RU 486

News Articles

October 11- October 22

2000

Groups Offer Abortion-Drug Variations

By Sarah Lueck
Staff Reporter of The Wall Street Journal

WASHINGTON—Even before the abortion drug Mifeprex is available in the U.S., abortion-rights groups are disseminating instructions for alternative ways to administer the drug that some say are simpler and less costly than the government-approved regimen.

The likely result will be an expansion of the ways women are given the drug commonly known as RU-486 and its companion drug misoprostol.

Under the standards, distributed by the National Abortion Federation and Planned Parenthood Federation of America, a woman wouldn't have to visit a doctor's office or clinic as many times as under the Food and Drug Administration approved regimen. The dosages of the drugs also are modified. The NAF also has advised its member clinics, doctors and hospitals about a variation that is effective for two weeks later in the pregnancy than under the FDA protocol.

Recent Data

The variations are based on data from recent studies that weren't part of the FDA review, the groups said. "We've just been looking at ways to make it a little more flexible," said Eric Schaff of the University of Rochester Medical Center, who has studied some of the new methods.

The medical community frequently adapts the way it administers approved drugs based on new studies and practical experience. The FDA doesn't usually interfere with the way the doctors practice medicine. But in this case, an FDA official says, "People should use the product according to the approved regimen."

If the manufacturer of Mifeprex, Danco Laboratories LLC, of New York, wants a change in dosage or the label, it would be required to submit new data for FDA review, the FDA official said. For its part, Danco is sticking to the FDA-approved regimen in its explanation on how to use the drug, said spokeswoman Heather O'Neill. However, the agreement that providers must sign to get the drug from the manufacturer doesn't appear to prohibit the variations.

Lower Dosage

Under the FDA regimen, a woman takes by mouth 600 milligrams of Mifeprex, which causes a miscarriage, in a doctor's office or clinic, then returns two days later to take 400 micrograms of misoprostol, which induces uterine contractions. Fourteen days later, the patient returns for a follow-up visit to determine whether the abortion occurred. The NAF and Planned Parenthood standards detail this regimen in addition to the variations.

But the NAF standards also tell providers they may lower the dose of Mifeprex to 200 milligrams, which reduces the number of pills to one from three and could make the procedure cheaper. Then, the NAF standards say, the misoprostol dose can be increased to 800 micrograms and inserted into the vagina two days later, which makes the method 95% effective through 63 days gestation, compared with 49 days under the FDA approved regimen.

The changes in dosage and insertion of misoprostol into the vagina are shown by research to make the method more effective, Dr. Schaff says. The follow-up examination can be done sooner than 14 days if the woman doesn't want to wait that long, the NAF standards say.

Some of NAF's members "will be adhering strictly to the FDA label," said Vicki Saporta, the group's executive director. "Many, I think, will be taking into account these other methods."

Planned Parenthood's standards also include the modified dosages and the option of home administration of misoprostol. If patients take the second drug at home, Planned Parenthood staff will counsel them by phone, President Gloria Feldt said. Planned Parenthood clinics will have to apply for waivers with the national office if they want to use one of the variations. In addition, the Planned Parenthood options don't include offering Mifeprex later in the pregnancy.

"We want to be on record with what our affiliates are going to do," Ms. Feldt said. "The easiest thing is to follow the FDA regimen exactly, but the other alternatives are going to be helpful for patients who have difficulty getting to a clinic."

Criticism Is Expected

In going beyond the FDA label for Mifeprex, the abortion-rights groups say they know they may invite more criticism from opponents of the drug. But, says Ms. Feldt, "Doctors are always figuring out different and better ways to use drugs."

Critics are watching closely. "To start improvising is a potentially dangerous adventure," said Bernard Nathanson, a professor at New York Medical College and a consultant to the American Life League, an antiabortion group. Rep. Tom Coburn (R., Okla.), an obstetrician and opponent of the drug, said he was worried the variations would increase side effects such as cramping and pain.

The drug is expected to be available next month.

FDA May Ban Drugs Of Bayer and Abbott Used to Treat Poultry

By a Wall Street Journal *Staff Reporter*

WASHINGTON—Federal regulators are taking a tough new look at the link between antibiotics given to farm animals and the increasing resistance of a number of human diseases to drugs.

The Food and Drug Administration this week plans to propose a ban on two antibiotics used to treat respiratory infections in poultry—Bayer Corp.'s Baytril and Abbott Laboratories' SaraFlox, both members of a drug class known as fluoroquinolones. The agency believes eating chickens and turkeys treated with these drugs has increased antibiotic resistance in humans, with the result of making common illnesses more difficult to treat.

The FDA is looking into how cattle given fluoroquinolones might be contributing to antibiotic resistance, said Stephen Sundlof, director of the FDA center that oversees animal drugs. The agency is working on a policy for classifying antibiotics used in animal drugs and expects to

October 13, 2000

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Chinese Factory Soon to Export Recently Approved Abortion Pills

By CRAIG S. SMITH

SHANGHAI, Oct. 12 — A Chinese factory near here will soon begin exporting to the United States RU-486, the abortion pill recently approved by the Food and Drug Administration, an official at the factory confirmed today.

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The Hualian Pharmaceutical Company, which owns the factory near the coast 25 miles south of Shanghai, has been making the drug since 1992 for use in the domestic market, where it is used to perform millions of abortions each year.

The state-owned company and its parent, the **Shanghai Pharmaceutical Group**, declined to comment on the plans, but a company official said privately that the factory had recently received F.D.A. approval to export the drug to the United States.

Because of strong opposition by anti-abortion activists, the F.D.A. has declined to identify the manufacturer that will supply the American market with the drug, which it approved for sale in the United States two weeks ago. But opponents of the drug reported weeks ago that the drug's United States distributor had contracted a Chinese factory to produce the RU-486 pills.

RU-486 has inflamed passions on both sides of the abortion debate for years, and the idea that it is manufactured in China, where the government policy of limiting families to one child is anathema to social conservatives in the United States, is only likely to add to these tensions.

Abortion opponents in the United States were quick to point out today that while the F.D.A. has kept the location of the RU-486 manufacturer a secret, the House of Representatives is investigating allegations that China has shipped tainted medicines to the United States.

