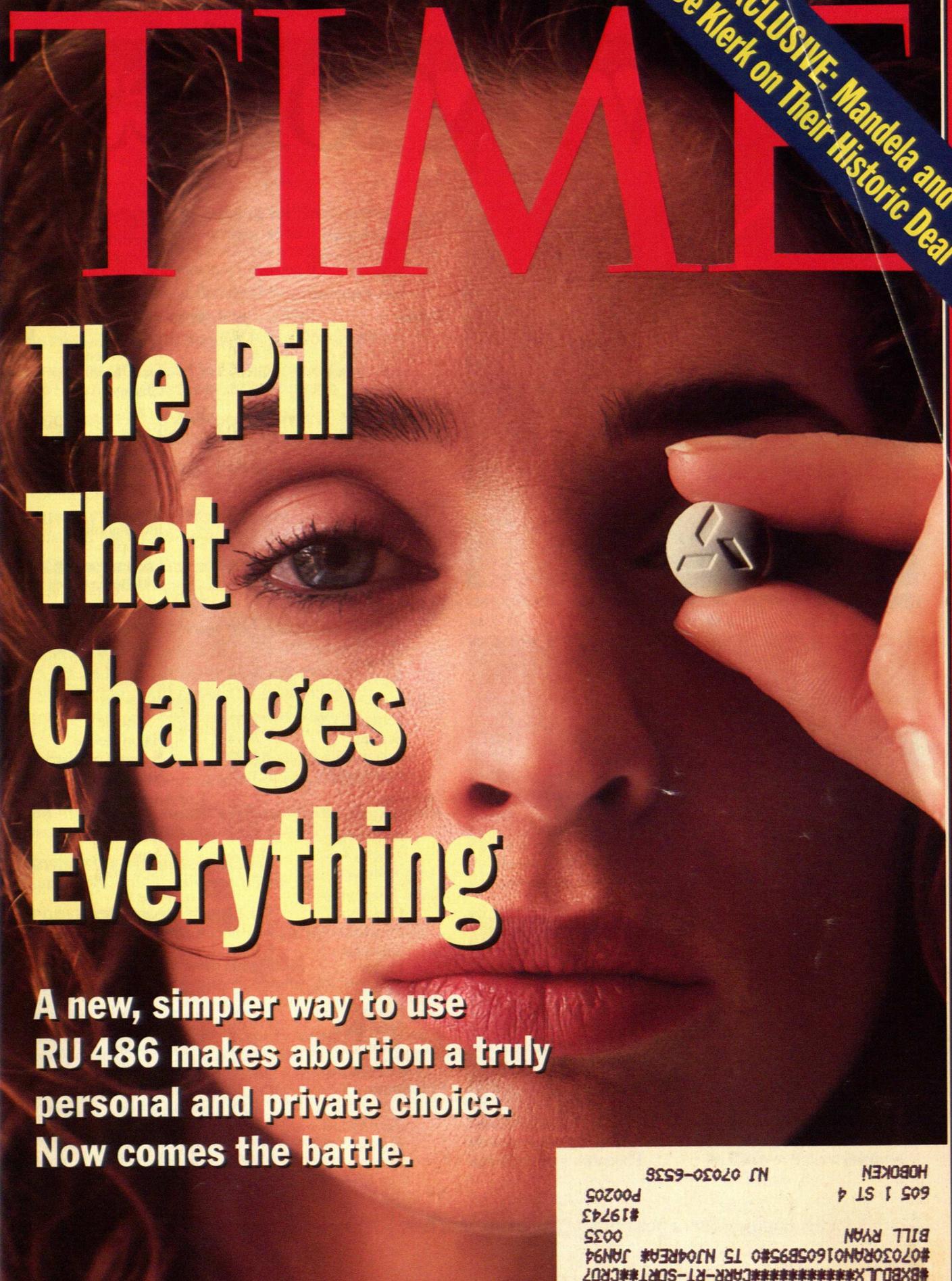


EXCLUSIVE: Mandela and De Klerk on Their Historic Deal



TIME

The Pill That Changes Everything

A new, simpler way to use RU 486 makes abortion a truly personal and private choice. Now comes the battle.

