The FDA approved a drug that kills unborn babies. But babies aren’t its only casualty.
The problems began as soon as Brenda Vise returned home from the abortion center after taking mifepristone—known as RU-486, the abortion drug. The pelvic pain worsened, and her body temperature plummeted. These symptoms were “normal and routine,” the staff told her each time she called for help. For three days, as the pain grew unbearable, she was instructed this was “to be expected.”

When staff members finally said she should seek emergency care, they insisted she return to Knoxville, three hours from her home in Chattanooga. Medical people in her area would not know how to deal with complications from mifepristone, they said. Barely making it to her local hospital, Brenda lapsed into a coma, then died.

The clinic failed to diagnose that Brenda had an ectopic pregnancy. It caused her fallopian tube to burst, and she died of an internal hemorrhage. Mifepristone does nothing to treat this condition.

Brenda’s tragic death was not unforeseen. The Food and Drug Administration’s (FDA’s) unusual approval under a rarely used regulation acknowledged the dangers of mifepristone, which it approved in September 2000. But the agency suddenly dropped most of the requirements that would reduce the risks to women—after the Population Council, the abortion advocacy group that owns the U.S. patent for mifepristone, waged a political and media campaign to pressure the FDA. These safety requirements might have saved Brenda’s life.

To some, her death is an acceptable price to have abortion easily accessible.

**Freedom of Information**

Soon after the FDA approved mifepristone, Concerned Women for America (CWA) filed Freedom of Information requests to discover how the drug was approved. CWA recruited lawyers, doctors and researchers to sort through medical journals, regulatory law and FDA documents—documents that took the FDA more than a year to release. What was found stunned them all.

In a formal legal document known as a Citizen Petition submitted to the FDA, CWA, the American Association of Pro-Life Obstetricians and Gynecologists, and the Christian Medical Association describe the FDA’s numerous safety violations and request the agency to pull mifepristone from the market. The Citizen Petition shows that the FDA put women’s health and lives at risk to appease the abortion industry.

**Mainstreaming Abortion**

“The whole idea of mifepristone was to increase access,” said Dr. Eric Schaff, who ran clinical trials of mifepristone, told The New York Times in of June 8, 2000.

Abortion proponents view
mifepristone as the vehicle to make abortion acceptable. “One of my real, and I think realistic, hopes for this method,” stated Carolyn Westoff, an obstetrician/gynecologist, in the July 11, 1999, issue of The New York Times Magazine, “is that it will help get abortion back into the medical mainstream and out of this ghettoized place it’s been in.”

Polls showed that some doctors would be willing to do abortions if it came in the easy form of a pill. However, the safety of a drug depends not only on the ingredients, but how it is used—the regimen. If the mifepristone regimen entailed more than popping some pills, it would cut down on the number of providers willing to become chemical abortionists.

The regimen followed in Europe and in the U.S. trials of mifepristone had many elements, each necessary to protect the mother. They included:

- an ultrasound examination to determine the date (since the complication rate skyrocketed after seven weeks) and place (in uterus or fallopian tubes) of the pregnancy;
- that both drugs in the regimen be taken under a physician’s observation;
- that mifepristone be administered only by doctors who know how to perform a surgical abortion (to extract parts of the baby not expelled) and have admitting privileges at a hospital less than an hour from the facility;
- training for providers in how to use the drug and what complications to expect.

The Population Council did not oppose these requirements—that is, until the approval deadline approached.

**No Concern For Patients**

The FDA believed mifepristone should be limited to trained physicians. A memo stated: “FDA requests that the ability to perform vacuum aspirations and/or D&Cs be added to provider qualifications. Providers also need to have access to emergency services. The need for surgical intervention is predictable, unlike with other drugs. All OB/GYNs and other practitioners of women’s health have these skills.”

An FDA Advisory Committee recommended additional restrictions to ensure “that this drug not be expanded to hands of physicians who are not already skilled in managing pregnancies, terminations and complications of both.” However, the Population Council insisted that the drug was safe. The FDA objected several times, insisting that the Population Council present a protocol “that addresses safety concerns of
patients receiving the drug product.” Since the Population Council refused to do so, the FDA did it for them.

Politics Trump Science
In June 2000, the Population Council leaked the FDA’s requirements to pro-abortion groups and the media. A spokeswoman for Danco, the company created by the Population Council to market and distribute mifepristone, complained to The New York Times (June 8, 2000) that “the agency’s initial approach is more restrictive than we had envisioned.”

A firestorm of protest, from newspaper stories to letters from pro-abortion congressmen, came down on the FDA. So, the FDA set up a teleconference with the Population Council and Danco. “Meeting Objective,” an FDA memo states, “To discuss the misrepresentations by the Press regarding the proposed distribution system, and to agree on the need for serious, candid, and confidential discussions to resolve deficiencies of the application.”