"China will add death and destruction to its list of imports," Senator Tim Hutchinson, an Arkansas Republican who is an outspoken abortion opponent, said in a statement today. Accusing the F.D.A. of jeopardizing the health of American women, Mr. Hutchinson said, "It is telling that no U.S. firm would manufacture the drug and the F.D.A. had to look to the home of forced abortion and the notorious one-child policy to find a manufacturer for the U.S. market."

Another abortion opponent in the United States, Douglas Johnson of the National Right to Life Committee, complained that the F.D.A. could not possibly monitor a factory in China effectively. But an F.D.A. spokesman in Washington, declining to discuss the location of the factory, said it had received a thorough inspection.

The identification of the Hualian factory as the supplier of RU-486 pills to the U.S. market was first reported today in The Washington Post.

The pills, also known by the trade name Mifepristone, will be marketed in the United States by **Danco Laboratories**, a company set up by the nonprofit Population Council of New York. It was given the American rights to RU-486 from the French pharmaceutical manufacturer, **Roussel-Uclaf**, in 1995.

Danco Laboratories, which is based in New York, declined to confirm that Hualian is the supplier of RU-486, saying in a statement that its contract "prohibits us from discussing the identity or location of the manufacturer."

China already exports Mifepristone, which is manufactured by two other Chinese companies besides Hualian Pharmaceutical. **Beijing No. 3 Pharmaceutical Factory** exports the drug to India and Pakistan and other developing countries, according to Li Yong, a sales manager at the factory. And the **Zhejiang Xianju Pharmaceutical** Company, in Zhejiang province, lists the drug on its Web site among the pharmaceuticals it exports to Europe.

Mifepristone has become an integral part of China's one-child policy since the drug was introduced on a wide scale here in the early 1990's. Gao Ersheng, director of the Shanghai Planned Parenthood Research Institute, estimates that 10 million abortions are performed in China each year, and says about half of those that are performed in the cities use the abortion drug.

"Most unmarried women prefer Mifepristone, which is less painful and more private than surgical abortions," Mr. Gao said.

He said the drug, which now requires a prescription in China, might soon be available over the counter for use as an emergency contraceptive, or "morning after" pill. Mifepristone blocks the action of progesterone, a hormone necessary to sustain pregnancy.

But the drug is already widely available in unlicensed Chinese pharmacies, as is Misoprostol, a companion drug that forces the uterus to contract, expelling the dead embryo.

October 11, 2000

The Enduring Battle Over Choice

Forum
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The subject of reproductive rights has long been difficult terrain for politicians. Abortion is an intensely private question and a moral issue for many Americans, but the debate over reproductive rights is also about the broader cultural struggle over women's social and economic autonomy and the role of government in policing the most private sphere of American life.

So it is not surprising that though abortion rights have been constitutionally protected for a generation, the political and cultural battle over this issue rages undiminished 27 years after Roe v. Wade. As Vice President Al Gore said in his first debate with Gov. George W. Bush, the issue of abortion rights "is on the ballot in this election, make no mistake about it." It emerged as a point of difference in the vice-presidential debate and the one on Sunday between Hillary Rodham Clinton and Rick Lazio in the Senate race in New York, and is animating Congressional and state legislative races across the nation.

The fact is that in the nearly three decades since the Roe decision, a woman's right to choose abortion is becoming ever more fragile. In thousands of communities it is nonexistent. Years of violent attacks on medical clinics by anti-abortion protesters and increasing efforts by state legislatures to hinder abortion rights have taken an enormous toll. The number of abortion providers has dropped by 30 percent since 1982. Some 86 percent of counties in the country have no abortion services.

In 1992 the Supreme Court upheld the right to choose abortion, but gave states greater latitude to discourage the practice. Anti-abortion forces have since seized on the opportunity to impose waiting periods, mandatory counseling and requirements for parental notification and consent before abortions can be performed. In 1999 alone, state legislatures enacted more than 50 measures to restrict choice. Some 31 states have enacted bans on so- called partial birth abortions that could apply to even common abortion procedures at any stage of a pregnancy. Versions of that ban were ruled unconstitutional by a divided Supreme Court this year.

While states have increased attacks on abortion, it is the president, Congress and the Supreme Court that will ultimately determine the limits of reproductive freedom in this country. Twice in the past five years Congress has passed partial birth abortion bans, which were vetoed by President Clinton. Congress's hostility to reproductive

rights is evident in measures that barred American military hospitals overseas from providing abortions and made drastic cuts in international family planning aid. Anti-choice Republicans even now are fighting to bar international women's health groups from receiving American aid, even if they use their own money to lobby foreign governments on abortion policies.

The harshest limits on abortion have been imposed on poor women in this country. Under federal law, Medicaid and other federal health insurance programs may not pay for abortions except in cases of rape, incest or endangerment of a woman's life. Currently only 18 states use their own funds to pay for abortions for low-income women for health reasons.

The next president will determine whether a woman's ability to make this private decision will be strengthened or dismantled. For starters, he may well make two or more appointments to the Supreme Court that could result in a profound shift on privacy and abortion rights.

The two presidential candidates have starkly different positions. Mr. Gore, who early in his political career opposed federal funding for abortion, now supports federal funding and is resolutely pro-choice. Mr. Bush is pro-life, though he seems eager to avoid extended debate on this matter so as not to alienate moderate voters. Mr. Gore says he will appoint justices who will respect women's reproductive rights. Mr. Bush, who says he will not impose a pro-life litmus test on a Supreme Court nominee, cites Justices Antonin Scalia and Clarence Thomas as his models. Both justices believe the Roe decision was wrong and should be overturned.

The president's power in this arena is not limited to Supreme Court appointments. Veto threats by President Clinton have killed several measures in Congress to limit abortion rights, and his pro-choice stance has also helped to curb efforts to restrict access to contraception. Just last week a bill was introduced in the House to severely restrict the use of RU-486, the abortion pill recently approved by the Food and Drug Administration. Mr. Gore has said he fully supports the F.D.A. decision on the drug. Mr. Bush, however, has questioned the F.D.A.'s review process. Although he has said he cannot overturn the approval, he might have to decide whether to sign or veto a bill to deny vast numbers of women access to the drug.

