95 percent effective in causing abortion.

Complications are rare; serious bleeding occurs in 1 percent of women. But the pill-caused abortion requires three doctor visits and, to ensure it is performed accurately, the FDA restricted its use to doctors with certain training and mandated that detailed patient-information brochures be given to every woman.

Evangelist Mum on Abortion Pill

Politics: Pat Robertson refrains from discussing the controversial issue at the Christian Coalition convention. He says he'll hold his tongue to help Bush.

By NICK ANDERSON, Times Staff Writer

WASHINGTON--The morning headlines blared the topic, and his audience of conservative Christian activists was primed for a fiery response. But the Rev. Pat Robertson, longtime foe of abortion rights, made no mention of the government's decision to allow distribution of a controversial abortion pill in a speech Friday opening the Christian Coalition's annual convention.

> The omission reflected the pragmatic approach Robertson is taking in a campaign season that he and other social conservatives describe as the most important

in years. With control of the White House, Congress and perhaps the Supreme Court all at stake, the last thing Robertson wants is for the November election to be about him.

So after his speech, which dwelt on the evils of big government spending, Robertson told reporters he was biting his tongue on the Food and Drug Administration's approval Thursday of the pill known as RU-486 for one reason: to help Republican presidential nominee George W. Bush. Robertson said the FDA action was a Clinton administration ploy to help Vice President Al Gore, the Democratic nominee.

"I think it's a trap for Bush, and I think he ought to stay out of it, and I will too," Robertson said. "Right now, to play this campaign on abortion would be a tragic mistake. Voters, by a vast majority, are more concerned about other issues."

Gore supports abortion rights. Bush favors an abortion ban except in cases of rape, incest or to save a woman's life. Bush told the GOP convention in August that he would sign legislation to ban so-called partial-birth abortions--a pledge that the coalition activists here remember. He also issued a statement Thursday condemning the FDA action. But the Texas governor generally has downplayed the abortion rights issue in an effort to reach the political center.

To most of the nearly 3,000 people expected this weekend for the annual gathering of the coalition Robertson founded in 1989, abortion is a front-and-center concern. Robertson acknowledged Friday that addressing the issue squarely could help energize Christian conservatives across the country, but he added: "It may also cost the election."

As his remarks indicated, Robertson clearly is

mindful of the political problems Bush might face with swing voters if he appears too closely tied to groups such as the Christian Coalition--even though most members of the coalition enthusiastically support his candidacy.

Robertson himself was labeled an "evil influence" on the Republican Party by Sen. John McCain (R-Ariz.) during this year's GOP presidential primary campaign. McCain later insisted his remark had been intended as a joke, but he sought to make the case that Bush would suffer from being tied too closely to Robertson and other Christian conservative activists.

Bush stood by Robertson during his primary fight with McCain. But he declined an invitation to address the Christian Coalition convention in person, scheduling instead a video appearance today. Representing the Bush campaign in person at the convention was Lynne Cheney, wife of GOP vice presidential nominee Dick Cheney.

Also on hand Friday were House Speaker J. Dennis Hastert (R-Ill.) and Senate Majority Leader Trent Lott (R-Miss.), who urged activists to mobilize to protect the fragile Republican majority in Congress. At stake, they said, were such GOP goals as limiting abortion rights, cutting taxes, containing federal spending and restoring local control on education policy.

"This is the year," Lott told the convention. "This is the most important election of my lifetime. I've been in the Congress 28 years, but never before has it all been on the line."

Frank Marsico, 47, who came to the convention from Mechanicsburg, Pa., said that Christian conservative activists are girding for the battle. "People are coming out of their slumber. It really is integrity and character that do count."

FDA Approves Abortion Pill

By LAURAN NEERGAARD, AP Medical Writer

WASHINGTON--Abortion foes bitterly denounced government approval of the abortion pill RU/486 and vowed to continue to fight a drug they called "baby poison" and a threat to women's health.

RU/486 was approved Thursday by the Food and Drug Administration, ending a battle that has involved two presidents, several countries and heated debate for 12 years.

Approval of the drug gives American women a pharmaceutical abortion method already in wide use in France, Britain, China and 10 other countries.

But since the FDA action took place in the closing weeks of a national political campaign, it drew quick and heated comments from both sides of the issue.

Texas Gov. George W. Bush, the Republican presidential nominee, called the FDA decision "wrong" and said he feared that the availability of RU/486 "will make abortions more and more common."

