

PROTECT  
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Health of Millions of Women and Threatens  
Entire U.S. Drug Approval Process

*Judge's Ruling Threatens Lifesaving Drugs  
Relied on by Millions*

April 2023

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## **Medical Abortion Case in Texas Endangers Health of Millions of Women and Threatens Entire U.S. Drug Approval Process**

*Judge's Ruling Threatens Lifesaving Drugs Relied on by Millions*

A federal judge in Texas issued a ruling late on Friday, April 7, to revoke authorization for mifepristone, a safe and effective medication essential for abortion access that was approved by the FDA more than 20 years ago. Anti-abortion advocates, represented by a far-right legal organization, brought suit before this specific judge in Amarillo, Texas, with the sweeping aim of achieving this nationwide ban. Judge Kacsmaryk's ruling in *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration* puts at risk not only the use of mifepristone for safe and legal abortions for millions of American women, but it opens the door for the politically-motivated removal of other safe and effective drugs from the market — throwing the entire U.S. drug approval process into chaos. The consequences of this ruling will be most detrimental for women of color, people living in rural areas, and poorer Americans who face the steepest barriers to accessing care.

### **What Comes Next?**

Judge Matthew Kacsmaryk issued a seven day stay of his ruling to allow the FDA time to appeal to the 5th Circuit. Hours after the ruling, the FDA filed a notice of appeal, and Attorney General Merrick Garland said the government will request a stay to block this ruling while the appeal is considered. The government will likely appeal immediately to the Supreme Court if the ruling is not blocked by the 5th Circuit during the appeal process. If no stay is provided, then the distribution of mifepristone could be halted across the nation pending the final outcome of the case.

On the same evening as Judge Kacsmaryk's ruling, another federal judge ruled in a case filed by the Oregon and Washington Attorneys General and joined by 16 other states. This suit challenged an FDA decision to impose some restrictions on prescribing and dispensing mifepristone and the ruling ordered the FDA to maintain the current availability of the drug in the 18 plaintiff states.

Because these two federal court rulings conflict, the Supreme Court may be called upon to resolve the conflict and decide the merits of both cases.

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## **What's At Stake?**

### **Access To Safe And Effective Reproductive Care For Millions Of Women Nationwide.**

The combination of mifepristone and misoprostol, an ulcer medicine, has been found to have a [98 percent](#) efficacy rate, and mifepristone has been found to be [safer than Tylenol](#) and [Viagra](#). The plaintiffs argue that the FDA's authorization of the drug over [two decades ago](#) was flawed and that the drug which has been used by [over 2.5 million women](#) is, in fact, dangerous. Twelve of the nation's leading medical and scientific organizations have filed an [amicus brief](#) demonstrating that the drug is safe and [studies](#) and [meta-analyses](#) involving tens of thousands of women have shown the same thing.

- **Outsized Impact On Women Of Color And Rural Populations.** An analysis by the Guttmacher Institute [found](#) that this decision will have an especially severe impact on people living in states where medication abortion plays a particularly critical role in ensuring access to care, including heavily rural states like Montana, Maine, and Iowa. As is true for all abortion restrictions, people of color, low-income individuals and those without regular access to a nearby health care provider will be [disproportionately harmed](#) by restrictions and uncertainty around medication access.

### **The Science-Based FDA Drug Approval Process That Has Served America Well Since**

**1938.** The Justice Department warned in their brief that this lawsuit has the potential to undermine the country's process for regulating pharmaceuticals. If the courts ultimately side with the plaintiffs, it will be an unprecedented situation. Professor Greer Donley of the University of Pittsburgh Law School [says](#), "We're talking about a judge who is a non-scientist overriding an agency full of experts about the safety and efficacy of a drug. That, to my knowledge, has never happened before." Lawrence O. Gostin, director of the O'Neill Institute for National and Global Health Law at Georgetown University [called](#) the ruling, "A frontal assault on the legitimacy of the F.D.A. and their discretion to make science-based decisions and gold standard approval processes."

**Safe And Legal Medications Targeted For Political Purposes.** Judge Kacysmarek's ruling opens the door to any third party with a political agenda to challenge a medication that they object to. Ameet Sarpatwari, an expert on pharmaceutical policy and law at Harvard Medical School, [said](#) the ruling is likely to encourage a spate of additional challenges.