The majority of Americans continue to support abortion rights, and for many that issue will be a key factor in their vote. This is a pivotal moment in the long struggle to allow women the right to make medical decisions about their own bodies. The next president's views will have much to do with whether reproductive freedom is protected here and promoted abroad.

What the FDA Should Learn From the RU-486 Marathon

By Diana Zuckerman
Sunday, October 22, 2000; Page B02

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The Food and Drug Administration did something truly surprising late last month: It made a cautious decision that put strong safeguards in place to protect the health of patients using a newly approved drug.

Unfortunately, that hasn't been the norm at the FDA lately. For years, Congress has gradually stepped up pressure on the agency, complaining that it blocked or delayed the sale of useful and profitable medications. In 1997, a new law directed the FDA to speed up the approval process, at the same time weakening the agency's resources and authority to protect consumers. Chastened, the FDA today approves more medical products and does so more quickly than ever before--but far too many of these drugs are approved before they have been adequately tested and scrutinized.

Last month, however, the FDA approved RU-486--mifepristone, the abortion pill--and its example has turned out to be instructive. The process of approving this controversial drug was agonizingly slow and obviously politicized, resembling a battle between warring ideologies more than a scientific review. But the outcome makes scientific sense and protects consumers.

In that way it reminds me of the kind of careful review and internal battles that once gave the FDA the reputation of a fierce watchdog--a reputation it earned when it kept thalidomide off the U.S. market 40 years ago, saving thousands of American babies from deformities.

Lately, the FDA has become more of a consumer adviser than a watchdog. FDA decisions have often saved lives; but the agency's efforts to please the companies that make drugs and medical devices--as well as Congress--have sometimes undermined its mission to protect consumers.

I have watched the FDA for years: first as a university researcher, later as an investigator for the House subcommittee that oversees the agency, and now as the head of a think tank that focuses on health issues. I have seen firsthand how often the FDA approves medical drugs and devices whose benefits are questionable compared to their risks--and claims that it has fulfilled its responsibility by pointing to the often-unintelligible warnings written in fine print on package inserts.

The few FDA watchdogs that are left share my concerns. For example, a report by the General Accounting Office early this year publicly stated what FDA insiders have admitted for years: The FDA lacks the ability to track problems caused by medical products once they are approved. That

track problems caused by medical products once they are approved. That means that drugs and devices continue to be sold long after dangers have become obvious.

The FDA is not supposed to make moral judgments. It is supposed to approve medications and devices solely in terms of how well they do what they promise, and what risks they pose to the people who take them.

By those standards, RU-486 should have been approved long ago: It had been safely used for years in France and other countries, and there was solid research evidence that it was effective at ending a pregnancy. Extensive data showed that it is at least as safe for pregnant women as the alternatives, which are surgical abortion or pregnancy and childbirth. And yet, while the abortion pill languished in FDA limbo, many more questionable products were quickly approved.

The reason was the intense ideological battle over abortion, and the fact that many members of the Republican congressional leadership--which has power over FDA funding and programs--are opposed to abortion. So the final FDA decision on RU-486 was a compromise: It approves the drug, but spells out very detailed rules for how it can be prescribed, by whom, and under what circumstances it can be used.

Under these rules, a woman must make three visits to the doctor or clinic. During the first, she must be examined to determine that she is no more than 49 days into her pregnancy; she must receive counseling and get a printed document with information on the drug; and she must sign an agreement saying that she understands the procedure and its potential risks. Then the doctor provides the mifepristone pill.

Two days later, she must return to the doctor to take the second drug in the abortion procedure, misoprostol (a drug previously approved by the FDA for other uses). Twelve days later, she must return to the doctor, who will confirm the end of the pregnancy or, if there are complications, arrange for her to see a surgeon.

Such restrictions are extremely rare. The FDA usually backs off from telling doctors what to do, saying it can only approve or reject medical products, not regulate how physicians use them.

For example, our think tank, as well as the National Women's Health Network and other health advocates, has repeatedly asked the agency to require that clearly worded informed consent forms be signed before patients receive long-acting contraceptives, breast implants and several other medical products, but the FDA has refused.

Patients will benefit from the RU-486 rules that require both the informed consent form and the patient information brochure be written by the FDA rather than the manufacturer. Instead of tiny print or unintelligible jargon, these materials clearly explain how the drug works, and describe possible side effects and warning signs of problems to watch for.

Abortion-rights advocates say this process will restrict the availability and affordability of RU-486. That's true. For example, doctors who cannot find surgeons to back them up will be unable to prescribe the

abortion pill. (Although the FDA lacks the resources to ensure that all doctors abide by the rules, doctors could certainly be vulnerable to lawsuits by any patient harmed when they do not.) But the process also protects women from potentially serious adverse reactions and thus provides safeguards for patients that we have not been able to obtain for other medical products that lack the politically supercharged atmosphere surrounding the abortion pill.

Three recent examples dramatically illustrate why such safeguards would benefit patients using other products.

Rezulin was approved by the FDA in 1997 to treat Type 2 diabetes only six months after its manufacturer submitted it for approval. That same year, Rezulin was taken off the market in England because it was linked to serious and sometimes fatal liver damage. The deaths due to liver damage of at least 61 Rezulin patients were reported before the agency finally concluded earlier this year that other available drugs were safer and just as effective. Even then, the FDA did not take Rezulin off the market: As is its usual practice, it requested that the manufacturer "voluntarily" withdraw the drug, which the manufacturer did in March.

Propulsid was a popular heartburn medication that was approved by the FDA in 1993. After more than 80 deaths from cardiac problems were linked to the drug in the United States, the FDA and the manufacturer announced in March that this drug also would be voluntarily removed from the market. Even then, the FDA allowed it to be sold for several more months.

Saline breast implants provide an especially dramatic comparison with the RU-486 process. Because they were first sold before the FDA was authorized to regulate medical devices, several hundred thousand women received such implants before the manufacturer was required to submit safety data and go through the approval process earlier this year. Saline implants were not widely used until a few years ago, but already more than 65,000 serious adverse reactions have been reported to the FDA. This is an amazingly high number of complaints.