Health experts, however, said abortions did not increase after the drug was introduced in Europe.

A Bush campaign spokesman said a president cannot order drugs off the market, but, if elected, Bush would appoint an FDA commissioner "to make sure the FDA considered the risk and did not take this action as a result of political pressure from the White House."

Vice President Al Gore, Bush's Democratic opponent, supported approval of the abortion pill, saying the decision was "not about politics, but the health and safety of American women and a woman's fundamental right to choose."

RU/486 was developed in France and became available there in 1988. In 1989, Bush's father, President George Bush, ordered the FDA to ban importation of the drug for personal use. In 1993, President Clinton ordered a re-evaluation of the ban and sought ways to provide RU/486 for U.S. researchers after its French manufacturer refused to supply it.

Abortion opponent Rep. Chris Smith, R-N.J., called the abortion pill "baby poison," adding that "RU/486 is not just poison for babies, it is potential poison for the mothers who take it." He said it can cause prolonged bleeding and severe cramps.

Rep. Tom Coburn, R-Okla., promised legislation calling for severe limits on which doctors could administer the abortion pill.

On the other side, Sen. Barbara Boxer, D-Calif., said the drug provides an abortion method "that avoids invasive surgery."

"Today is a day that women should remember because their health and their choices are finally being

respected," she said.

The pill, known chemically as mifepristone and by the brand name Mifeprex, will be available to doctors within a month.

Mifepristone blocks a hormone vital to sustaining pregnancy and works only during the first seven weeks of pregnancy, when an embryo is about one-fifth of an inch.

Two days after taking mifepristone, women take a second drug that causes cramping and bleeding as the embryo is expelled, much like a miscarriage.

"For those who choose to have an early termination of their pregnancy, this is a reasonable medical alternative," said FDA Commissioner Jane Henney. She approved mifepristone based on studies that found it 92 percent to 95 percent effective in causing abortion.

Researchers say complications are rare, with serious bleeding in 1 percent of women. The pharmaceutical abortion does require three doctor visits and the FDA restricted prescribing RU/486 to doctors with certain training. The agency required that detailed patient-information brochures be given to every woman.

But Smith claimed in a statement that a French study showed that out of 950 women who used the drug, 270 required narcotics to control intense pain and seven required blood transfusions.

Richard Hausknecht, medical director of Danco Laboratories, marketer of mifepristone, called it "a very, very safe drug."

"At long last, science trumps anti-abortion politics and medical McCarthyism," said Eleanor Smeal of the Feminist Majority Foundation.

Mifepristone may "turn the tide against anti-choice intimidation," because doctors not offering surgical abortion can use the pill in private offices instead of protester-targeted clinics, added Planned Parenthood president Gloria Feldt.

A Kaiser Family Foundation survey of 767 physicians found that a third of doctors who don't now provide surgical abortions would consider prescribing RU/486.

But anti-abortion groups pledged to continue their opposition, with Judie Brown of the American Life League saying: "We will not tolerate the FDA's decision to approve the destruction of innocent human persons through chemical abortion."

The pill's journey to the United States began in 1995, when French manufacturer Roussel-Uclaf turned over U.S. rights to the drug to the nonprofit Population Council of New York. The council began clinical trials needed for FDA approval and created Danco Laboratories to market mifepristone.

The FDA in 1996 declared mifepristone a safe and effective early abortion method, but delayed full approval because Danco had problems satisfying

manufacturing and other final requirements.

President Clinton said the FDA's four-year investigation shows the decision was "purely one of science and medicine." He said the FDA "bent over backward to do a lot of serious inquiries."

Foes Swear to Battle Abortion Pill

By LAURAN NEERGAARD, AP Medical Writer

WASHINGTON--Abortion foes bitterly denounced government approval of the abortion pill RU/486 and vowed to continue to fight a drug they called "baby poison" and a threat to women's health.

But Thursday's approval by the Food and Drug Administration alters that fight, promising to make abortions more accessible in private doctors' offices instead of the surgical clinics routinely staked out by anti-abortion protesters.

The drug's approval ends a battle that has spanned two presidencies, several countries and heated debate for 12 years. It gives American women a pharmaceutical abortion method already in wide use in France, Britain, China and 10 other countries.

Since the FDA action took place in the closing weeks of a national political campaign, it drew quick and heated comments from both sides of the issue.