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“This opens the door to the courts’ second-guessing any FDA approval – especially for drugs for controversial areas like gender-affirming care, or PrEP for HIV prevention.” He argued it would also instill uncertainty in the pharmaceutical industry. “This should worry every manufacturer out there,” he said. “They are now not assured of a uniform market for their drug based on FDA approval.” Other experts have echoed this [fear](#) that a wide range of approved medicines could be targeted including mRNA vaccines, COVID-19 vaccines, HIV medications, hormone therapies, drugs that are derived from stem cells, or any class of medicines that may be politically unpopular.

**Access To Life-Saving Drugs That Patients Count On Every Day.** An amicus [brief](#) filed by 19 leading scholars of food and drug law states, “We are not aware of any case in which a court has removed a drug from the market over FDA’s objection. The effects could extend far beyond mifepristone. No drug is without risk, and a ruling for Plaintiffs could lead to challenges to FDA’s benefit-risk determinations for drugs it has approved to treat other diseases and conditions. Patients who rely on life-saving medications could see their drugs removed from the market with little notice.”

**Innovation And Investment In New Drug Development.** Pharmaceutical companies must plan years in advance which diseases and therapies to invest in. Injecting a huge dose of political uncertainty into the process could make investors and companies more hesitant to pursue innovative new treatments. Law Professor Rachel Sachs and Professor Donley [recently explained](#) that “[o]btaining approval for a new drug is expensive, time-consuming and risky. It typically involves years or decades of research and can cost hundreds of millions, or even billions, of dollars. Most drugs that enter the research and development process fail, never making it to market. The prize at the end of this ordeal is the FDA’s approval to sell the product.” Therefore, “[i]t could chill innovation nationwide if political actors could circumvent the agency’s data-driven process by engaging the courts. Manufacturers might become wary of investing time and money into products for a wide range of conditions which may – decades down the line – be the subject of nuisance litigation.”

**Chaos In The Established Regulatory System.** Following the ruling, R. Alta Charo, a professor emerita of law and bioethics at the University of Wisconsin [said](#), “The biggest threat that a decision like this brings is the threat of creating chaos.” Charo also told the *New York Times* that a decision to invalidate an F.D.A. drug approval could have ripple effects for other federal agencies with technical expertise, including those that oversee

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regulations related to the environment, energy and digital communications. “Imagine what you could do when you’ve got commercial interests that are upset about a whole slew of” issues, he said, adding, “There’s just no end to this really.”

## **What Are The Legal Arguments?**

### **The plaintiffs assert several different claims:**

- They contend that the FDA’s approval of mifepristone in 2000 should be invalidated because (a) the agency cited regulations governing drugs that “treat serious or life-threatening illnesses” and, plaintiffs contend, mifepristone does not fall within that category, and (b) the conditions for use specified by the agency were inadequate.
- When the agency approved the drug in 2000, it used its “risk evaluation and mitigation strategy” (REMS) authority to impose restrictions designed to ensure the drug is distributed and prescribed safely. In 2016, FDA loosened those restrictions, allowing the drug to be used later in a woman’s pregnancy (up to 70 gestational days), prescribed after only one in-person clinic visit and by a broader set of healthcare providers, and taken by the woman at home rather than in a doctor’s office. The plaintiffs assert that these changes were not supported by the data relied upon by FDA and ask the court to restore the original, more stringent restrictions.
- The plaintiffs also invoke the Comstock Act, a [criminal law](#) prohibiting the “knowing[]” mailing of “obscene or crime-inciting matter” that includes in its long list of items “article[s] or thing[s] designed, adapted, or intended for producing abortion.” They claim that this law required the FDA to prohibit the distribution of mifepristone by mail or common carrier.

### **This is a meritless lawsuit that should have been thrown out of court – for multiple reasons.**

- **The plaintiffs lack “standing” to sue.** To file a lawsuit in federal court, a plaintiff must assert an “actual” or “certainly impending” real-world injury. These plaintiffs are not regulated by the FDA and do not prescribe mifepristone. Their claim – that

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patients will come to them for help after taking the drug, which will require them to divert attention from other patients, inflicting costs and risking potential liability and emotional distress – is indistinguishable from standing arguments that have been repeatedly rejected by the Supreme Court because they “depend[] on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict.”