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PUBLISHER'S LETTER 4
LETTERS 6
THE WEEK 11
MILESTONES 21

22 THE WHITE HOUSE: Searching for the Center
 In a calamitous week, Clinton lurches toward middle ground, but his own confusion about his Administration's course and a chaotic staff contribute to one more episode of Amateur Hour

25 Lani Guinier: The views that drew fire
26 David Gergen: Sharing the boss's habits
27 The Political Interest: Another Blown Opportunity

29 APPOINTMENTS: And in Firing Range . . .
 Sheldon Hackney may be the next Lani Guinier

30 THE CABINET: Can Bentsen Deliver?
 Clinton needs him to round up the Senate's votes

31 TEXAS: Hasta la Vista, Bobby
 A G.O.P. candidate wins Bentsen's Senate seat

34 SOUTH AFRICA: A Nation Reborn
 Elections next April promise to end 300 years of white rule

42 THE BALKANS: A War of Many Battlefields
 A TIME photographer focuses on death in one Muslim village

48 COVER: Here Comes the Abortion Pill
 U.S. testing of France's RU 486 will begin soon, and a breakthrough that eliminates follow-up shots will make the drug easier to use. Will it end the abortion debate?

57 MEDICINE: Death on the Reservation
 A mysterious illness has stricken the Navajo nation

60 CYBERTECH: Microsoft's Blueprint for the Future
 Billionaire Bill Gates takes aim at the paperless office

66 ADVENTURE: Mountain Mania
 Too many Americans are discovering the lure of the peaks

68 SPORT: A Clash of Titans
 Barkley and Jordan, earth and air, meet in the N.B.A. finals

69 CINEMA: Monsters with Real Bite
 Dinosaurs run brilliantly amuck in Spielberg's *Jurassic Park*

72 REVIEWS
CINEMA *Made in America* is a deft comedy. **MUSIC** Chris Isaak is again steeped in cowboy blues. **TELEVISION** Two men dying of AIDS film a searing account of their last days. **BOOKS** *Lenin's Tomb* is a superb account of the fall of the U.S.S.R. **THEATER** *Later Life* shows A.R. Gurney at his wistful best.

77 SPECTATOR: Is the Future Too Cool?
 The digital superhighway may lead to boredom.

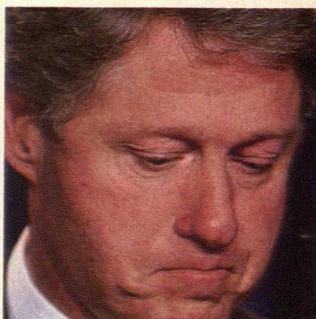
PEOPLE 79
ESSAY 80

Cover: Photograph for TIME by Gregory Heisler



GERARD UFFERAS—AGENCE VU

COVER STORY: Does Mifegyne (RU 486) make abortion too easy?



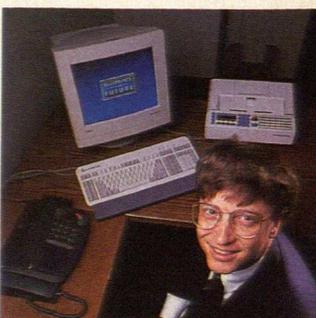
DIRCK HALSTEAD FOR TIME

DOWNCAST: Clinton
 announcing the latest snafu



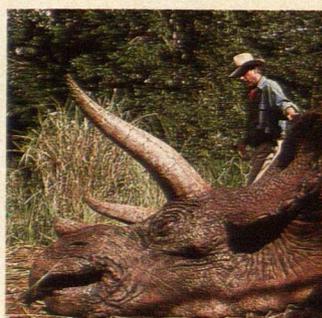
LOUISE GUBB—J.B. PICTURES FOR TIME

SOUTH AFRICA: Mandela sees
 Soweto school through bars



MATTHEW MCVAY—SABA FOR TIME

BUSINESS: Bill Gates wants to
 automate your office



MURRAY CLOSE—UNIVERSAL

CINEMA: Jurassic Park is a
 Museum of Natural Fantasy

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NEW, IMPROVED AND READY FOR BATTLE

THE ABORTION PILL is finally coming to the U.S., and a breakthrough that eliminates the follow-up shots will make it simpler to use

By JILL SMOLOWE

ABORTION IS NEVER EASY. THERE IS the anguish of the decision, the invasive nature of the procedure, and sometimes an ugly confrontation with right-to-life forces lying in wait outside the clinic door. But imagine if abortion could be a truly private matter. Say, something as easy as visiting a doctor, getting a few pills, returning home to swallow them, then checking back a few days later to make sure that all went as planned.