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RU/486 was developed in France and became available there in 1988. In 1989, the FDA banned importation of the drug for personal use. In 1993, President Clinton ordered a re-evaluation of the ban and sought ways to provide RU/486 for U.S. researchers after its French manufacturer, under anti-abortion pressure, refused to supply it.

Abortion opponent Rep. Chris Smith, R-N.J., called the abortion pill "baby poison," adding that "RU/486 is not just poison for babies, it is potential poison for the mothers who take it." He said it can cause prolonged bleeding and severe cramps.

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Abortion Pill Sales Face Challenge

By PHIL GALEWITZ, AP Business Writer

Despite years of anticipation, don't expect overwhelming demand for the abortion pill RU/486, say doctors and women's health advocates.

Surgical abortion will remain the predominant method of terminating a pregnancy because it can be done in a day rather than the two to three days for RU/486, which won U.S. approval Thursday. Other factors that may block acceptance of the pill is that only a limited number of doctors will prescribe it and women may hesitate to take it once they learn about the pain and discomfort it causes, doctors say.

"Most people think you take the pill and the pregnancy is gone, and nothing else is involved," said Dr. Deborah Oyer, a family doctor with Aurora Medical Services in Seattle who was involved in the clinical trials of RU/486. "Women who have gone through a spontaneous miscarriage know it does not feel good."

The pill-induced abortion can be painful, causing bleeding and nausea for days. Heavy bleeding is a potentially serious but rare side effect.

RU/486 can be used only within 49 days of the beginning of the woman's last menstrual period. The woman takes three mifepristone pills. Two days later, she returns to the doctor to swallow a second drug, misoprostol, that causes uterine contractions to expel the embryo. She returns for a follow-up visit within two weeks to make sure the abortion is complete.

Oyer said she expect only about 10 percent of the 1.3 million annual abortions in the United States to be done with the pill, which will become available for American women in about a month.

Danco Laboratories LLC, a small, privately owned New York based company that was formed in the late 1990s for the sole purpose of introducing the abortion pill, will sell RU/486 in the United States under the brand name Mifeprex. Danco has revealed little about its business strategies, though it's expected to soon launch a massive consumer advertising campaign about the drug.

Backers of the drug say they expect critics to try to scare women, by focusing on the possibility of heavy bleeding after taking the pills. But they say that such bleeding is rare.

"Is if safe? Yes! Up to 49 days, the safety margin is wonderful," said Dr. Richard Hausknecht, medical director for Danco. "This is a very, very safe drug," Hausknecht said. "The FDA would not have approved it if they didn't think so."

After a decade of use in France, about 40 percent of abortions in the country are completed with RU/486.

But doctors involved in the drug's clinical trials in the U.S. say demand will be less among U.S. women.

RU/486 was more popular in Europe because abortions are generally not done there until at least eight weeks into the pregancy -and thus the pill gave women the chance to abort their pregnancy earlier. In contrast in the United States, doctors routinely perform abortions as early as five weeks.

Gloria Feldt, president of Planned Parenthood Federation of America, estimated about 20 percent to 30 percent of women seeking abortions will use the pill. "The process will be less prolonged with the surgical procedure," she said.

Women's access to the pill will be determined largely by how many doctors choose to prescribe it. Many doctors are willing to prescribe RU/486 because of risk possible harassment from anti-abortion advocates.

About one-third of family physicians and gynecologists who don't currently provide elective surgical abortions said they would consider prescribing RU/486, according to a recent survey of 767 physicians by the Kaiser Family Foundation.

Abortion by Pill Not That Simple

By LAURAN NEERGAARD, AP Medical Writer

WASHINGTON--Getting an abortion with the drug RU/486 isn't quite as simple as taking a pill.

So the Food and Drug Administration issued detailed requirements Thursday to ensure that women fully understand the process and that properly trained doctors use the drug accurately.

The abortion pill, which doctors call by its chemical name mifepristone, is only for use very early in pregnancy -49 days from the beginning of a woman's last menstrual period; it requires three doctor visits to complete.

First, a woman swallows three mifepristone pills. Mifepristone blocks action of a hormone essential for maintaining pregnancy. Without that hormone, progesterone, the uterine lining thins so the embryo cannot remain implanted and grow.

To fully detach the embryo from the uterus and expel it, two days later a woman must swallow a second drug, misoprostol, that causes uterine contractions -miscarriage-like cramping and bleeding.