- **Most of the claims are, in addition, barred by the statute of limitations and/or failure to raise the arguments before the FDA.** Federal law provides that a party seeking to challenge a decision by an administrative agency must file suit no later than six years after the decision. The challenge to the FDA’s approval of the drug in 2000 is therefore untimely. (The plaintiffs try to rely on their 2002 petition to the FDA challenging that approval, but that petition was denied in 2016, more than six years before the filing of this lawsuit.) The plaintiffs filed a separate petition urging the FDA to withdraw its 2016 decision loosening the REMS standards applying to mifepristone, which the agency denied in 2021 – making the challenge to the REMS standards timely; but the plaintiffs did not challenge the 2000 approval in that petition and their claim that the petition implicitly “reopened” the approval decision is contrary to basic principles of administrative law. Also, the plaintiffs have never raised their Comstock Act argument before the FDA. Finally, even the challenge to the 2016 REMS standards is not properly before the court because it has been superseded by FDA’s 2023 action further revising those standards: the 2016 decision, therefore, is no longer operative.
- **The plaintiffs are wrong on the merits.** As the [Justice Department](#) and [a company that manufactures the drug](#) explain in detail: there is no basis for overturning FDA’s expert determination in 2016 regarding the proper REMS standard for this drug, which was fully supported by the data cited by the agency; FDA properly rested its approval of mifepristone on its authority with respect to drugs treating serious illnesses, because pregnancy can be, many times is, accompanied by complications posing serious risks to a woman’s health; and FDA’s 2000 approval and accompanying standards were a proper exercise of the agency’s expertise. The REMS and approval decisions are subject to deferential review and may be set aside only if found to be “arbitrary and capricious” – a high standard that the plaintiffs do not come close to satisfying. With respect to the Comstock Act, the

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government explained that, by 1960, “federal courts of appeals settled upon a consensus view that the Comstock Act did not prohibit the mailing or other conveyance of contraceptives or items designed to produce abortions where the sender does not intend them to be used unlawfully.” (A [Justice Department opinion](#) explains in detail the basis for this conclusion.) Therefore, “even if FDA were required to consider the Comstock Act, because the Comstock Act does not prohibit the mailing or other conveyance of abortion-inducing drugs where the sender does not intend them to be used unlawfully, and given that these drugs may be used lawfully, neither FDA’s decisions related to in-person dispensing nor the absence of a prior FDA affirmative prohibition on distribution by mail was inconsistent with the Comstock Act.”

- **The plaintiffs are not suffering, or threatened with, irreparable injury.** A party is entitled to an injunction only if it can show that, without the injunction, it will suffer irreparable injury. Here, for the same reasons they lack standing, their speculative arguments about harm cannot satisfy the irreparable injury requirement. And plaintiffs’ delay in filing suit – more than two decades after the drug was first approved and nearly a year after the FDA’s denial of their petition regarding the REMS standards – further supports that conclusion.
- **The balance of harms weighs sharply against the plaintiffs.** Even when a plaintiff can demonstrate irreparable injury, a court may not grant injunctive relief if the harm to the plaintiff is outweighed by the harm that would be suffered by other parties and the harm to the public interest. Eliminating the availability of a drug that millions of women have used over two decades will inflict serious harm on Americans across the country who rely on the drug for safe and effective reproductive care. (Plaintiffs’ claims that mifepristone is unsafe are wrong: a [mountain of evidence](#) demonstrates the drug’s safety.) As the government explains, “[r]emoving access to mifepristone would cause worse health outcomes for patients who rely on the availability of mifepristone to safely and effectively terminate their pregnancies.” It would interfere with Congress’s decision to entrust the FDA with technical decisions regarding the safety and efficacy of drugs. And it would create a legal precedent that could disrupt the new drug approval system that has produced myriad life-saving treatments that benefit tens of millions of Americans.

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**Law professor Jonathan Adler, a noted conservative who was a leading voice in support of the legal challenges to the Affordable Care Act, agrees that this lawsuit should be rejected.** [He states](#): “I think it fairly clear that the plaintiffs have severe jurisdictional hurdles to overcome under existing law, and that they have failed to make their case on these questions . . . Whether one agrees with the FDA or [the plaintiffs] on whether it is a good idea for mifepristone to be widely available, there is little doubt about how the underlying legal issues in [the case] should be resolved. The barriers to this suit are substantial, and [the plaintiffs’] attempts to surmount them are wholly unpersuasive.”