But the restrictions cut at the heart of the Population Council’s objective: to expand abortion availability beyond those already doing surgical abortions. The Population Council actually argued that these requirements were counterproductive for patients.

Approval Granted
Reluctantly, the FDA gave in to the pressure and dropped many of the requirements. It even allowed anyone—no qualifications necessary—under the supervision of any physician to administer it. But it announced to the Population Council that mifepristone would be approved under a special procedure. This signaled its concern about the safety of mifepristone.

In the early 1990s, the FDA carved out an exception from its rigorous approval process for drugs that treat “a severe or life-threatening disease or illness” for which there is no safer treatment.

Called Subpart H, the “restricted distribution” section allows for less initial testing before a potent drug is released to the public—on the condition that the drug is restricted and will undergo studies of its effects, with the results submitted to the FDA. The FDA retains the right to withdraw its approval.

Subpart H has been used for drugs that treat cancer, AIDS, leprosy—and, inexplicably, for mifepristone.

The Population Council disagreed with this designation. “[I]t is clear that the imposition of Subpart H is unlawful, unnecessary and undesirable,” it responded. “Neither pregnancy nor unwanted pregnancy is an illness [nor] a ‘serious’ or ‘life-threatening’ situation as that term is

“A firestorm of protest, from newspaper stories to letters from pro-abortion congressmen, came down on the FDA.”
used in Subpart H.”

The Population Council worried that this designation would label the drug as dangerous. It demanded that the restrictions be hollow, and it got nearly all that it wanted.

**Tainted Trials**

The FDA relies on data from clinical trials to determine if a drug and its regimen are safe. Trials must meet rigid standards to ensure the results are unbiased and scientific. For mifepristone, the Population Council submitted data derived from two French clinical trials and one in the United States. None met the FDA’s standards.

Trial records from a “French government-supported abortion clinic” suggested fraud, evidence tampering, and under-reporting of serious complications. In a memo to the Population Council, the FDA expressed concern that “convulsions [were] reported as fainting,” and “expulsion” of a fetus was actually a surgical abortion performed after mifepristone apparently failed.

As for the women, almost 86 percent in one French trial and almost 93 percent in the other experienced at least one complication. Ninety-nine percent of U.S. patients suffered, most with multiple complications, and 23 percent experienced severe complications.

However, in a classic case of negligence, the FDA did not review the results of the U.S. trial. The statistical reviewer excused this failure by claiming the clinical results “were similar enough” to the European studies. The reviewer for the French studies said that, in the absence of valid trials, it was impossible to make a meaningful statistical review.

Surprisingly, one important test was never done. Called the Pediatric Rule, it requires that drugs that will be used on adolescents to first be tested on adolescents. When the FDA considered abolishing the Pediatric Rule last March, Sen. Hillary Clinton (D-New York) strenuously objected. Yet, for mifepristone, the FDA ignored this regulation—with no explanation—thus blatantly violating its own rule.

**Wanted: Approvals**

Alone, mifepristone is ineffective, resulting in incomplete abortions in about one-third of cases. It must be used with a second drug, misoprostol, taken two days later to expel the baby. But misoprostol’s distributor, Searle, opposes this use of its drug. One month before the FDA’s approval, Searle sent a letter to health care workers warning that misoprostol should not be used for abortion.

The FDA can endorse the use of a
Women may find it difficult to follow the FDA’s guidelines when abortionists tell them differently. Mifepristone providers openly defy the FDA’s restrictions. Dozens of abortion clinic Web sites advertise the violations, specifically:

**FDA Restriction**  
Approved up to 49 days gestation.

**Abortion Facilities**  
Offering up to 63 days gestation.

Take misoprostol orally, in the doctor's office or clinic, after abortionist determines the abortion is incomplete.

Self-administer misoprostol vaginally at home.

The FDA requires women to sign a Patient Agreement stating, “I believe I am no more than 49 days (seven weeks) pregnant. … I will … return to my provider’s office in two days … to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.” Offering mifepristone to women beyond seven weeks, and having women take misoprostol outside the physician's oversight, requires patients to sign an untruthful statement. The patient is told to disregard the regimen that she pledges to follow in the Patient Agreement. When a drug is approved under Subpart H, the drug's sponsor--Danco--is responsible for ensuring compliance with the restrictions.

—Wendy Wright

“**As harmful as surgical abortion is, mifepristone is even worse, causing ‘significantly more blood loss than did surgical abortion,’ according to an FDA official.**”

Drug only if the owner files a New Drug Application (NDA) requesting it. Without an NDA from Searle, the FDA has no authority to mandate the use of misoprostol in the mifepristone regimen. And yet, it did just that.