Because of the highly publicized court settlements and multimillion-dollar public relations efforts of implant manufacturers, few medical products have been as controversial as breast implants. So, you might expect that the FDA would take extra care in reviewing the safety of the newly popular saline implants. You'd be wrong.

The FDA advisory panel considering approval was never given information about the 65,000 adverse reactions already reported. The FDA required no long-term safety data and made its decision without waiting for the not-yet-published results of long-term cancer and mortality studies conducted by the National Cancer Institute. Meanwhile, the manufacturers' studies reported extremely high complication rates within the first three years--affecting approximately three out of four mastectomy patients, for example. And yet, the FDA approved saline implants, with no restrictions on which doctors could use them under what circumstances and no requirements that patients receive clear warnings about risks in a consumer brochure or informed consent form.

How could this happen? The purpose of the approval process is

supposed to be to determine whether a product is safe. The FDA that I used to respect, and that consumers have counted on, had a dual mandate--to warn consumers of possible risks and to keep products off the market that were not proven safe. And the lack of proof that a product is deadly is not the same as proof that it is safe. That's why long-term research is important for products that may have long-term risks.

The FDA's review of RU-486 took too long and was much too influenced by political pressure. But the final decision showed that the FDA still knows how to think through the risks of a medical product, and put safeguards in place to protect patients while giving them an informed choice.

Women choosing RU-486 will be protected from most potential risks and will understand the choice they are making. But the rest of American consumers--like the patients harmed by Rezulin, Propulsid and implants--had better beware.

Diana Zuckerman is the director of the National Center for Policy Research for Women and Families, a Washington think tank.

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Medical Findings

Compiled from reports by the Associated Press
Wednesday, October 18, 2000; Page A34

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Study: Ease RU-486 Rules

The abortion pill can safely be given a week further along in pregnancy and with fewer doctors' visits than the U.S. government requires, a study suggests.

The RU-486 regimen approved last month by the Food and Drug Administration "is unnecessarily restrictive and creates scheduling and additional cost barriers to women," the study's authors wrote in today's Journal of the American Medical Association.

At least three physicians' visits, including a follow-up to make sure the abortion is complete, are required in the FDA-approved process.

In approving RU-486, the FDA said doctors must sign an agreement promising to adhere to the approved regimen and patients must sign a statement saying they will make the necessary doctors' visits. In addition, the Population Council, which owns U.S. rights to the drug mifepristone, agreed to check to make sure patients and physicians are signing the agreements.

The study found high success rates with only two visits, which would make the process cheaper and available to many more women. The study was funded in part by the advocacy group Abortion Rights Mobilization.

Under the FDA regimen, women use mifepristone, RU-486's chemical name, within 49 days of their last menstrual period. Mifepristone blocks the action of progesterone, which allows an embryo to develop. Two days later women return to their doctors to take a second medication, misoprostol, under observation. Misoprostol causes contractions that expel the embryo.

Both medications are taken orally in the FDA regimen, which previous studies have found to be between 92 and 95 percent effective.

The new study of 2,295 women, led by Eric A. Schaff, a professor at the University of Rochester Medical Center, found success rates of 96 to 98 percent. Mifepristone was taken up to 56 days after the last menstrual period, followed by vaginal misoprostol tablets at home one to three days later.

HIV-Infected Doctors

A leading health policy expert says the government should no longer compel HIV-infected physicians to tell patients about their disease, reopening a debate that raged a decade ago after Kimberly Bergalis got AIDS from her Florida dentist.

Lawrence Gostin of Georgetown University Law Center said the current rules "pose significant human rights burdens" and are not supported by recent data showing the risk of doctor-patient transmission is extremely low.

The guidelines are being evaluated under a routine review by the U.S. Centers for Disease Control and Prevention. Gostin's proposal was published in today's Journal of the American Medical Association.

Bergalis's death nine years ago prompted the CDC to adopt guidelines in 1991 that say HIV-infected health workers should reveal their disease to patients undergoing invasive procedures. Gostin was among the advisers who urged the CDC to adopt those guidelines.

Wednesday October 18, 12:59 pm Eastern Time

Pharmacia drug caught in US RU-486 abortion debate

By Lisa Richwine

WASHINGTON, Oct 18 (Reuters) - A drug that has been on the U.S. market since 1988 to prevent ulcers but also plays a role in drug-induced abortions has become entangled in the debate over the pill RU-486.

The drug, sold by Pharmacia Corp. (NYSE:PHA - news) unit Searle under the brand name Cytotec, causes uterine contractions. The Food and Drug Administration (FDA) requires U.S. doctors to give it to women two days following the use of the abortion-inducing RU-486 in order to expel the contents of the uterus.

Searle, however, never has sought approval for using Cytotec, known generically as misoprostol, as part of an abortion regimen and recently advised doctors not to give the drug to pregnant women.

The FDA, which on Sept. 28 approved RU-486 for ending early-term pregnancies, has called some of Searle's statements about its drug misleading. Plus, physicians say the company's efforts are restricting access to a drug needed not only to complete abortions but to induce labour safely and effectively.

``This is forcing us to be deprived of a very useful, effective and very inexpensive agent which we really have come to depend on," said Dr. Charles Lockwood, who chairs the American College of Obstetricians and Gynecologists (ACOG) committee on obstetrics practices.

Doctors can prescribe drugs for purposes other than their approved uses, and many choose Cytotec to induce labour or prepare a woman's cervix for delivery of a baby, Lockwood said. Other options are more expensive and do not work as well, meaning a woman could spend hours more in labour, Lockwood said.

But on Aug. 23, Searle sent a letter to 200,000 health care professionals warning that Cytotec should not be used by pregnant women because it could cause a miscarriage. The letter cited reports of complications such as maternal and foetal death and uterine ruptures in cases in which the drug was used for purposes other than ulcer prevention.

The letter also said Cytotec's effect on a child's development was unknown.

HOSPITALS PULLING DRUG

Many hospitals saw the letter and pulled Cytotec from their shelves over fears of potential legal liability, Lockwood said. He added that ACOG reviewed the FDA's records on Cytotec and found no new

information that would merit a fresh warning.