## **Who Is Behind The Lawsuit?**

**A Newly Formed “Alliance” Of Right Wing Medical Groups Is The Lead Plaintiff In The Case.** The plaintiffs in this case are led by the newly-formed Alliance for Hippocratic Medicine. This group was seemingly created for the [sole purpose](#) of filing this lawsuit. The Alliance for Hippocratic Medicine was only incorporated in August of 2022 and the group’s website is even sparser and [newer](#) than that.

**The Other Plaintiffs Include Peddlers Of Anti-Choice Misinformation And Anti-LGBT Extremist Groups.** The other plaintiffs include the American Association of Pro-Life Obstetricians and Gynecologists, the American College of Pediatricians, and the Christian Medical & Dental Associations. The American College of Pediatricians is a [fringe extremist group](#) that trades on its name similar to the premiere U.S. association of pediatricians to push anti-LGBTQ junk science via the far-right media and filing amicus briefs in cases related to abortion or LGBT rights. The American Association of Pro-Life Obstetricians and Gynecologists and the Christian Medical and Dental Associations are other far-right groups that use their members’ medical certifications to push [false information](#) regarding abortion and birth control. Including the [dangerous pseudoscience](#) of “abortion reversal.”

**The Plaintiffs Are Represented By The Alliance Defending Freedom, An SPLC Designated Hate Group.** The legal team for the plaintiffs is the Alliance Defending Freedom (ADF), one of the most prolific extremist advocacy groups in the country. Designated a [hate group](#) by the Southern Poverty Law Center, the ADF has advocated both in the U.S. and abroad for forced sterilization of trans people, criminalization of same-sex relationships, and strict restrictions on abortions. ADF receives [tens of millions](#) of dollars



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in dark money annually, coming often from the [same sources](#) that led the right-wing [attacks](#) on the Affordable Care Act, Social Security, and Medicare.

**More Than 20 Republican Attorneys General Have Filed An Amicus Brief Supporting The Suit.** Twenty-two GOP attorneys general have filed an [amicus brief](#) in support of the plaintiffs. In the brief, they argue that the 23-year-old FDA approval of mifepristone [undercuts](#) state abortion bans because the pill can be mailed or accessed online through international human rights groups. In a clear attempt to change [200 years](#) of legal precedent, this brief holds that the federal government's obligation under the Commerce Clause to regulate interstate commerce is not only wrong but has never existed. The brief [states](#) that "no federal law manifests" Congress's ability to regulate the interstate business of abortion medication if it subverts state abortion bans.

## **Who Is Judge Kacsmaryk?**

***Alliance for Hippocratic Medicine v. FDA* Is Being Heard By A Trump-Appointed Judge With A Long History of Anti-Abortion Advocacy.** U.S. District Judge Matthew Kacsmaryk is hearing the mifepristone case. Kacsmaryk ascended to the federal bench from the conservative legal group First Liberty Institute and according to a Washington Post [profile](#), the judge "has been shaped by his deep anti-abortion beliefs." As a college student, Kacsmaryk endorsed a Republican Party platform granting fetuses the full legal protections of personhood, writing that, "The Democratic Party's ability to condone the federally sanctioned eradication of innocent human life is indicative of the moral ambivalence undergirding this party." Kacsmaryk continued to develop his stridently anti-choice views in law school and in his work with First Liberty Institute.

**Plaintiffs Filed Their Lawsuit In Amarillo Specifically Seeking To Have It Heard By Judge Kacsmaryk.** Since his appointment to the bench by Donald Trump, Judge Kacsmaryk has been one of a group of Texas-based judges who [have](#) "largely behaved as rubber stamps for whatever far-right cause shows up in their courtrooms." Because of the way case assignments work, more than 95 percent of the civil cases filed in Amarillo go to Judge Kacsmaryk and right wing-litigants from all over the country travel to Amarillo to judge shop.

**Vox.com Called Kacsmaryk "The Worst Judge In The United States."** An [analysis](#) in Vox called Kacsmaryk "arguably the worst judge in the United States." He has [claimed](#) that

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being transgender is a “mental disorder,” and that all gay people are “disordered.” Kacsmaryk was the first federal judge to [endorse](#) an attack on the right to contraception after the Supreme Court struck down *Roe v. Wade* and he handed down a [decision](#) holding that LGBTQ people are not protected under a federal law prohibiting certain forms of discrimination by health providers.