Science and politics are now conspiring to make that scenario—scary to some, a godsend to others—a reality, one that could allow abortion to be a truly private decision, albeit still not an easy one. Doctors have reported on a pivotal breakthrough in the use of the controversial French abortion drug known as RU 486: a woman who takes the drug will no longer have to go to a clinic for a follow-up injection to induce contractions. Instead, the entire procedure will involve simply taking two sets of pills. Concurrently, President Clinton has firmly signaled a willingness to reconsider the policies of the Reagan and Bush Administrations, which barred RU 486 from the U.S.

The resulting social upheaval could transform one of the nation's most divisive political debates by making abortion far more difficult to regulate. And eventually it could mean abortions will become simpler, safer and more accessible not only throughout the U.S. but also around the world.

Dr. Etienne-Emile Baulieu, the inventor of RU 486, and his French colleagues describe the successful tests of the no-injection method in the *New England Journal of Medicine*. "This new regimen," they conclude, "is simpler and potentially allows greater privacy than any other abortion method." In a tough ac-

“This new regimen is simpler and potentially allows greater privacy than any other abortion method.”

—DR. ETIENNE-EMILE BAULIEU,
INVENTOR OF RU 486

companying editorial, the *Journal* brands efforts to block use of the drug in the U.S. a “disgrace.”

Those political barriers, however, are quickly crumbling. Two days after his Inauguration, President Clinton ordered his Administration to “promote the testing, licensing and manufacturing” of RU 486. Until then, the French manufacturer of the drug, Roussel Uclaf, and its German parent company, Hoechst AG, had steadfastly shied away from becoming involved in the American market for fear of infuriating antiabortion activists. But in April, at the instigation of the U.S. Food and Drug Administration, Roussel announced a compromise: it agreed to license RU 486 to the U.S. Population Council, a nonprofit organization based in New York City, which in turn would run clinical tests.

As a result, the abortion pill could become available through a testing program later this year. The Oregon and New Hampshire legislatures have already volunteered their states as test sites, and the FDA is enthusiastic. Says commissioner David Kessler: “If there is a safe and effective medical alternative to a surgical procedure, then we believe it should be available in this country.” Although testing a new drug generally takes seven to 10 years, RU 486 has been so widely used in France that U.S. approval could come in as little as two to three years. In the meantime, the testing will enable at least 2,000 women to use the pill.

“When they invent new ways to kill children, we will invent new ways to save them.”

—THE REV. KEITH TUCCI,
OPERATION RESCUE NATIONAL

“We will not allow anti-choice zealots to deny RU 486 to American women,” vows Pamela Maraldo, president of the Planned Parenthood Federation of America. The pro-life forces are no less determined. “When they invent new ways to kill children, we will invent new ways to save them,” warns the Rev. Keith Tucci of Operation Rescue National. A coalition of antiabortion forces has

scheduled a demonstration in front of the French embassy in Washington on June 18, just three days before Roussel Uclaf holds its annual meeting in Paris.