The group now is working to alert its 40,000 members that it believes Cytotec can be used safely for inducing labour if given in the right circumstances.

An FDA official who spoke on condition of anonymity said Pharmacia also made changes to the drug's label, the information directing physicians how to use the product, without agency approval.

``FDA believes some of those changes are inappropriate and misleading, and FDA has notified the company of the need to correct the labeling," the official said.

Despite the passion against abortion that frightened big drug makers from wanting to make RU-486, also known as mifepristone or Mifeprex, Pharmacia said it was not trying to distance itself from the abortion issue.

The company said it had suggested some unspecified label changes but still was in discussions with the FDA.

Cytotec always has come with a warning that it should not be used by pregnant women because it can cause a miscarriage. The August letter, which had been in the works for more than a year, was designed to remind doctors of that after the company received reports of serious side effects when the drug was used for purposes other than ulcer prevention, Pharmacia said.

At a U.S. congressional hearing Oct. 3, FDA Commissioner Jane Henney said the agency supported a new warning that women who wanted to remain pregnant should not be given Cytotec. But she said abortion was a ``different issue," and the agency was in discussions with the company about the matter.

Cytotec is a minor product for New Jersey-based Pharmacia. While it would not release specific sales figures, Pharmacia said Cytotec commanded only 0.4 percent of the market for ulcer drugs. Nonetheless, the company said it still plans to keep making the product.

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Wednesday October 18 10:55 AM ET

RU-486 Regimen Can Be More Flexible

NEW YORK (Reuters Health) - Women who take the abortion-inducing drug RU-486 (mifepristone) need to return to the doctor's office 2 days later to take a second drug, misoprostol. Now, results of a new study suggest that women can safely take misoprostol at home anywhere from 1 to 3 days after taking mifepristone.

Thus, the restrictions placed on the drug when it was recently approved by the US Food and Drug Administration (news - web sites) (FDA) may be unnecessarily strict, according to Dr. Eric A. Schaff, of the University of Rochester School of Medicine in New York, and associates. Their findings are published in the October 18th issue of The Journal of the American Medical Association (news - web sites).

The FDA requires that misoprostol--a drug that induces uterine contractions and expulsion of the fetus--be given in the doctor's office 2 days after mifepristone, and that women be observed for 4 hours before leaving--similar to the requirements in place in France. However, this practice limits treatment days to Monday through Wednesday, as most doctors' offices and clinics are not open on the weekend for the follow-up appointment.

In the new study, women vaginally administered misoprostol at home 1, 2 or 3 days after taking mifepristone, while the FDA-approved regimen includes an oral dose of misoprostol.

The study included 2,088 women from 16 sites in the US. All of the women were aged 18 or older and were no more than 56 days pregnant. The success rates of the treatments were 98%, 98%, and 96% for women who received misoprostol on day 1, day 2 and day 3, respectively.

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- Mifepristone Fact Sheet - information from Planned Parenthood. Also provided are a brief history of the drug and other analysis.

The only major difference between the three groups was the acceptability in terms of waiting time, according to the women. Only 76% of those in the day 3 group found the waiting time acceptable, compared with 86% in the day 1 group and 79% in the day 2 group. Otherwise, more than 90% in each group ``agreed or strongly agreed that the overall procedure was acceptable."

Based on these findings, Schaff's team concludes that "clinics that offer mifepristone administration only on Monday through Wednesday can now offer it Monday through Friday, even if they wish to observe patients taking both drugs and remain closed on weekends."

SOURCE: The Journal of the American Medical Association 2000;284:1948-

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- Population Council: Mifepristone FAQ - answers to frequently asked questions on early pregnancy termination with Mifepristone (RU-486) and Misoprostol.
- The RU-486 Files - news articles, web sites, and other resources.
- Food and Drug Administration (FDA) - home page.
- National Right to Life - anti-abortion organization. Site includes warnings on the risks and dangers of the pill RU 486.

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Tuesday October 17 4:41 PM ET

Study: Flexibility Possible with Post-RU-486 Drug

By Lisa Richwine

WASHINGTON (Reuters) - Women trying to end pregnancy with the recently approved abortion pill can have some flexibility in using the medication that normally follows RU-486, the author of a study released on Tuesday said.

The study of 2,295 women found the drug combination was 96 to 98 percent effective at ending pregnancy whether the second drug, misoprostol, was given one, two or three days after RU-486, the abortion drug U.S. health officials approved last month.

RU-486, also known as mifepristone, blocks a hormone needed to sustain pregnancy. It usually is followed by misoprostol, a drug approved for treating ulcers that causes contractions to expel the contents of the uterus.

The Food and Drug Administration (news - web sites) requires U.S. doctors who prescribe RU-486 to give misoprostol to women two days later, the regimen studied in clinical trials.

That schedule is ``unnecessarily restrictive,'' the study's lead author, Dr. Eric Schaff, wrote in Wednesday's edition of the Journal of the American Medical Association (news - web sites).

If the regimen was relaxed, women could take the drug in at home at a time most suited to them, Schaff said.

Lower Costs

Also, doctors whose clinics close on weekends could give mifepristone on a Thursday or Friday, and physicians could save patients from an extra office visit by distributing misoprostol during the first appointment, Schaff said.

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``This is not only more convenient to women but could reduce their costs by decreasing the number of required office visits," said Schaff, a professor at the University of Rochester Medical Center.

Side effects, including cramping and nausea, were similar no matter when misoprostol was given.

In the study, misoprostol was given vaginally, which increases the time the drug stays in the body compared to oral doses, Schaff said.

The study results also reflected earlier surveys that showed women preferred to administer misoprostol at home. Fewer than 1 percent of women opted to use it in a doctor's office.

The study was done at 16 primary care centers and abortion clinics between March 1998 and June 1999. Women were randomly placed in three groups, each of which was told to use misoprostol one, two or three days after mifepristone.

Pharmacia Corp. (NYSE:PHA - news) unit Searle sells misoprostol under the brand name Cytotec and recently warned that the drug is not approved for abortion. Physicians, however, are free to prescribe it for uses they consider appropriate.

