Clinton-Era FDA Action Keeps Women in Danger

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The Food and Drug Administration (FDA) is a government agency whose work often goes unnoticed. Yet it has broad authority to affect our day-to-day lives—not only the food we eat, but also the medicines and drugs we use.

Part of the FDA's mission is to be "responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices."

Unfortunately, for decades, the FDA has not been fulfilling this mission when it comes to its decisions about chemical abortion drugs. In 2000, the FDA approved chemical abortion drugs by running roughshod over the law and science. Since then, the agency has not followed the science, reversed course, or fixed its mistakes—to the detriment of women and girls. Instead, it has been dismantling the few safeguards that were in place when the drugs were originally approved.

But now, thousands of doctors are standing up to the FDA, and Alliance Defending Freedom is representing them in the first lawsuit ever to challenge the FDA's approval of chemical abortion drugs.

Let's delve into the details of this case.

What is the Alliance for Hippocratic Medicine?

The Alliance for Hippocratic Medicine is a nonprofit membership organization representing nearly 30,000 health-care professionals. According to its mission statement, "The Alliance for Hippocratic Medicine (AHM) upholds and promotes the fundamental principles of Hippocratic medicine. These principles include protecting the vulnerable at the beginning and end of life, seeking the ultimate good for the patient with compassion and moral integrity, and providing healthcare with the highest standards of excellence based on medical science."

The Alliance for Hippocratic Medicine's member organizations include major medical groups such as the American College of Pediatricians, the American Association of Pro-Life Obstetricians and Gynecologists, and the Christian Medical & Dental Associations.

Alliance Defending Freedom is representing all four of these organizations, as well as four individual doctors, against the FDA.

Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration

This lawsuit is the culmination of decades-long efforts by ADF's clients to hold the FDA accountable for its irresponsible actions. The FDA approved chemical abortion drugs without basis and has spent decades removing what few protections were initially in place.

Mifepristone was originally developed and tested by French pharmaceutical company Roussel Uclaf S.A. under the name RU-486. By 1990, the drug had become widely available in France.

Roussel Uclaf's German parent company, Hoechst AG, prohibited the drug manufacturer from attempting to enter the U.S. market and filing a new drug application with the FDA.

But between 1993 and 1994, under pressure from President Bill Clinton's administration, Roussel "donated" the U.S. patent for RU-486 to the Population Council, an organization founded by John D. Rockefeller III to address supposed world overpopulation. The Population Council conducted clinical trials in the U.S., then filed a new drug application with the FDA in March 1996.

The FDA gave it priority review, and by September 1996, it had received initial approval. But the FDA requested more information from the Population Council. After further review, in 2000, the FDA approved chemical abortion drugs for use in the United States with minimal restrictions.

The only way the FDA could have approved these pills was to characterize pregnancy as an "illness" and argue that these deadly drugs provide a "meaningful therapeutic benefit." What's more, in approving these pills, the FDA needed to disavow science because the FDA never studied the safety of the actual drug regimen, ignored the potential impacts of the hormone-blocking chemical on the developing bodies of adolescent girls, and disregarded the substantial evidence that chemical abortions cause more complications than even surgical abortions.

In fact, chemical abortion has a complication rate four times higher than surgical abortions. One in five women who undergo a chemical abortion will suffer a complication and require further medical attention. Women can face severe bleeding, life-threatening infections, and the inability to have future successful pregnancies—requiring emergency medical treatment, surgeries, blood transfusions, and hysterectomies.

In response to these concerns and the FDA's actions, ADF's clients submitted a citizen petition to challenge the FDA's approval in 2002. Fourteen years later, the FDA denied their petition.

In 2016, on the same day it rejected the citizen petition, the FDA dangerously expanded the availability of chemical abortion drugs from seven weeks of pregnancy to 10 weeks, changed the dosing regimen, reduced the number of in-person doctor visits from three to one, expanded who could prescribe and administer chemical abortion drugs beyond medical doctors, and eliminated the requirement for prescribers to report non-fatal complications from chemical abortion drugs.

ADF's clients again submitted a citizen petition to challenge these reckless changes. The FDA again denied their petition.

In April 2021, during the COVID-19 pandemic, the FDA continued eliminating what few safeguards were left. Based on incomplete and unreliable data, the FDA removed the requirement that an abortionist physically meet with the woman and give her the chemical abortion drugs, thus allowing for chemical abortions by mail and telemedicine. This is illegal and wrong and has only increased the

danger to women, not to mention the children whose lives will be ended. In December 2021, the FDA made this change permanent.

That's why ADF attorneys have now filed a lawsuit challenging the FDA's approval of chemical abortion drugs and subsequent evisceration of the few protections for this drug regimen. This is the first lawsuit ever to challenge the FDA's approval of chemical abortion drugs and the removal of necessary protections for women and girls. ADF is asking the court to order the FDA to withdraw these dangerous chemical abortion drugs from the market.

What's at stake?

All abortions end the life of the child and pose risks to the mother. But chemical abortions are far more dangerous to the mother than even surgical abortions. The FDA must protect the health, safety, and welfare of women and girls by rejecting dangerous chemical abortion drugs.

Women need to be able to trust medical professionals. The FDA's approval of chemical abortion drugs under false pretenses and its decades of stonewalling legal challenges have broken that trust.

Case timeline

- **May 1994**: At the urging of the Clinton administration, French drug manufacturer Roussel Uclaf donated the U.S. patents rights to RU-486 to the Population Council.
- **March 1996**: The Population Council submitted an application for chemical abortion drugs to the FDA.
- **September 2000**: The FDA approved the Population Council's application. Chemical abortions then became legal in the United States.
- **August 2002**: ADF clients submitted a citizen petition to challenge the FDA's approval.
- **March 2016**: Nearly fourteen years later, the FDA denied the citizen petition. On the same day, the FDA extended chemical abortion for babies from seven weeks' gestation up to 10 weeks' gestation. The FDA changed the drugs' dosage and route of administration, reduced the number of in-person doctor visits from three to one, expanded who could prescribe and administer chemical abortion drugs beyond medical doctors, and eliminated the requirement for prescribers to report non-fatal complications from chemical abortion drugs.
- **March 2019**: ADF clients submitted a citizen petition to challenge the FDA's 2016 changes.
- **April 2021**: The FDA announced a temporary removal of the in-person dispensing requirement while the COVID public health emergency remained.
- **December 2021**: The FDA denied the citizen petition. On the same day, the FDA announced the permanent removal of the in-person dispensing requirement.
- **November 2022**: ADF attorneys—representing medical associations and individual doctors who treat women harmed by chemical abortion—filed a lawsuit challenging the FDA's approval of chemical abortion drugs.

The bottom line

The FDA's approval of chemical abortion drugs has always stood on shaky ground. After evading responsibility for years, it is time for the FDA to do what it is legally required to do: protect women and girls.

Alliance Defending Freedom
Non-profit organization
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