Abortion pill maker shows reluctance to enter U.S. market

Whether or not the abortion pill RU-486 will ever be sold in the United States remains a mystery following the White House order to "re-evaluate" the pill's status with the FDA congressional aides and executives say.

As recently as last month, Paris-based pharmaceutical manufacturer Roussel-Uclaf showed no interest in entering the U.S. market, estimated to be worth anywhere from $22 million to $500 million annually. Anti-abortion groups have threatened to boycott Roussel and its other products, and some believe a fear of this backlash and bad publicity has made the French company reluctant to market the pill in the United States.

Roussel's lack of interest comes despite what amounted to an invitation in December from the FDA to apply for approval for sale of the pill here, and despite recent inquiries from several U.S. medical companies claiming to have the desire, the money, and the experience to market the drug successfully.

Even with that kind of fast-track approval, industry experts say it could be one to two years before the drug would be available to consumers.

"We've been getting mixed signals from Roussel," said Steve Jenning, staff director of the House subcommittee on regulation, business opportunities and energy, which has written the company on behalf of three U.S. companies eager to win the license to market RU-486.

"My opinion is that they are terrified of the right-to-life groups," said Warren Wood, chairman and chief executive of Cabot Medical Corp. of Langhorn, Pennsylvania, one of the companies that has told the subcommittee it wants to market the drug here. "I think they have decided they just don't need that kind of trouble."

Gynex of Vernon Hills, Illinois, and Adeza Biomedical of Sunnyvale, California, are the two other companies that have written to the subcommittee expressing their interest in the pill.

Wood said his contact with Roussel over several years has elicited nothing but a "don't call us, we'll call you" response.

During the past 10 years, the federal government gave the French company many signals that the pill wasn't welcome, and in 1989, the FDA put the pill on an import alert list of substances to be confiscated at the border no matter how small the quantity being imported. In a highly publicized case last summer, the government seized the drug from a pregnant California woman who tried to bring it into the country. She took her case to the Supreme Court, which refused to hear an appeal from a lower court upholding the Government policy.

Even with Clinton's decision to reevaluate the pill's placement on the FDA list, Wood and others said they aren't hopeful. They point out that there was no apparent change of attitude after a recent statement from the FDA that if Roussel did apply for approval, the agency probably would not require clinical trials here and would instead accept the results of trials in Europe. That would cut the estimated cost of winning FDA approval to $5 million from $150 million, Wood said.

Anti-abortion groups believe that the pill, because it has been marketed as a methold of abortion that is simpler than surgery, makes the decision to abort easier for women. But the multi-pill process, which has a reported 95 percent success rate in destroying developing children, still carries many risks (See sidebar.)

Jenning said that it has been unclear whether Roussel or its part-owner, Hoechst AG of Germany, was the more reluctant to enter the U.S. market.

Hoechst Celanese is a majority owner of drugmaker and marketer Hoechst-Roussel Pharmaceuticals Inc., also of Somerville. Roussel owns a minority stake in Hoechst-Roussel. Hoechst AG is the corporate heir of I.G. Farben, the firm which produced Zyklon-B, the chemical used by the Nazi regime to gas Jews.

Many executives have thought that Roussel would use Hoechst-Roussel to market and distribute RU-486 in the United States.

But Hoechst Celanese spokesman Andrea Stine said that Hoechst gave up its right to market the drug in the United States in 1989 because the Hoechst line of pharmaceuticals does not include contraceptives. "It's not a strategic area for us." Stine said.

If that is true, executives said, then to sell the abortion pill here Roussel would have to build its own marketing network, or, more likely, sell a license to an American company with an established distribution system. ■

"But of course it's safe Gentlemen, Miss Smith here has tested it herself."

French abortion pill easier?

RU-486, the French abortion pill, has been sold since 1990 in France, where its use is limited to authorized hospitals and clinics. Britain is the only other country to have legalized the pill.

Groups contend that since its use is simpler than surgery, it makes abortion a more attractive choice over child bearing.However, some women who have used RU-486 say the multipill process can be psychologically wrenching.

The abortafacient drug works by blocking the flow of the hormone progesterone, inducing uterine contractions and opening the cervix so the baby can be expelled "in a menstrual-like flow."

The most common side effect reported by drug industry profiteers is a "heavy cramping." Information provided by the drug company states that "some RU-486 abortions require a mild pain killer." However, buried in the literature are reports of prolonged hospitalization due to hemorraging, severe abdominal pain, and surgical abortion after failure to expel the baby.

Clinical administration requires that five pills be taken over a three-day period—three 200-milligram tablets of RU-486, then 36 to 48 hours later, two 200-milligram tablets of synthetic prostaglandin hormone that further stimulate contractions.

After the prostaglandin is taken, the child is expelled, usually several hours later at the hospital, or sometimes a day later at home.

More than 70,000 women in France have had abortions using the pill since large-scale testing started in 1986, according to Roussel-Uclaf, the company that makes RU-486. However, RU-486 can be used to kill a developing baby only in the first seven weeks after a missed menstrual period.

Women over 35 and heavy smokers are disqualified. Studies indicate that both of these factors contributed to a death that has occurred from using the pill with the use of the drug. One woman, a heavy smoker, died of a heart attack from the procedure. Two others had nonfatal heart attacks.

Roussel Uclaf claims that no further deaths have occurred since 1991. ■

Polish parliament votes on abortion bill

After three years of debate, the Sejm the Polish parliament approved a bill restricting abortions. The original draft was softened by the addition of seven amendments, including a requirement to introduce sex education in schools and to retain adult rights to contraception.