Peter Barton Hutt, former FDA general counsel, told The Wall Street Journal on October 18, 2000, that the agency’s treatment of misoprostol “set an extraordinary precedent.” The FDA is in an “embarrassing and uncomfortable position,” he added.

Adding insult to injury, when claiming mifepristone is safe, Danco blames any deleterious effects on misoprostol.

**Out of the Frying Pan**

Drugs approved under Subpart H must be safer than any alternative treatments. Yet, as harmful as surgical abortion is to women, mifepristone is even worse.

“On the whole,” an FDA medical officer noted, “medical abortion patients reported significantly more blood loss than did surgical abortion patients.” The officer characterized this as a “serious
potential disadvantage of the medical method."

This trait can challenge even an experienced physician. One doctor described an incident in the U.S. trials:

“In November of 1994, I was called to the [emergency room] for a woman who was bleeding due to a miscarriage, and was in obvious shock. A blood test showed that she had lost between one-half to two-thirds of her blood volume. …

“I had thought she was having an incomplete miscarriage, but her husband … told me that she had taken RU-486 approximately two weeks before. It was my clinical opinion that she would die soon if she did not have an immediate [dilation and curettage].

“… I took her to the operating room and removed the contents of her uterus surgically. I gave her two units of packed red blood cells intraoperatively.

“Even later that evening, … [s]he required two more units of blood.”

Even after following strict guidelines, mifepristone can cause serious or fatal problems. Yet the FDA increased the possibility of complications by reducing the qualifications.

On April 17, 2002, Danco alerted health care providers of reports of complications suffered by mifepristone patients. Among them were women who had ruptured ectopic pregnancies, and one—Brenda Vise—who died. Two 15-year olds experienced life-threatening infections. One 21-year old suffered a heart attack. This likely is an incomplete list, as abortionists have no incentive to report their failures and emergency care physicians may not know to report complications.

The FDA claimed mifepristone might not be the direct cause. But it did not explain why healthy women end up in the hospital or morgue.

The Population Council agreed to submit study results of the drug under actual conditions to FDA. Predictably, the organization pared down what it initially agreed to, complaining it would be “burdensome” and “expensive.”

The results were due six months after the FDA's approval. More than two years later, CWA still awaits a response to our Freedom of Information request for this study.

**Correct the Mistakes**

It is not unusual for the FDA to recall a drug it has approved. From September 1997 to November 2000, the agency took at least eight drugs off the market due to safety problems.

President George W. Bush, when asked whether he would act on the FDA's approval of mifepristone, said,
“Rebecca” told the counselor at The Life Center in New York that she had recently ended a pregnancy with RU-486. Something went wrong—she didn’t know what, but things didn’t go right. Now she was pregnant again. The pro-life counselor arranged for an ultrasound. It showed she was not six weeks pregnant, but more than 20 weeks. This wasn’t a new pregnancy—her baby had survived RU-486!

Instead of being angry that the abortionist did not kill her child, Rebecca was alarmed that the pill may have hurt him. Nevertheless, she welcomed this child, no matter what.

In the 20 minutes she spent at the abortion center, Rebecca was not told:
★ the name of the drug that she was taking;
★ the developmental process of her unborn baby;
★ what the pill would do to her unborn baby;
★ to return in two weeks, according to RU-486 guidelines.

Rebecca did not receive any papers explaining the abortion pill or expected side effects—nor did she see her sonogram. She came away with only the pills and a receipt for an “office visit” of $500.

Rebecca told staff members at The Life Center of the deep regret she felt when she thought that the abortion pill had worked. She realized her love for her child, and it pained her to think the little life had just ended. God protected her. She is living out this difficult pregnancy and having lots of medical appointments. Miraculously, her baby boy appears to be healthy.

At press time, this little one was expected any day. Pray for this family. God’s protection has brought Rebecca and her son this far.
—Debra Crean

“A Survivor

“Once the decision’s made, it’s been made ... unless it’s proven to be unsafe to women.”

This Citizen Petition lays out irrefutable evidence that the FDA violated numerous safety regulations and shows how women have suffered because of it. The only way to correct this is for the FDA to withdraw its illegal approval of mifepristone.

Wendy Wright is CWA’s senior policy director. She has specialized for more than 10 years in the abortion issue.

To read the complete Citizen Petition on the problems with the approval of RU-486 (mifepristone), visit www.ru486.cwfa.org, use the coupon on page 46, or call 800-323-2200 to order your copy. $15.00.

How You Can Help

**Pray** that the FDA will pull mifepristone from the market.

**Praise** God for the opportunity CWA has had to file the Citizen Petition.

**Act** Contact President Bush (202-456-1111 or 1600 Pennsylvania Ave. N.W., Washington, D.C. 20500) and FDA Commissioner Mark McClellan (commissioner@fda.gov). Ask them to respond to the CWA Citizen Petition by withdrawing mifepristone’s unlawful approval.