



Written by [Bob Adelman](#) on November 21, 2022

Lawsuit Claims FDA Declared Pregnancy an “Illness”

The public interest law firm Alliance Defending Freedom (ADF) [filed the first lawsuit of its kind on Friday](#). It sued the Food and Drug Administration (FDA), claiming that for decades the agency has operated outside its legal boundaries, has failed to protect young pregnant women, and has ignored science in favor of politics in the process:

The FDA failed America’s women and girls when it chose politics over science and approved chemical abortion drugs for use in the United States.

And it has continued to fail them by repeatedly removing even the most basic precautionary requirements associated with their use....

Plaintiffs ... ask that the Court hold [the agency’s actions] unlawful, set them aside, and vacate them.



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The use of RU-486, aka mifepristone, was successfully blocked by pro-life groups for years after it was developed in France. But during the Clinton administration, then-president Bill Clinton instructed the FDA to promote the testing, licensing (for profit), and manufacture of the drug.

This led to the French pharmaceutical company that held the patent on the life-ending drug to donate it for free to the Rockefeller Foundation-sponsored Population Council. From there it was a short hop to approval by the FDA. By September 2000, the FDA had approved the council’s application, and abortion by ingesting poisonous chemicals became legal in the United States.

There was major pushback against the FDA, including two citizen petitions, both of which were ignored for years by the agency before finally being rejected. Along the way the agency continued to make the drug ever more accessible, finally even making it available by mail.

Ironically, one of the plaintiffs in the case, the Alliance for Hippocratic Medicine, has adopted its own version of the Hippocratic Oath:

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.



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This is a softer, kinder, gentler version of the original Hippocratic Oath:

I will use those dietary regimens which will benefit my patients according to my greatest ability and judgment, and I will do no harm or injustice to them.

Neither will I administer a poison to anybody when asked to do so, nor will I suggest such a course. Similarly, I will not give to a woman a pessary [prosthetic device] to cause abortion.

[The lawsuit](#) reminds the U.S. District Court for the Northern District of Texas, where it was filed, that the only way the FDA was able to approve the drug was to lie:

The *only* way the FDA could have approved chemical abortion drugs was to use its accelerated drug approval authority, necessitating the FDA to call pregnancy an “illness” and argue that these dangerous drugs provide a “meaningful therapeutic benefit” over existing treatments.

But pregnancy is not an illness, nor do chemical abortion drugs provide a therapeutic benefit over surgical abortion.

In asserting these transparently false conclusions, the FDA exceeded its regulatory authority to approve the drugs.

What’s more, the FDA needed to disavow science and the law because the FDA never studied the safety of the drugs under the labeled conditions of use despite being required to do so by the Federal Food, Drug, and Cosmetic Act (FFDCA).

The agency also ignored the potential impacts of the hormone-blocking regimen on the developing bodies of adolescent girls in violation of the Pediatric Research and Equity Act (PREA).

And the FDA disregarded the substantial evidence that chemical abortion drugs cause more complications than even surgical abortions.

The FDA knew then, and knows now, that administering RU-486/mifepristone has a complication rate four times higher than surgical abortions. In fact, one in five pregnant women who use the chemical to force the abortion of her living child will suffer complications requiring further medical attention, perhaps facing severe vaginal bleeding, life-threatening infection, and/or becoming sterile, and often requiring a blood transfusion followed by a hysterectomy.

According to ADF senior counsel Erik Baptist, the FDA’s approval has always been based on questionable ethical and legal grounds:

The FDA’s approval of chemical abortion drugs has always stood on shaky legal and moral ground, and after years of evading responsibility, it’s time for the government to do what it’s legally required to do: protect the health and safety of vulnerable girls and women.

On behalf of the national health care organizations and physicians we represent, we ask the court to hold the FDA accountable for its reckless, unlawful behavior.

We urge the court to reject the marketing and distribution of dangerous chemical abortion drugs so that the health, safety, and welfare of women are protected.



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The lawsuit claims that the FDA knew all of these things and approved the drug anyway, cowing to political pressure from the White House and the profit motive of the pharmaceutical companies to which it owes its loyalty and allegiance:

In addition to the legal and scientific infirmities referenced above, all of the FDA's actions on chemical abortion drugs — the 2000 approval, the 2016 major changes, the 2019 generic drug approval, and the two 2021 actions to eliminate the in-person dispensing requirement — failed to acknowledge and address the federal laws that prohibit the distribution of chemical abortion drugs by postal mail, express company, or common carrier.

Instead, the FDA's actions permitted and sometimes even encouraged these illegal activities.

After two decades of engaging the FDA to no avail, Plaintiffs now ask this Court to do what the FDA was and is legally required to do: protect women and girls by holding unlawful, setting aside, and vacating the FDA's actions to approve chemical abortion drugs and eviscerate crucial safeguards for those who undergo this dangerous drug regimen.



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