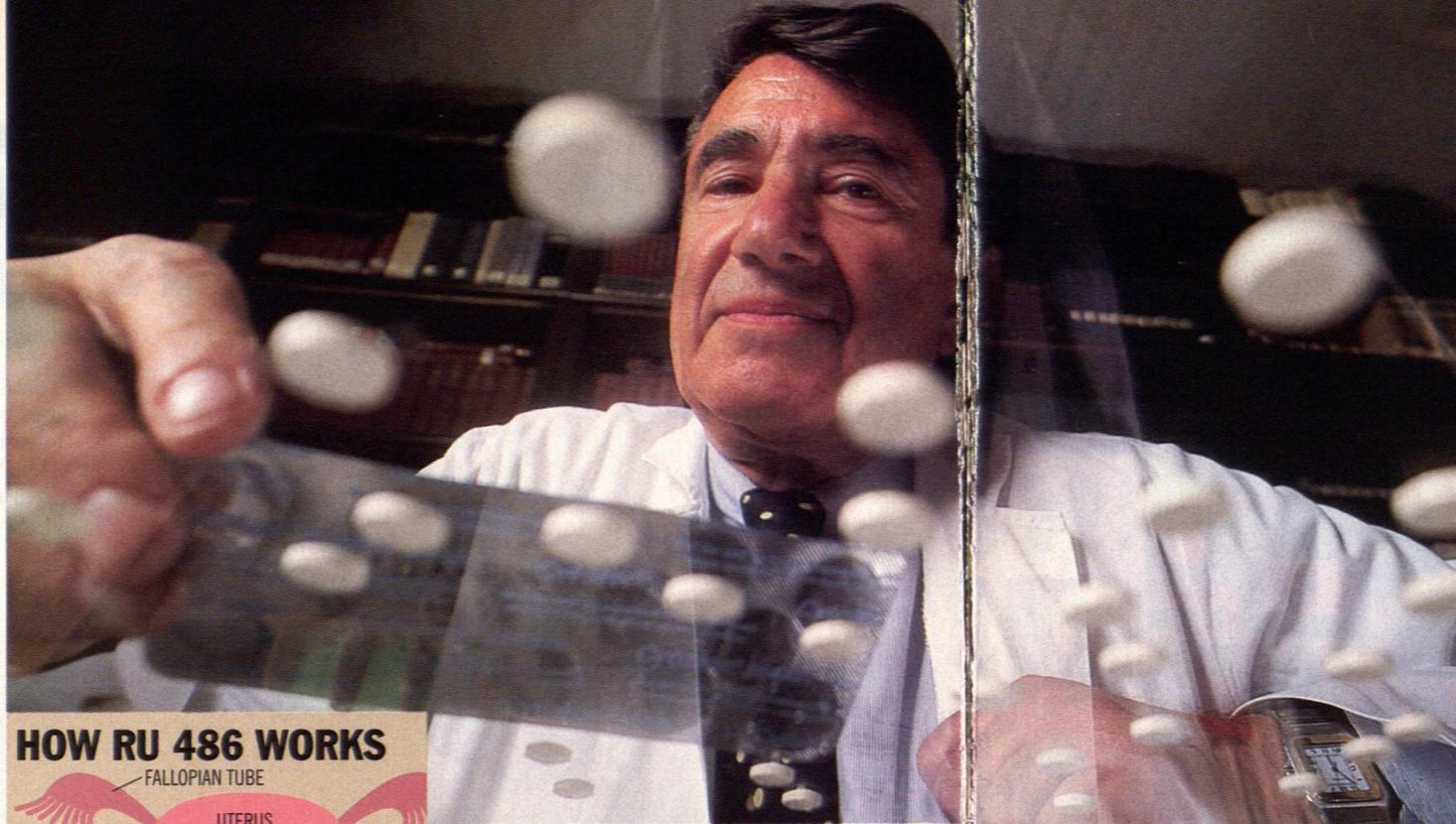
THE ABORTION DRUG HAS BEEN A source of controversy ever since its invention was announced in 1982 by Baulieu, a French physician who worked as a researcher at Roussel Uclaf. The concept was rather simple: RU 486, an antiprogestin, could break a fertilized egg's bond to the uterine wall and thus induce a miscarriage. An injection two days later of prostaglandin, a hormone-like substance, would force uterine contractions and speed the ejection of the embryo. It took six more years and tests on more than 17,000 women before the French government announced that RU 486 would be made available for public use.

The news spawned furious reaction in the press, an outpouring of outraged letters from Roman Catholic doctors, and a church-sponsored protest through the streets of Paris. A month later, a shaken Roussel Uclaf yanked the drug from the market, saying the company did not want to engage in a "moral debate."