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Tuesday October 17 7:18 PM ET

Study: Abortion Pill Rules Strict

By LINDSEY TANNER, AP Medical Writer

CHICAGO (AP) - The abortion pill can safely be given a week further along in pregnancy and with fewer doctors' visits than the U.S. government requires, suggests a study funded in part by an abortion rights advocacy group.

The RU-486 regimen approved last month by the Food and Drug Administration (news - web sites) ``is unnecessarily restrictive and creates scheduling and additional cost barriers to women,'' the study's authors wrote in Wednesday's Journal of the American Medical Association (news - web sites).

At least three doctors' visits, including a follow-up to make sure the abortion is complete, are required in the FDA-approved process.

In approving RU-486, the FDA said doctors must sign an agreement promising to adhere to the approved regimen and patients must sign a statement saying they will make the necessary doctors' visits.

In addition, the Population Council, which owns U.S. rights to mifepristone, agreed to check to make sure patients and doctors are signing the agreements.

Doctors who are caught not following the regimen could lose their supplies of the drug, according to the FDA.

The study found high success rates with only two visits, which would make the process cheaper and available to many more women. The study was funded in part by the advocacy group Abortion Rights Mobilization.

Under the FDA regimen, women use mifepristone, RU-486's chemical name, within 49 days of their last menstrual period. Mifepristone blocks the action of progesterone, which allows an embryo to develop. Two days later they return to their doctors to take a second medication, misoprostol, under observation. Misoprostol causes contractions that expel the embryo.

Both medications are taken orally in the FDA regimen, which previous studies have found to be between 92 percent and 95 percent effective.

The new study of 2,295 women, led by Dr. Eric A. Schaff, a New York abortion provider and professor at the University of Rochester Medical Center, found success rates of 96 percent to 98 percent. Mifepristone was taken up to 56 days after the last menstrual period, followed by vaginal misoprostol tablets at home one to three days later.

Thirteen unexpected or serious side effects occurred, including two hospitalizations, for pelvic infections. Other complications included four women treated for either excessive bleeding or vomiting and dehydration.

Spokeswoman Laura Echevarria of the National Right to Life Committee said allowing women to take misoprostol at home without a doctor present is ``playing Russian roulette with women's lives."

An FDA representative said the government-approved process is based on studies of safety and effectiveness in the United States and France. To consider changes, the FDA would probably seek more data and the Population Council would have to submit a request.

Dr. George Huggins, chairman of Planned Parenthood's national medical committee, said if Schaff's findings are confirmed in further research, ``my expectation would be that people would begin to change the protocol, because it does give more flexibility," better results and better control.

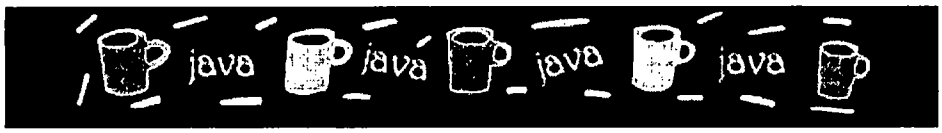
-

On the Net:

JAMA: http://jama.ama-assn.org

FDA: http://www.fda.gov/cder/drug/infopage/mifepristone

National Right to Life Committee: http://www.nrlc.org



Saturday October 14 9:49 AM ET

Reported Abortion Pill China Link Blasted in U.S.

By Lisa Richwine

WASHINGTON (Reuters) - Reports that a Chinese factory is the source of the RU-486 abortion pill that will be sold in the United States drew angry responses on Friday from critics who said it could put patients' health at risk.

The Washington Post identified the Hua Lian Pharmaceutical Co. factory in Shanghai on Thursday as the supplier of RU-486 to the U.S. market.

The U.S. Food and Drug Administration (news - web sites), citing concerns about possible anti-abortion violence, refused to disclose the maker since it approved RU-486, also known as mifepristone, on Sept. 28.

An FDA spokesman said on Friday the agency would not be commenting about where the drug is to be manufactured.

Privately held Danco Laboratories has U.S. marketing rights to the drug, which is scheduled to become available to doctors soon.

Abortion opponents said allowing a Chinese plant to make mifepristone would make it difficult for the FDA to monitor production. The agency

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has identified China as a source of substandard drug ingredients.

``It is a public health issue because China is a major source of impure drugs, and the FDA cannot possibly monitor a Chinese factory effectively," said Douglas Johnson, legislative director of the National Right to Life Committee.

But Sandra Waldman, a spokeswoman for The Population Council, the nonprofit group that applied for mifepristone's approval, said questions about the manufacturer were ``a phony issue."

She too declined to comment on the plant's location but said the FDA thoroughly scrutinized it just as the agency does all facilities that make U.S.-marketed drugs.

``There's no reason to believe the drug that comes out of there would not be a high quality drug," Waldman said.

It is not unusual for drug ingredients to come from overseas, Waldman added. About 80 percent of ingredients in drug products sold in the United States come from foreign firms.

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Friday October 13 3:05 PM ET

Foes Criticize RU-486 Manufacturer

By PAUL RECER, AP Science Writer

WASHINGTON (AP) - Abortion foes said that allowing a plant in China to make abortion pills for American women is an ``outrage'' that puts patients at risk, but a sponsor says the drug meets all the ``rigorous standards'' required by law.

Officials in China confirmed on Thursday that the Shanghai-based Hua Lian Pharmaceutical Co., will make the raw compound for RU-486, or mifepristone, an abortion drug approved last month for use in the United States.

The Food and Drug Administration (news - web sites) refused to identify the manufacturer when it approved mifepristone two weeks ago, saying it feared for the safety of the drug plant and its workers. The agency persisted in its refusal Thursday, even though family planning officials in Shanghai confirmed Hua Lian's role in the manufacture of the abortion drug.

Rep. Christopher Smith, R-NJ, a persistent abortion foe, denounced the arrangement in China, a country he has accused of committing crimes against humanity for requiring abortions as a population control measure.

``The company that produces baby poison for enforced abortion in China will now be producing it for American women,'' said Smith. ``The Chinese government will make money on the killing of unborn children in America. ... This is an outrage.''

The FDA still refuses to discuss the manufacturing arrangement for RU-486.

