BY KATRIN BRIDGET SNOW

THE BANNING OF RU-486

At the rim of America's abortion debate hovers the French abortion pill, distant and potent, access to the drug controlled by a combination of government regulation, stormy abortion politics, and rigid company policy.

The federal Food and Drug Administration classifies the pill known as RU-486 as an inherently dangerous drug, and in 1989 issued an import alert that bars Americans from bringing it into the country for medical use. Oregon Congressman Ron Wyden (Democrat) held hearings last November on the FDA import alert and, contending it was motivated by politics and not health concerns, has introduced legislation to reverse it.

Pro-life leaders fear its use will increase the number of abortions, and have publicly threatened a boycott if Roussel-Uclaf, the French company with the patent, brings it to America.

Pro-choice advocates look to RU-486 as a less expensive, less invasive alternative for women, as safe as a surgical abortion. More safe in developing countries, where poor conditions drive the estimated number of deaths worldwide from surgical abortions to 200,000 annually.

Medical researchers say abortion politics is obstructing medical advances on other diseases where RU-486 shows promise. In studies conducted through the National Cancer Institute, the National Institutes for Health and other institutions, evidence mounts that RU-486 may offer treatment for breastcancer, which kills 44,000 American women annually; the inoperable stage of a brain cancer called meningioma; and endometriosis, which causes infertility in women. The California Medical Association and the American Medical Association have passed resolutions supporting the legal availability and testing of the drug.

New Hampshire passed a resolution recently offering itself as a test state for abortion research. Legislatures in Minnesota, New York, California and Vermont are developing or have passed legislation supporting the drug. The Nation magazine reports that organizations in California are looking at testing and distributing the pill within state borders under a "mini-FDA" law.

The abortion pill met with no less resistance in France in 1988, when Roussel-Uclaf withdrew it after only one month, citing intense international pressure from anti-abortion groups.

The French government ordered Roussel to put the drug back on the market, saying that "From the moment governmental approval for the drug was granted, RU-486 became the moral property of women."

RU-486 is an anti-hormone that blocks the normal activity of progesterone, the hormone that causes the uterine lining to thicken and retain a fertilized egg. The body has progesterone receptors in only a few areas, suggesting to early researchers that a hormonal drug that could control fertility by targeting progesterone receptors might have few effects on the rest of the body.

Clinical trials in France achieved a ninety-six percent success rate using RU-486 with a synthetic hormone that causes uterine contractions, called prostaglandin. It is effective only in the early weeks of pregnancy, and the French government does not allow its use after the seventh week.

Because of one recent death, a woman who was a heavy smoker and took RU-486 when she was also taking medication that can cause cardiovascular disorders, the French government has banned heavy smokers and women over thirty-five from using the drug.

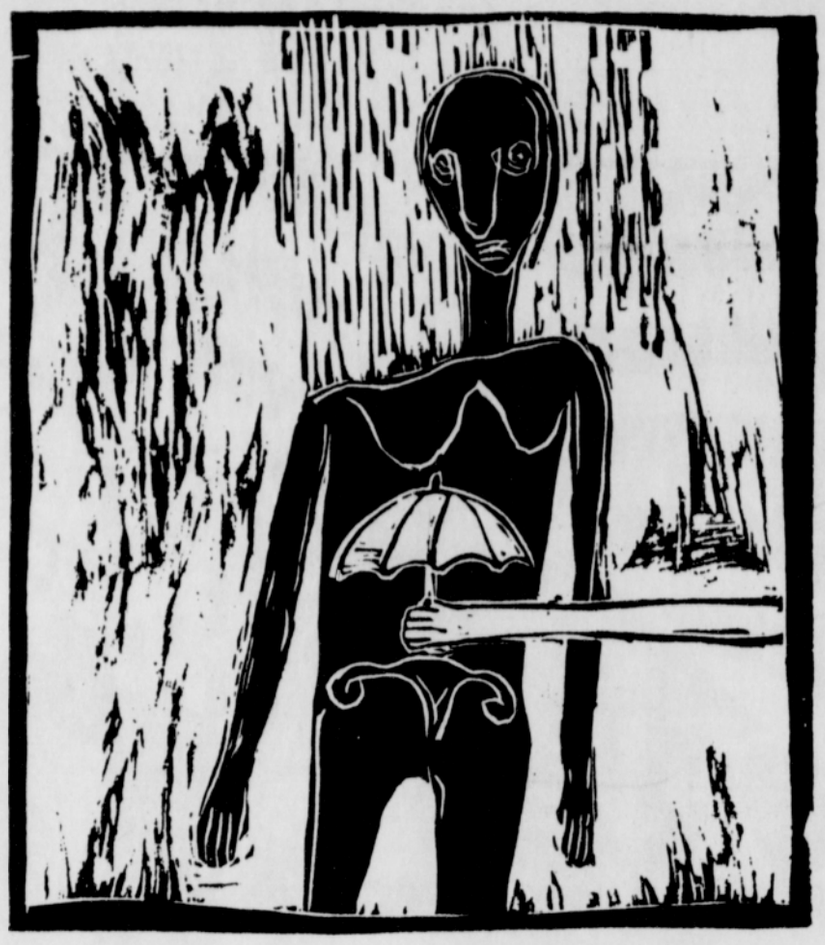
The drug is now available only to French citizens, although Roussel, responding to a request from the British government, will begin marketing it there next year. China has reportedly developed its own version of the pill.

Investigators working through the University of Southern California recently completed the only clinical trials in this country of RU-486 as an abortifacient. Funded by the Population Council, the six-year study of 400 women achieved a ninety percent success rate using RU-486 without prostaglandin.

"It replicated the findings in Europe, that the drug is safe, effective, and well liked," investigator Dr. David A. Grimes said, adding he has tried to continue the research, but can't get the drug.