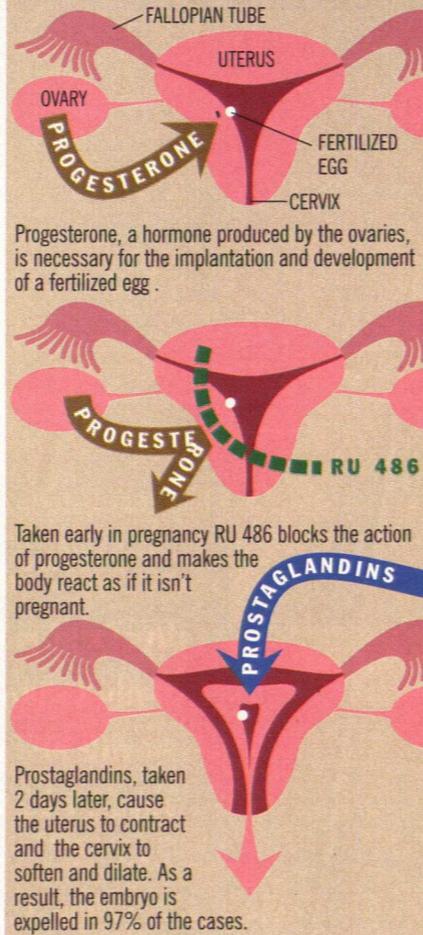
Doctors around the world certainly did. Thousands of physicians had convened that month at a medical congress in Rio de Janeiro, and most of them signed a petition demanding that the French government reverse Roussel's decision. Within 48 hours, Health Minister Claude Evin declared that once government approval had been granted, "RU 486 became the moral property of women," and he ordered Roussel to resume distribution. In 1989 RU 486 was made available to all licensed abortion clinics and hospitals in France. The results proved encouraging, save for a freak incident in 1991 when a woman who was an avid smoker suffered a heart attack while trying to use RU 486 to abort her 13th pregnancy. After that mishap, the government banned use of the pill by heavy smokers and women age 35 and older, who have a greater than usual risk of complications.

Using RU 486 was less painful, carried less risk of infection and gave women greater control over the process than a surgical procedure. Over the next 3½ years, 100,000 Frenchwomen used it successfully. Of those who made the decision early enough, about 85% chose RU 486 over surgery. (The pill is currently used in France only within seven weeks of the first day of a woman's last menstrual period; there is now talk of extending usage to a 10-week interval.) Almost all judged the method satisfactory.

Such promising results persuaded both Sweden and Britain to license RU 486; India is testing the drug. China is manufacturing clones that as yet are not widely available. Other countries, most



HOW RU 486 WORKS



Progestosterone, a hormone produced by the ovaries, is necessary for the implantation and development of a fertilized egg.

Taken early in pregnancy RU 486 blocks the action of progesterone and makes the body react as if it isn't pregnant.

Prostaglandins, taken 2 days later, cause the uterus to contract and the cervix to soften and dilate. As a result, the embryo is expelled in 97% of the cases.

notably Canada, are waiting for the U.S. to take the lead. "The U.S. is the leader in advanced research, the main source of development funds and the heart of worldwide networks that can allow RU 486 to help women everywhere," explains Baulieu.

In 1991 the French began testing the new method of using RU 486 that does not

THE INVENTOR: Baulieu hopes his pill can help women avoid ugly confrontations with protesters

require going to a clinic for a follow-up shot. An oral prostaglandin, commercially marketed as Cytotec by the American manufacturer G.D. Searle, enabled women to abort simply by swallowing a combination of pills. The efficiency rate rose from 95.5% to 96.9%, and the speed of the procedure improved. In 61% of the cases, the uterine contents were expelled within four hours after taking Cytotec, in contrast to 47% in the case of prostaglandin injections. Although there were instances of nausea and diarrhea, which are also common side effects with injections, those who took the pills reported considerably less pain. "Women tolerate it much better," says Dr. Elisabeth Aubeny of the Broussais Hospital in Paris, a testing ground for RU 486 in 1984. For French taxpayers, who foot 80% of the bill for each abortion through their national health-care system, there is also an advantage: a dose of Cytotec costs only 72¢, vs. \$22 for the prostaglandin shot.

Once again, controversy erupted. When Baulieu first began experimenting with RU 486 in combination with an oral prostaglandin, Roussel balked. As a result, Baulieu had to persuade French public health officials to defray insurance costs. After preliminary trials, the government compelled Roussel to participate, arguing that the proposed testing of an oral prostaglandin was important for women. Although Searle raised no objections, its executives remain uncomfortable about

being linked to the abortion business. "Searle has never willingly made [Cytotec] available for use in abortion," a company official wrote in a letter to the *Wall Street Journal* in February. "It is not Searle's intention or desire to become embroiled in the abortion issue." Searle's reservations echo that of Hoechst president Wolfgang Hilger, who has been open about his ethical objections to RU 486.