FDA Commissioner Jane Henney has cited anti-abortion violence for her decision to keep secret both the manufacturer and the names of FDA employees who scrutinized the drug. The FDA also increased security in some of its offices.

The Washington Post first revealed the name of the Chinese plant on Thursday, reporting that Hua Lian is one of two Chinese factories that make RU-486 for abortions in China.

China has a policy permitting urban couples to have only one child and uses compulsory abortion to enforce that quota.

Douglas Johnson, legislative director of the National Right to Life Committee, said that permitting the import of a Chinese-made abortion drug poses a health risk for American women.

``It is a public health issue because China is a major source of impure drugs, and the FDA cannot possibly monitor a Chinese factory effectively," Johnson said in a statement.

But the FDA spokesman said the agency thoroughly inspected the Hua Lian plant before mifepristone was approved. The plant will be re-inspected every two to four years to ensure quality.

``Foreign supply of drug ingredients is not at all unusual," said the spokesman. ``About 80 percent of the ingredients for American drugs are from foreign sources."

Hua Lian got help from the U.S.-based Rockefeller Foundation in winning the production license for RU-486 under FDA specifications, said Gao Ersheng, a research director at the Shanghai Family Planning Commission.

In July, FDA inspectors toured the Hua Lian plant, the Xin Lian factory on Shanghai's outskirts. A family planning commission technical expert, Zhu Huibin, said Xin Lian was now upgrading its production line.

RU-486 was first developed by the French manufacturer Roussel-Uclaf, but that company declined to make or distribute the drug in the United States. Instead, at the urging of the Clinton administration, U.S. rights to the drug were turned over to the Population Council of New York, a nonprofit organization that promotes reproductive research.

The Council awarded U.S. distribution rights to Danco Laboratories, a New York firm with an unlisted phone number and address. The Washington Post reported that Danco was formed in the Grand Cayman Islands in 1995. Danco is to market RU-486 under the brand name Mifeprex.

Sandra Waldman, a spokeswoman for the Population Council, said questions about the quality of the Chinese-made drug ``is a phony issue" because the drug has met ``all the vigorous standards" that FDA -approved products must meet.

``People should be assured that they are not getting shoddy merchandise," she said.

Waldman said the Council was still concerned about the safety of groups, including workers at the Chinese factory, who are involved in producing and distributing RU-486 in the U.S. The Council recently hired a guard for its New York offices.

No Danco official would talk with the Associated Press, but a statement faxed from the company said the plant that will make RU-486 for the U.S. market meets ``both Danco's drug specifications and the current good manufacturing practices of the FDA."

The statement said Danco had a contractual agreement that ``prohibits us from discussing the identity or location of the manufacturer."

Smith, the New Jersey congressman, said he fears patients who are injured by RU-486 will not be able to seek damages from the manufacturer because the plant is located in China.

``There is the dark motive of denying women injured by this dangerous chemical ... (a) real means of suing for recompense for their pain and suffering," Smith said.

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China Plant To Make RU-486 for U.S. (October 12)

Thursday October 12 8:15 AM ET

China Plant To Make RU-486 for U.S.

By CHARLES HUTZLER, Associated Press Writer

BEIJING (AP) - A leading Chinese pharmaceutical company that has made the abortion pill RU-486 for at least seven years will manufacture the drug for the U.S. market, officials said Thursday.

The China link adds to the controversy that has suffused RU-486's hotly contested entry to the United States. Anti-abortion campaigners who fought for eight years to keep the pill off the U.S. market have criticized China's widespread use of abortion, some of them forced, to limit family size.

The U.S. Food and Drug Administration (news - web sites) approved the pill two weeks ago for U.S. consumption, but did not disclose the manufacturer's identity and location because of safety and security concerns. The drug distributor in the United States, Danco Laboratories, has also refused to identify the company.

The Hua Lian Pharmaceutical Co., based in the eastern city of Shanghai, has been contracted to make the raw compound in RU-486, mifepristone, for export to the United States, company executives and Shanghai family planning officials said.

Hua Lian got help from the U.S.-based Rockefeller Foundation in winning the production license for RU-486 under FDA specifications, said Gao Ersheng, a research director at the Shanghai Family Planning Commission.

In July, FDA inspectors toured the Hua Lian plant, the Xin Lian factory on Shanghai's outskirts, said a plant manager, a Ms. Yang. Another family planning commission technical expert, Zhu Huibin, said Xin Lian was now upgrading its production line.

The Washington Post first reported in its Thursday edition that the China plant will manufacture the U.S. pill. Abortion opponents in the United States assailed the China connection, saying it undermined the FDA's stated reasons for secrecy over RU-486's production.

China began making mifepristone in 1993, Gao said, and Hua Lian is one of three Chinese companies producing the drug under different brand names. Founded in 1939 and nationalized after the communist revolution in 1949, Hua Lian is a leading company in a domestic industry often marked by shoddy production.

Of the estimated 10 million abortions performed annually, about half are done with abortion drugs, Gao said. Half of those, or about 2.5 million abortions, involve RU-486, he added.

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For nearly 25 years, China has limited most urban families to having one child and rural families to two. Reports of forced abortion and sterilization are common, although the government insists its policy does not approve those measures. Abortion drugs have played an increasingly important role.

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Thursday October 12 5:50 AM ET

Bush Would Sign RU-486 Restrictions

WINSTON-SALEM, N.C. (AP) - George W. Bush (news - web sites) supports legislation to tighten standards for doctors administering the newly approved abortion pill RU-486, a spokesman said Thursday.

Bush had been prepared to say he would sign such a bill, if elected, but wasn't asked at Tuesday night's presidential debate, said spokesman Scott McClellan.

A Republican-sponsored bill, filed last week in both the House and the Senate, would set up restrictions on how the drug could be dispensed.

It 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.

Bush ``would be inclined to support it. It provides certain reasonable protections for the safety of women," said McClellan.

Abortion rights groups have denounced the bill, saying it would impose restrictions that would hamper the ability of many doctors to prescribe the drug.

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.

In the first presidential debate, Bush said he was disappointed in the FDA 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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Thursday October 12 8:23 PM ET

Foes Criticize RU-486 Manufacture

By PAUL RECER, AP Science Writer

WASHINGTON (AP) - Abortion foes said that allowing a plant in China to make abortion pills for American women is an ``outrage'' that puts patients at risk, but a sponsor says the drug meets all the ``rigorous standards'' required by law.