Then, she must return for a follow-up visit within two weeks to make sure the abortion is complete. While studies show mifepristone is 92 percent to 95 percent effective in causing early abortion, some women need surgical abortion to finish the job.

If the fetus survived either the mifepristone or misoprostol steps and surgical abortion is not done, a woman could have a malformed child, something that has occasionally happened overseas. If the fetus died but was not completely expelled, a woman could suffer infection or other problems, the FDA warned.

In studies where women had the necessary doctor visits, complications were rare. The FDA said 1 percent of women suffer serious bleeding that requires a surgical abortion-like procedure to staunch, and a handful needed a transfusion.

The FDA mandated that women be given a special brochure fully explaining the procedure and side effects, and that they sign a form agreeing to the necessary visits.

The FDA ruled that mifepristone can be distributed only to doctors trained to accurately diagnose duration of pregnancy and detect ectopic, or tubal, pregnancies, because those women cannot receive mifepristone.

Also, the FDA restricted mifepristone's use to doctors who can operate in case of bleeding or a surgical abortion is needed, or to doctors who have made advance arrangements for a surgeon to be on call for such care.

Unlike with surgical abortions, mifepristone does not require anesthesia. Planned Parenthood's Dr. Paul

Blumenthal, who helped test the drug, said most women take over-the-counter ibuprofen for the pain, but some need a prescription-strength painkiller.

The FDA also demanded that the Population Council, which owns U.S. rights to the abortion pill, track any post-mifepristone pregnancies in the United States to see if further safeguards are needed.

Abortion Pill May Face Competition

By PHIL GALEWITZ, AP Business Writer

Despite years of anticipation, don't expect overwhelming demand for the abortion pill RU/486, say doctors and women's health advocates.

Surgical abortion will remain the predominant method of terminating a pregnancy because it can be done in a day rather than the two to three days for RU/486, which won U.S. approval Thursday. Other factors that may block acceptance of the pill is that only a limited number of doctors will prescribe it and women may hesitate to take it once they learn about the pain and discomfort it causes, doctors say.

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About one-third of family physicians and gynecologists who don't currently provide elective surgical abortions said they would consider prescribing RU/486, according to a recent survey of 767 physicians by the Kaiser Family Foundation.

RU/486 Approval Sparks Fresh Debate

By REBECCA SINDERBRAND, Associated Press Writer

WASHINGTON--The government's approval of an abortion pill reignited a long, fiery debate that has been aired frequently in the halls of Congress, outside the Supreme Court and across the country.

Proponents say RU/486, which has been used by millions of European women since it was approved nearly a decade ago, could fundamentally alter the abortion debate by making the procedure less difficult and more private.

Anti-abortion advocates, who have fought hard to keep the drug out of the United States since it first appeared in France, said the fight was far from over.

President Clinton hailed the decision, saying the administration "treated that issue as purely one of science and medicine."

"I think that they (FDA) have bent over backward to do a lot of serious inquiries," he said, "but FDA is basically doing its job."

The volatile issue has been pervasive in the national policy debates, particularly since the Supreme Court ruled it constitutional in 1973. The issue often surfaces in Congress as anti-abortion lawmakers seek to place abortion restrictions on appropriations bills.

On Thursday, much of the congressional Republican leadership, including House Majority Whip Rep. Tom DeLay and House Majority Leader Dick Armey, both Texans, blamed the administration for the drug's approval.

"Bill Clinton got the legacy he was looking for," said House Republican Conference chairman Rep. J.C. Watts, R-Okla.

"The FDA's approval of RU/486 appears to be motivated by election-year politics rather than a thorough review of the facts," said Sen. Sam Brownback, R-Kansas.

Democrats praised the FDA's decision, calling it a step forward in women's reproductive medicine, and aimed their rhetorical fire at GOP lawmakers.

Rep. Rosa DeLauro, D-Conn., called the decision a "true victory of medicine over politics."

"The anti-choice lawmakers sought to tell the scientists and researchers at the FDA what was best for the health of the American public," she said. "But this year they did not succeed."

But Sen. Tim Hutchinson, R-Ark., said: "It is highly offensive that the Clinton Administration accelerated the drug approval process for RU/486 ... This process has been tainted by politics in an unprecedented manner."