Because of Congressional restrictions applied to the use of federal funds, abortifacient research cannot be supported by the National Institutes of Health, the Agency for International Development or the World Health Organization.

According to the Reproductive Health Technologies Project, a program pressing for testing of RU-486 for abortions in the U.S., Roussel has said it will not bring RU-486 into the U.S. for abortion use until there is a political consensus on abortion. "It's difficult for them to see consensus when the President is pro-life, the Attorney General is pro-life, and the FDA imposes a ban on personal import," associate Lucia Giudice said.



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"When we've asked (Roussel) what their intentions are in this country either regarding research or its use as an abortifacient, they said the U.S. is not in their strategic plans," said Steve Jennings, aide to Congressman Wyden.

As for other research, an FDA spokesperson says the agency is not stopping it, and that Roussel controls who gets the drug. Though Roussel has said it will supply RU-486 for legitimate research, researchers say the abortion controversy and the FDA import alert makes Roussel skittish about negative publicity. During Congressman Wyden's hearing on the FDA policy, researchers with two breast cancer studies testified that the research could not be done because the drug was not available to them.

Says Jennings, "It's all going to happen overseas. One of the real tragedies here is that the U.S. has checked out of a whole area of medical research.

"It is a very dangerous precedent when you have narrow-minded political groups commandeering drugs and holding them hostage from the broader public," Grimes said. "It is without precedent, and hence the more serious implications of this for society are far more compelling than the abortion aspect of this, which is a small question."

"That's just a flat-out distortion. We are opposed to its use as an abortificient, not to other medical uses," said Richard Glasow, Ph. D., education director for the National Right to Life Committee. "This is a definite strategy on the part of RU-486 proponents to turn this into a debate not only on abortion but also on other medical issues."

For Glasow, the RU-486 is no better choice. "The heart has started to beat," says Glasow. "The American public is not fully aware of the characteristics of unborn babies. That's the basic thrust of our educational effort."

That the drug can be used in the early weeks of pregnancy is one reason most proponents of testing think it will alter the abortion debate in the United States. "It's intuitive that the value of fetal life increases throughout the duration of the pregnancy," Frances Kissling, president of Catholics for A Free Choice, said. "The ability to make a decision to have an abortion very early in pregnancy will be of great relief to Catholic women who are concerned with the value of fetal life."

National Conference of Catholic Bishops spokesman Richard Doerflinger acknowledged early abortions are harder to fight, but said government should protect all human life. "It should not stop at the born, but should include life at its earliest."

The state's interest in protecting fetal life has always been central to abortion law. Attorney Michelle Oberman, director of research at the Institute for Health Law at Loyola University Law School, says RU-486 could alter the legal debate surrounding abortion because RU-486 aborts an embryo or pre-embryo, on which the law currently does not confer the legal status of a person. Moreover, legislatures are reluctant to do that, since current arguments about the legal status of a fetus turn largely on when it was viable, or could survive outside the womb.

"If the woman can use RU-486 as soon as she misses her period, unless we're willing to give the state an interest in the developing life that early," Oberman said, "RU-486 could make a lot of the abortion argument moot."

In other words, widespread use of a substance that allows abortion early in pregnancy, when the state does not claim an interest in the life in the womb, places the decision and the ethical struggle about whether to have an abortion squarely in the hands of the individual woman (and, for the use of RU-486, her physician). RU-486 seems to force the issue of a fundamental and societally unresolved question — who has the right of procreative choice — and this may be why RU-486 has generated such a storm of controversy. "People don't trust women as moral agents," Oberman said.

Kissling believes early abortions could deeply affect theological debate, noting that new treatments for infertility have challenged theologians to reexamine their understanding of the fertilized egg and embryo. For example, when a physician fertilizes several eggs in a petrie dish, and attempts to implant only the most successful one or two, how does theology view the other fertilized eggs?

"Once we deal with it in the arena of infertility, then the policies, and the theology and the science that is articulated relates to what is permissible in the case of abortion," Kissling said. "Once one accepts that a fetus, or early embryo, at that stage does not have the characteristics of a unique, individual human life, then perhaps an abortion that has the potential to act in the early days could be as acceptable as techniques used to treat infertility.

Mary Hunt, co-director of Women's Alliance for Theology, Ethics, and Ritual, notes that the context in which a pregnant woman must make a decision about abortion includes the biological stage of the fetus, the women's support network and economic situation, and what resources and services the broader society around her makes available to women and children. Hunt supports RU-486 as another option.

"There is something fundamentally wrong with society which from a purely business point of view keeps people from medical advances which are to a certain degree proven to be helpful, to be useful, to solve a problem at an earlier stage rather than a later stage, to be less invasive, to be economical rather than expensive."

Pope John Paul II has called on pharmacists not to sell abortifacients, and contracted a Spanish bioethicist to develop a position paper on RU-486, which appeared in "Origins" in May and blasted the drug's abortion uses. The Vatican is showing interest in the potential of other medical research to redeem the pill from its "bad reputation," and informal discussions on the drug are coming later between Archbishop Augustino Cacciavillan, apostolic pro-nuncio to the U.S. and a National Cancer Institute researcher.

Despite Roussel's reluctance to make RU-486 available in the United States, all sides take the abortion pill seriously.

"We are very concerned," Glasow said. "The proponents are looking at every possible avenue to bring it here. Even if they don't bring in this one there are other chemical abortifacients in the pipeline. We know this is a trend and we're fighting it as hard as we can."

"The New Hampshire resolution is evidence that it is politically unacceptable to keep a promising new drug out of the country simply because a small minority of people oppose it," said David J. Andrews, executive vice-president of Planned Parenthood Federation of America. "I'm confident that RU-486 or some other drug just like it is just around the corner."

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