The uses of RU 486 could extend well beyond dealing with some of the 37 million abortions carried out around the globe each year. European studies have shown that it is an effective morning-after pill, inducing less nausea or vomiting than other drugs used for the same purpose. There are also indications that RU 486 can combat endometriosis, a leading cause of female infertility, and fibroid tumors, a condition that often necessitates hysterectomy. Thus the same drug that can help some women end unwanted pregnancies may enable others to bear children. Assorted studies have found that RU 486 may also combat breast cancer and Cushing's syndrome, a life-threatening metabolic disorder.

Despite the many potential uses for RU 486 and its effectiveness as an abortion method, efforts to legalize it in the U.S. have met with repeated failure. Last year a pro-choice group called Abortion Rights Mobilization

decided to force a court challenge of the import ban imposed on RU 486 by the Bush Administration in 1989. The organization helped Leona Bente, a pregnant 29-year-old California social worker, fly to England, obtain a dose of RU 486, then try to bring it into the U.S. through New York City's Kennedy Airport. Customs officials seized the pills. The ensuing legal battle went up to the Supreme Court, which refused to order the government to return the pills. Bente subsequently had a surgical abortion.

The Clinton Administration has not yet revoked the ban, but its significance is minor. Because distribution of the pills is tightly controlled in Europe and they cannot easily be purchased and imported, the real issue is how quickly the Administration will encourage the manufacture and marketing of the drug in the U.S.

When the pill does become available in America, abortion will not be as easy as going to the doctor and taking some of the tablets home—at least not right away. In France, for instance, a woman is required to pay four visits over a three-week period to one of the country's 800 licensed clinics or hospitals. The first step is a gynecological exam. Doctors make sure the pregnancy is in its early stages, and a social worker or psychologist discusses with her the decision to abort. Then the woman is sent home for a weeklong "reflection" period.

When she returns, she is required to sign a government form requesting the abortion. She must also sign a Roussel form that confirms her understanding that a malformed fetus might result if she does not see the abortion through to completion. (As yet no defects have been found in the small number of babies born to women known to have taken RU 486.) At that point, the woman is given three aspirin-like RU 486 tablets, each containing 200 mg of the drug. After swallowing the pills, she again goes home.

Except in the rare instance where the RU 486 is enough to induce a quick abortion, the woman must take two 200-mg Cytotec pills within the next 48 hours. Because the timing is critical and doctors want to monitor the effects of this contraction-inducing drug, women are required to

return to the clinic. They are encouraged to remain for four hours, even if the expulsion happens earlier. Eight to 10 days later, they must pay a final visit for an exam to make sure no part of the egg remains.

Even with all these steps, the procedure seems blessedly simple to most women. "Taking a pill seems far less murderous and violent to the child than using a vacuum cleaner," says a 31-year-old woman who has had both types of abortion. "You feel so helpless when they put you to sleep and you know they're going to be using their tubes and knives on you." Some women, however, become traumatized by the thought of performing an abortion with their own hand. After her experience with RU 486, Joelle Mevel, 34, vows that if there is a next time, she will choose surgery. "I spent the whole time worrying that I would see the child in the basin, that I would be able to discern something human in the blood," she says. "I would rather have gone to sleep and awakened later knowing it was all over."

American abortion-rights advocates talk of boiling France's time-consuming RU 486 procedure down to just two visits to the doctor. It would be possible, though controversial, for the government to let RU 486 be administered in any doctor's office or possibly even by trained nurse practitioners. If that happened, many women could avoid running a gauntlet of protesters outside an abortion clinic. Still, it won't take all the anguish out of the procedure. "It's insulting to women to say that abortion now will be as easy as taking aspirins," says Baulieu. "It is always difficult, psychologically and physically, sometimes tragic."

—Reported by
J. Madeleine Nash/Chicago, Frederick Painton/Paris, Janice C. Simpson/New York and Tala Skari/Paris

TO THE BARRICADES: In Washington RU 486 advocates take their fight to the streets; at J.F.K. Airport, a bespectacled Bente begins her battle to bring the pill into the U.S.



ROBERT MAAS—SIPA



JEFFREY MARKOWITZ—SIPA



Will abortion clinics disappear?

They will be less busy, but not gone altogether. If women do not decide on abortion early in pregnancy, RU 486 is not an option. Planned Parenthood estimates that two-thirds of abortions will still be surgical procedures.

BUT WILL IT END THE ABORTION DEBATE?