Rep. Tom Coburn, R-Okla., pushed futilely to block FDA approval of RU/486 in 1998 and 1999. He

vowed to introduce legislation that would require physicians who prescribe the drug, also called mifepristone, to be trained and licensed in surgical abortion, among other procedures.

"I am appalled that the FDA appears to have bowed to the political pressure from the abortion lobby and White House and approved the drug with inadequate patient protections," Coburn said.

Said Rep. Jerrold Nadler, D-N.Y.: "This is a victory for science, the pro-choice movement, and for women in this country. My only regret is that politics delayed the importation of this drug for far too long."

Rep. Lynn Woolsey, D-Calif., said that making RU/486 available for women and doctors "will offer women in the United States a safe alternative to a surgical abortion." She added that her first act eight years ago as a newly-elected congresswoman had been to sign a letter to the Food and Drug Administration urging the drug's approval.

Some pro-choice groups sounded a less than laudatory tone, however, saying the effect of the ruling was being overstated.

"It is not a magic pill" that will lessen abortion restrictions already in place or prevent new ones, said Janet Benshoof, president of the Center for Reproductive Law and Policy.

That sentiment was echoed by anti-abortion advocates. "A new administration, I am certain... will reverse this Clinton-Gore decision," Watts said.

Quotes About Abortion Pill Approval

By THE ASSOCIATED PRESS

Quotes about FDA approval of the RU486 pill.

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"For the first time, American women who choose abortion will have the option of taking a pill to end a very early pregnancy. They will now have access to a method that has been used safely and effectively by more than 500,000 women in Europe for over a decade." -Vicki Saporta, executive director, National Abortion Federation.

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"RU/486 is dangerous to women. Unlike medicine, which heals, it has no purpose other than to kill a human life. After years of research, there are still too many questions left unanswered. There are no studies on the long-term affects on women and their future pregnancies." -Wendy Wright, Dir. of Communications, Concerned Women of America.

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"President Clinton and Vice-President Gore Administration used to say they wanted abortion to be 'rare,' but everything they've done is to make abortion more common." -House Majority Leader Dick Armey.

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"Approving mifepristone goes a long way in providing real reproductive health care choices for women. FDA did the right thing by ensuring that good science and the health of women prevailed, despite the enormous obstacles erected by opponents of choice." -Marcia Greenberger, co-president, National Women's Law Center.

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"This administration treated that issue as purely one of science and medicine. I think that they (FDA) have bent over backward to do a lot of serious inquiries .. but the FDA is basically doing its job." -President Clinton.

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"It is about time that American women have the same access as millions of other women around the world to this safe, effective, and private option for early abortion. Conditions of this approval also safeguard the privacy of physicians who provide this important service." -Wayne C. Shields, president and CEO, Association of Reproductive Health Professionals.

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"The Clinton-Gore administration, which claimed it wanted to make abortion rare, has embraced an abortion pill that will result in more abortions and new

risks to women." -Laura Echevaria, spokeswoman for the National Right to Life Committee (NRLC).

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"Bill Clinton got the legacy he was looking for. On his third day in office, he issued an executive order to get the ball rolling on the approval of the abortion pill. Nearly eight years later, President Clinton got what he wanted, and the losers in his victory are women and children across the country. This is a sad day for America." -J.C. Watts Jr. of Oklahoma, House Republican Conference chairman.

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"Mifepristone's approval is one of the most significant advances in women's reproductive health that we have seen in decades. Its approval today is yet another milestone on the long road to women's reproductive freedom and equality in this country." -Kate Michelman, president of NARAL.

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"The FDA's approval of RU/486 appears to be motivated by election-year politics rather than a thorough review of the facts. This administration seems to be seeking a political coup at the expense of our nation's women and children." -Sen. Sam Brownback, R-Kan.

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"This decision is unprecedented. Never before has the FDA approved a drug intended to kill people. The FDA's mission is to promote health, not facilitate the taking of life. Sadly, the FDA has approved a drug that will kill an unborn child and put mothers at grave risk." -Rep. Tom Coburn, R-Okla.

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"This decision will help ensure that women in the United States will have access to a safe and effective option that women in other countries have had for years." -First lady and Democratic Senate candidate Hillary Rodham Clinton.

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"It is highly offensive that the Clinton Administration accelerated the drug approval process for RU/486, evn faster than the average time for 'fast-tracked' drugs. Fast-track timetables are supposed to be reserved for drugs that will combat life-threatening diseases like cancer or AIDS. In this case, the Administration rushed a drug through that will take lives instead of saving them." -Sen. Tim Hutchinson, R-Ark.