Proponents of a total ban on abortion supported the bill in its more liberal form. Opponents of criminalizing abortion decided that the amendments did not go far enough and finally voted against a "milder" law. "Everybody lost and nobody is really satisfied," commented Democratic Left Alliance (SLD) Deputy Ryszard Zechowski, who called the law "hybrid and grotesque."

The law does not allow for abortion because of social concerns. According to Izabela Sierakowska, another SLD deputy, Polish women who have abortions are frequently in difficult living conditions. "As you can see, the law avoids the most significant problem," Sierakowska says. The law also does not answer the question of social welfare benefits for the mother and child which, according to Democratic Union (UD) Deputy Joanna Starega Piasek, absolutely disqualifies it.

A deep and unexpected shift of opinion occurred among members of the Christian-National Union (ZchN). Almost all of its members voted for amendments which directly contradict the intent of the original draft, although the party had been the main sponsor of the original draft allowing abortion only when pregnancy was a threat to a woman's life.

"A bird in the hand is better than two in the bush," was how ZchN press spokesman Ryszard Czarnecki summed up the attitude of his fellow party members. The party officially admits that it is counting on its senators, who will try to return the law to its original shape. Voting for the "watered down" version was, according to Czarnecki, "an element of political strategy."

According to the legislative process, the bill must be debated by the Senate. The upper house may reject the Sejm's amendments and introduce its own, which, in the opinion of most deputies, will once again make the law more protective. That method was already used during the vote on the broadcasting law when a clause about respecting Christian values, rejected by the Sejm, was reinstated by the Senate.

By the narrowest of margins, the Senate on January 31 accepted without change the text of a bill restricting access to abortion in legislation that will require final approval by President Lech Walesa.

On Feb. 15, Walesa signed the bill which provides for penalties of as much as two years in prison for those aiding in an illegal abortion but refuses to penalize abortionists in cases of rape, incest or deformity. The 100-member Senate approved the bill 35-34, with 20 abstentions. It had been expected that the Senate would introduce many amendments making the law tougher, but these changes were rejected in an earlier 57-26 vote, with 7 abstentions. ■

Points of the Bill

Points of the Bill on Family Planning and Protection of the Unborn

Child-killing is allowed when pregnancy endangers the mother's life or health, when prenatal examinations show the baby to be seriously and irreversibly handicapped, or when the pregnancy is the result of rape or incest.

A doctor who performs an abortion because of social concerns may be imprisoned for up to two years.

Abortions may only be performed in state health care facilities.

The accidental death of an unborn child during a medical check is not punished.

A woman is not punished under any circumstances.

The minister of education is obliged to introduce a sex education program into the school curriculum.

Access to all means and methods of contraception, including abortafacients, is guaranteed.

Pre-amendment Version

Before it was amended, the bill on protection of the unborn included the following:

Killing the child was allowed only when the mother's life was at risk from a pregnancy.

In all other instances, both the doctor who committed the abortion and a woman who performed an abortion on herself faced prison terms of up to two years.

Harming a baby as a result of medical intervention (for instance during pre-natal tests) would have been punishable by up to two years' imprisonment.

The state was to be under obligation to provide for the mother and the unborn child (the range and types of aid were not specified.)

Sex education and contraception were not mentioned.

Rejected Amendments

During discussions, the Sejm rejected the following proposed amendments:

Conducting a referendum on the criminalization of abortion.

Allowing abortions because of the woman's social and economic situation.

Specifically determining the obligations of the state welfare system to pregnant women, such as benefit payments, insurance and special rights. ■

Woman faces death instead of abortion, stirs debate over Italy's laws

Rome, Italy—A woman's decision to refuse cancer treatments that might have harmed her baby has touched a nerve in a country with one of Europe's most liberal abortion laws and lowest birth rates.

The Vatican hailed Carla Ardenghi, who died eight hours after the baby's premature birth, for her decisions not to abort and to stop her cancer treatments. It said her sacrifice "gave meaning to all of our lives."

"Every day in my life is another day for the child I have inside," read an entry from the 28-year-old woman's diary, which has been released by her husband, Valerio, for publication by newspapers.

But some critics called her selfish for having the baby boy knowing that he and his 11-year-old brother would be without a mother. Pro-life advocates wryly wondered if abortion zealots wanted the 11-year-old "terminated" too. Abortion advocates said they will not let their opponents use the case to restrict Italy's abortion law.

Doctors removed a tumor from Ardenghi's uterus three years ago and warned her to avoid pregnancy. When she learned she was pregnant, doctors found the cancer had returned and had spread to her spine.

They told her that only an abortion would save her life, and urged chemotherapy or an operation. She refused treatment, and received only morphine for the pain until a week ago, La Repubblica newspaper said.

The 23-ounce baby, three months premature, was delivered by Caesarean section after his mother went into a coma. He is fighting to survive.

The case has been seized upon by Italy's anti-abortion lobby. As Italian media gave front-page treatment to Ardenghi's death and baby Stefano's fragile life, a legislator filed a bill to severely limit abortions.

Although Italy is overwhelmingly Roman Catholic, lawmakers in 1978 allowed abortions on demand through the 12th week of pregnancy. From the 13th to the 20th week, abortions are allowed if the mother's health is in danger or the baby is handicapped.

Italian voters supported the law by a 2-1 margin in a 1981 referendom.

But Socialist Premier Giuliano Amato, whose party supports the law, may be trying to prepare the ground for restrictions. He has said that only in "essential cases" should the "right to life" be dismissed.

The archbishop of Lecce, in southern Italy, called Ardenghi's decision a "heroic act" and likened her to Gianna Beretta Molla, who refused an abortion and died after giving birth in 1962. ■