Protesters will have a hard time finding targets, but they won't give up

By DAVID VAN BIEMA

TAKE AN ABORTION CLINIC. DRAW some protesters around it. Someone holding a sign with a fetus on it. Someone else, perhaps, holding a real fetus. Add the miracle drug: the protesters disappear. So do the signs, the fetus. Why? Because the clinic, too, is gone, replaced by the privacy of thousands of anonymous doctors' offices. That, say some, is the elementary physics of RU 486. Although the philosophical center of the abortion debate has always been the woman and what was going on in her womb, its public center was the doctor who performs abortions and what was going on in his clinic. RU 486, its adherents hope, will permit medicine to achieve

what politics has made problematic: allowing the issue of abortion to be a private matter between a woman and her doctor. "You can't stop a woman from visiting a doctor," a securities analyst who follows the drug industry told the *Wall Street Journal*. "It becomes a private transaction. And that's the end of the abortion battle." Congressman Ron Wyden of Oregon claims that once the drug arrives, "it will no longer be possible for these extremists to target centralized locations like clinics." Harvard law professor Laurence Tribe, grimly alluding to the murder earlier this year of an abortion doctor in Florida, says, "You won't know whom to kill. You won't know where to lie down." With the arrival of RU 486 in the U.S.—especially in a form that requires the woman merely to take pills rather than also get a shot—the vision of some pro-choice advocates, that the drug could abort the abortion debate, will be tested. Will antiabortion activists find ways to restrict the availability of the abortion pill?

And if not, will RU 486 really obviate the clinics and confound the picketers? Jerry Falwell sits in the chancellor's office of Liberty University, his school in Lynchburg, Virginia, and describes his abhorrence of RU 486. The host of the *Old Time Gospel Hour* on 200 television stations, he still has the contacts and much of the clout that he enjoyed in his Moral Majority days. He compares unprotesting acceptance of the new drug to the German churches' inaction during the Holocaust: "We can't make that mistake again," he says. "Morally we will have no recourse except to do whatever is available to us." Peg Yorkin sits in the high-tech Los Angeles office of the Feminist Majority Foundation, an organization she co-founded and into which she has poured \$10 million. Her worth has been estimated at up to \$100 million. The RU 486 "genie" is "out of the bottle," she says. To get it to American women, "we are prepared to do whatever we have to do." In the middle, until recently, was the

been filed, the agency will do its utmost to streamline the process. It was, after all, FDA chief David Kessler, a Bush holdover kept on by Clinton, who persuaded Rousset Uclaf to allow its drug to be reviewed for use in the U.S. market. And it is Kessler's aggressive advocacy—plus the relative impregnability of large agencies like the FDA to public pressure—that has convinced even so devoted a foe as Gary Bauer, an antiabortion leader and former Reagan policy czar, that "if the Administration is intent on bringing RU 486 into the country... they can do it." Not all Bauer's allies are so fatalistic, however. The American Life League has developed a six-point strategy for opposing the pills, including protest rallies, calls for government investigations and plans for deluging the FDA with mail. Pennsylvania Governor Robert Casey, perhaps the country's highest-profile pro-life Democrat, wonders if Kessler's enthusiasm for the new pills could backfire. "The U.S. government is guilty of a flagrant abuse of its authority" in this case, he says. "The FDA should not be an advocate for a drug that hasn't been tested here." He speculates that pro-lifers might use the alleged conflict of interest as the basis for a legal suit enjoining the drug's introduction until the FDA can prove its objectivity. On the state level, the right-to-life forces will no doubt fight for the same kind of regulations already used to limit surgical abortions: mandatory counseling, parental consent for minors and a required waiting period—maybe an extensive one, after the French model. Such regulations might help ease qualms about the pill among the people who make up the vast conflicted middle ground in the abortion