FDA Approves Abortion Pill

By LAURAN NEERGAARD, AP Medical Writer

WASHINGTON--Capping a bitter 12 -year battle, the government on Thursday approved use of the abortion pill RU/486, a major victory for abortion-rights advocates that could dramatically alter abortion in this country.

The long-expected decision by the Food and Drug Administration allows Americans an early-abortion method already used in France, Britain, China and 10 other countries. The action is expected to make abortion in the United States more accessible and more private.

Coming in the final weeks of the presidential campaign, the move also is sure to renew fierce political debate. Republican candidate George W. Bush, whose father's administration banned RU/486 imports in 1989, opposes abortion. Vice President Gore supports the pill option.

The pill, known chemically as mifepristone and by the brand name Mifeprex, will be available to doctors within a month.

Mifepristone, which blocks a hormone vital to sustaining pregnancy, only works during the first seven weeks of pregnancy, when an embryo is about one-fifth of an inch; that is earlier than surgical abortions often are offered.

Two days after taking mifepristone, women take a second drug that causes cramping and bleeding as the embryo is expelled, much like a miscarriage.

"For those who choose to have an early termination of their pregnancy, this is a reasonable medical alternative," said FDA Commissioner Jane Henney, who approved mifepristone based on studies that found it 92 percent to 95 percent effective in causing abortion.

Complications are rare; serious bleeding occurs in 1 percent of women. But the pill-caused abortion requires three doctor visits and, to ensure it is performed accurately, the FDA restricted its use to doctors with certain training and mandated that detailed patient-information brochures be given to every woman.

Proponents hailed FDA's move. Although some doctors already use a cancer drug called methotrexate to cause abortion -legal although not formally FDA-approved -they said mifepristone will increase access to the nonsurgical method.

"At long last, science trumps anti-abortion politics and medical McCarthyism," said Eleanor Smeal of the Feminist Majority Foundation.

Mifepristone may "turn the tide against anti-choice intimidation," because doctors who don't offer surgical

abortion can use the pill in private offices instead of protester-targeted clinics, added Planned Parenthood president Gloria Feldt.

But anti-abortion groups, which fought mifepristone by threatening U.S. drug companies with boycotts, pledged to continue fighting.

"We will not tolerate the FDA's decision to approve the destruction of innocent human persons through chemical abortion," said Judie Brown of the American Life League.

"Never before has the FDA approved a drug intended to kill people," said Rep. Tom Coburn, R-Okla., who promised legislation calling for severe limits on which doctors could administer mifepristone.

On the campaign trail, Bush called the FDA's decision "wrong," saying "I fear that making this abortion pill widespread will make abortions more and more common." His campaign said if elected, Bush wouldn't have the authority to overturn the FDA's decision, but he would order a probe of whether the agency's review was influenced by politics.

Gore praised the pill's availability. "Today's decision is not about politics, but the health and safety of American women and a woman's fundamental right to choose," he said.

Health experts note abortions did not increase when RU/486 debuted in France in 1988, or later across Europe.

The pill's journey to the United States began in 1994, when French manufacturer Roussel-Uclaf turned over U.S. rights to the drug to the nonprofit Population Council of New York. The council began clinical trials needed for FDA approval and created Danco Laboratories, a small company that will market mifepristone.

The FDA in 1996 declared mifepristone a safe and effective early abortion method, but delayed full approval because Danco had problems satisfying manufacturing and other final requirements.

President Clinton said the FDA's four-year investigation shows the decision was "purely one of science and medicine." He said the FDA "bent over backward to do a lot of serious inquiries. ... They took so long to try to make sure they were making a good decision."

But the National Right to Life Committee condemned the FDA's unprecedented decision to let Danco keep secret the identity of the manufacturer, reportedly located in China, that actually makes the pills.

"The public has a right to know whether the abortion pill will be imported from the People's Republic of China, a nation that is a leading source of tainted drugs," NRLC said.

FDA's Henney cited anti-abortion violence in her decision to keep the manufacturer secret, and to keep

secret the names of FDA employees who scrutinized the drug. The FDA also increased security in some of its offices.

"The climate around the reproductive rights issue and personal safety issues are in our minds," she said.

But FDA inspectors did travel to the mifepristone factory, and it passed all federal safety and quality rules, she said.