Officials in China confirmed on Thursday that the Shanghai-based Hua Lian Pharmaceutical Co., will make the raw compound for RU-486, or mifepristone, an abortion drug approved last month for use in the United States.

The Food and Drug Administration (news - web sites) refused to identify the manufacturer when it approved mifepristone two weeks ago, saying it feared for the safety of the drug plant and its workers. The agency persisted in its refusal Thursday, even though family planning officials in Shanghai confirmed Hua Lian's role in the manufacture of the abortion drug.

Rep. Christopher Smith, R-NJ, a persistent abortion foe, denounced the arrangement in China, a country he has accused of committing crimes against humanity for requiring abortions as a population control measure.

``The company that produces baby poison for enforced abortion in China will now be producing it for American women,'' said Smith. ``The Chinese government will make money on the killing of unborn children in America. ... This is an outrage.''

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FDA Commissioner Jane Henney has cited anti-abortion violence for her decision to keep secret both the manufacturer and the names of FDA employees who scrutinized the drug. The FDA also increased security in some of its offices.

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China has a policy permitting urban couples to have only one child and uses compulsory abortion to enforce that quota.

Douglas Johnson, legislative director of the National Right to Life Committee, said that permitting the import of a Chinese-made abortion drug poses a health risk for American women.

``It is a public health issue because China is a major source of impure drugs, and the FDA cannot possibly monitor a Chinese factory effectively,'' Johnson said in a statement.

But the FDA spokesman said the agency thoroughly inspected the Hua Lian plant before mifepristone was approved. The plant will be re-inspected every two to four years to ensure quality.

``Foreign supply of drug ingredients is not at all unusual,'' said the spokesman. ``About 80 percent of the ingredients for American drugs are from foreign sources.''

Hua Lian got help from the U.S.-based Rockefeller Foundation in winning the production license for RU-486 under FDA specifications, said Gao Ersheng, a research director at the Shanghai Family Planning Commission.

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China Plant To Make RU-486 for U.S. (October 12)

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LA Times
Friday, October 20, 2000

RU-486 Firm Linked to Drug Impurities

Investigation: Chinese company that produces abortion pill for U.S. market was cited for violation of federal laws, House committee learns.

By AARON ZITNER, Times Staff Writer

WASHINGTON--The Chinese company producing the abortion pill RU-486 for the U.S. market has been cited by federal regulators for bringing mislabeled and impure drugs into the United States, according to congressional investigators.

This and other information, turned up by the House Commerce Committee staff, suggest that the long battle over bringing RU-486 to American women may not have ended last month when the Food and Drug Administration approved the drug for distribution. Critics of the abortion pill quickly cited the new information as evidence that the FDA did not conduct an adequate review and that Congress should force the agency to reconsider.

But supporters of the abortion pill said there is no evidence that the Chinese plant is not meeting FDA standards in producing the abortion pill, known formally as mifeprestone. The drug should reach U.S. doctors within a few weeks.

"As part of the approval process, the FDA had to review the manufacturing process and the manufacturer met the specifications of the FDA," said Heather O'Neill, a spokeswoman for Danco Laboratories, the New York firm marketing the drug in the United States.

Danco conducted a worldwide search for a manufacturer after large pharmaceutical companies said that they did not want to produce the drug, fearing lawsuits and boycotts from anti-abortion groups. After a deal with a Hungarian plant fell through, Danco signed a contract with the state-owned Shanghai Hua Lian Pharmaceutical Co. Ltd., according to people familiar with events.

According to FDA records cited by the House

investigators, a drug produced by Hua Lian was detained earlier this year by agency officials in Cincinnati because of false or misleading labeling. That drug, betamethasone sodium phosphate, is sometimes used in skin creams and asthma drugs.

Contamination Found in Herbal Remedy

Samples of another product, an herbal remedy called composite tegafuri capsules, were found to be tainted in a 1998 study by the California Department of Health Services. That study found high contamination in hundreds of similar products made at the same plant.

The tegafuri was made by the Shanghai No. 12 Pharmacy Factory, which is cited as the previous name for the Hua Lian factory on the company's Web site. The product was found to be contaminated with fluorouracil, which in some forms is a chemotherapy drug.

Rep. Thomas J. Bliley (R-Va.), chairman of the House Commerce Committee, wrote to the FDA on Wednesday asking whether the agency knew that the Chinese plant had previously run afoul of U.S. regulators and whether that information was considered during the approval process for the abortion pill.

Irregularity Noted in Plant's Documents

In his letter, Bliley also cited the report of an FDA official who inspected the Shanghai plant in October 1999 in connection with the agency's review of the pill. In that report, the FDA inspector said that the plant copied data from another application in filling out required paperwork, rather than using data from its own laboratory tests.

The plant passed a later FDA inspection in July. But in his letter to the FDA, Bliley asked whether the "discrepancies" during the first inspection suggested a wider "data integrity problem" at the plant.

The information turned up by Bliley's inspectors could become fodder for lawmakers who want to create hurdles for the abortion pill in Congress. Moreover, Texas Gov. George W. Bush, the Republican presidential nominee, has said that he opposes distribution of the abortion pill and, as president, might look for any new evidence that the FDA should revisit its decision on use of the drug. Vice President Al Gore, the Democratic nominee, supports

distribution of the drug, if it meets FDA standards.

Douglas Johnson of the National Right to Life Committee, an anti-abortion group, called it "appalling" that the FDA approved production of the drug "by a Chinese plant that has been cited for producing both contaminated and mislabeled drugs . . . and that falsified FDA documents."

"We conclude that the Clinton-Gore administration is willing to place American women in jeopardy in order to win short-term political points from pro-abortion special interest groups," Johnson said.

Clinton, Gore and the FDA all have said that the FDA made its decision based on the safety of the abortion pill, not on politics.

"As with all drugs the FDA approves, in the case of mifeprestone, the FDA thoroughly inspected its manufacturer and the facility passed," an FDA spokesman said. "It fully met the FDA's standards."