debate: those who support a woman's right to choose yet might worry that a pill could, in some cases, lead to choices that are too hasty or unreflective. In any case, the political debate will certainly make it more difficult to find an American company willing to distribute the drug. After the pill appeared in France, opponents sent 1.5 million critical postcards to Hoechst's U.S. subsidiary, Hoechst Celanese, and they will inevitably call a boycott against all products of any company that gets into the RU 486 business. And that's just the first volley. "Do you think the pharmaceutical corporate executive wants someone picketing in his neighborhood?" asks the Rev. Patrick Mahoney, spokesman for Operation Rescue. Aware of such potential problems, the pill's inventor, Dr. Etienne-Emile Baulieu, is leading his own effort to establish a non-profit foundation that would set up a new company both to manufacture and distribute RU 486 worldwide. Since the pill would be its only product, he says, the boycott threat would evaporate. The Population Council has expressed a willingness to discuss the plan with him. When the pill finds a maker, how will it reach the taker? Its proponents, especially those hoping to make the clinic protesters vanish, agree that France's tightly controlled distribution method was devised, as a *New England Journal of Medicine* editorial put it, "for political rather than scientific reasons." One common yet radical suggestion is that RU 486 and prostaglandin could be sold to women as prescription drugs and taken at home. "To even suggest that you could do that is ridiculous," protests Judie Brown, president of the American Life League. That sentiment finds some support even from Baulieu. He opposes distribution by prescription because of what he calls "the cousin syndrome"—the woman for whom the drug was prescribed might pass it on to a cousin or friend, who has not had a gynecological exam. In rare cases, that woman may be having un-

Will it be taken in the home?

Most pro-choice experts believe the RU 486 pills should be taken in the presence of a doctor so that their distribution can be controlled. Some feel the follow-up prostaglandin could be taken at home if a physician is on call.



CUSTOM MEDICAL STOCK



Will the pill be used all over the world?

The World Health Organization runs RU 486 studies in 12 countries, including China and India. Yet tough abortion laws in most developing nations (and some developed ones) make universal use unlikely.

detected problems, such as a tubal pregnancy, a potentially lethal complication

that the pills would not halt.

Baulieu does, however, believe the pill could be administered by gynecologists outside of a clinic environment. He supports the "two-visit" plan: the woman is examined, takes the first set of pills, goes home, takes the second two days later, and returns to the doctor to make sure the process has been completely effective. Advocates of this method make two assumptions about the woman: that she will have the emotional fortitude to go through an experience on her own, and that she will get to a hospital if she becomes one of the rare cases where there is excess bleeding or other complications. Lynne Randall, director of an Atlanta abortion clinic that has volunteered to be an RU 486 test site, sees no long-term obstacle: "The supervision would be a doctor's saying, 'I'm on call. If you get bad cramps, call me and I'll meet you in my office or at the hospital.'"

Randall and other would-be pioneers are also making a scientific assumption: that if a woman takes the first set of pills but neglects the second, and her pregnancy comes to term, the child will be normal. For years RU 486 opponents have warned of Thalidomide-like tragedies, "the absence of hands, a foot grown out of a knee," as one spokesman put it. Baulieu and other informed advocates argue that this is chemically impossible; that in the handful of known cases where RU 486 did

not stop pregnancy, the children born were all healthy.

If the process could be as simple as Baulieu and Randall suggest, private physicians, who have shunted off the majority of abortions on clinics, might be willing to perform them again. "I think a lot more private physicians would quietly give RU 486 in their practices," says Susan Hill, head of the National Women's Health Network. "It wouldn't happen overnight, but if they felt it was safe and they weren't going to be protested every day, I think they would start offering it to their patients. . . . It's a lot easier to protest 400 clinics than 10,000 doctors."

Not so, says Joseph Scheidler, author of *Closed: 99 Ways to Stop Abortion*. "We will probably know which physicians are dispensing it," he warns. "We'll send in women to ask for RU 486. . . . There will be doctors who will not deal with it." For those who do, "we'll go to their homes, to their offices, to their hospitals." Bonnie Quirke, president of the Illinois Right to Life Federation, promises "a massive educational effort with physicians and pharmacists."

The two to three years needed for testing and approval of RU 486 could delay its debut until the middle of the next presidential-election campaign. And as Jerry Fal-

well is happy to conjecture, "I think RU 486 will be a major issue in the campaign if it is not yet distributed." His goal, he says, will be to elect a leader "with different morals than the President." The lifers will talk about death that hides in the palm of a hand; the choicers about empowerment a woman can hold between two fingers. Al-

though the advent of RU 486 could greatly change the nature of the abortion debate, it is unlikely to make it go away. —Reported by Adam Biegel/Atlanta, Julie Johnson/Washington, Frederick Painton/Paris and Janice C. Simpson/New York

How will the pro-lifers protest the pill?

They will stage demonstrations this month and boycott any company that agrees to produce RU 486 in the U.S. They may take legal action against the FDA and, eventually, try to "target" doctors who administer the pill.

