

News Update: What You Need to Know About the Court Case Attacking Access to Mifepristone in the United States

February 2024 Update



Name of the Case: Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.

This overview is based on an analysis by [Bans Off Our Bodies](#), a U.S.-based abortion rights campaign of which PAI is a coalition member.

What happened?

In November 2022, a group of anti-abortion activists and organizations sued the U.S. Food and Drug Administration (FDA) over its approval of mifepristone, one of two drugs most commonly used in medication abortion in the United States. In the Texas case, *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, the plaintiffs asked the court to order the FDA to rescind its approval of mifepristone — removing the medication from the market despite its approval more than 20 years ago. This case was [deliberately filed](#) in the Amarillo division of the Northern District of Texas, a single-judge division that automatically assigns cases to Judge Matthew Kacsmaryk, a Trump administration appointee who is well known for his opposition to abortion.

While Judge Kacsmaryk ruled in favor of Alliance for Hippocratic Medicine in early April 2023, ordering a hold on FDA approval of mifepristone, the Supreme Court of the United States granted a stay in the case on April 21, as requested by the Department of Justice and abortion pill maker Danco Laboratories. This stay allowed the FDA's approval for mifepristone to remain unchanged as the case proceeded through the Fifth Circuit Court of Appeals and the Supreme Court. Oral arguments at the Fifth Circuit were held on May 17, and on August 16, this court ruled to reinstate preexisting restrictions on mifepristone, but not to remove the drug from the market.

Importantly, the U.S. Department of Justice submitted a petition to the U.S. Supreme Court on September 8 asking it to review the Fifth Circuit's ruling from August 16.

On December 13, the U.S. Supreme Court agreed to take up the case in its current term and will hear oral arguments in March 2024. This means mifepristone will remain accessible and on the market in the United States until the U.S. Supreme Court rules on this case later in 2024. Until then, mifepristone remains available under current regulations as a safe and effective medication abortion method.

What's at stake?

[Mifepristone is safe](#) and has helped ensure that patients are able to make their own private medical decisions regarding termination of pregnancy. It expanded access to vital reproductive health care in [at least 94 countries](#), starting with France and China in 1988 and then the United Kingdom in 1991.

The [FDA first approved mifepristone](#) for medical termination of pregnancy in the United States in September 2000. The goal of this 2023 court case is to revoke the FDA's approval of mifepristone, but the case is not based on data or evidence. Rather, it is a targeted political attack on abortion access. Removing mifepristone from the market would be devastating as medication abortion accounts for more than half (53%) of all abortions in the United States, as of the [most recent estimates from 2020](#).

As of June 2019, mifepristone is also on the core list of lifesaving medicines for reproductive health according to the [World Health Organization's Model List of Essential Medicines](#), because it is an important medicine to prevent the leading causes of maternal morbidity and mortality: postpartum hemorrhage and unsafe abortion. The map on the following page, created by [Gynuity Health Projects](#), indicates countries where mifepristone has been approved as of March 2023.

What are the potential implications outside of the United States?

Alliance for Hippocratic Medicine v. FDA is just one element of the broader [anti-abortion](#), [anti-gender](#) and [anti-rights](#) movements operating within the United States and around the world. Director-General Tedros Adhanom Ghebreyesus has spoken up on behalf of the World Health Organization, re-affirming the agency's [support for abortion rights](#) and highlighting that the latest attacks on abortion access in the United States are out of step with most countries around the world.

This court case is also unique and alarming because it is targeting the FDA's approval process, which has long been recognized as a gold standard for determining the safety and efficacy of medications and medical devices. The case sets a precedent authorizing a court — rather than scientists and clinicians — to determine the medication approval process. As a result, similar court cases could be brought against other medications, even decades after their approval, and [despite overwhelming evidence confirming the safety and efficacy](#) of the drug.

What are the next steps?

- ▶ Learn more about the safety, effectiveness and legality of mifepristone and the importance of medication abortion in the [Toolkit for Policymakers and Partners](#) by Physicians for Reproductive Health (PRH).
- ▶ Get familiar with the [evidence and data](#) related to mifepristone to ensure that scientific evidence is informing your communications outreach and messaging, as well as policy and regulatory approval processes in your context.
- ▶ Share accurate information about mifepristone and medication abortion with other advocates, researchers, policymakers and your local networks of civil society organizations.
- ▶ Monitor anti-abortion actors and initiatives in your region and note if they are beginning to challenge the use of mifepristone or its regulatory status.
- ▶ Document and report out potential threats to mifepristone and abortion access with your networks and global advocates, [such as PAI](#), to inform and identify opportunities for advocacy across country contexts.

Want more information?

Please refer to these resources to learn more about mifepristone, medication abortion and this specific court case:

- [What You Need to Know About the Latest Attack on Abortion Care: the Mifepristone Abortion Pill by Bans Off Our Bodies](#)
- [Nationwide Threat to Medication Abortion: Alliance for Hippocratic Medicine v. FDA](#) by the Center for Reproductive Rights
- [PHR Medical Experts React to Texas Judge's Mifepristone Ruling: "A Profound Breach of Medical Best-Practice and Human Rights"](#) by Physicians for Human Rights (PHR)
- [Alliance for Hippocratic Medicine v. FDA Talking Points](#) from PRH

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