

Following the overturning of Roe v. Wade and the numerous attacks on bodily autonomy and abortion rights happening throughout the country, the Alliance for Hippocratic Medicine v. Federal Drug Administration (FDA) lawsuit has created more barriers and confusion for people seeking reproductive healthcare and for people who rely on the drug to chronic conditions.

## What is mifepristone?

- Mifepristone (miff-ay-priss-tone) is one of two medications used to end a pregnancy by blocking the development of a hormone called progesterone. Pregnancies need in order to continue. Due to its ability to block the hormone, it is used to end pregnancies. Mifepristone is also used to help manage pregnancy loss by helping the body to miscarry safely.
  - Mifepristone was approved by the FDA more than 20 years ago after a comprehensive review and determined to be completely safe and effective
  - Only a certified prescriber who meets specific qualifications can order the drug



## What is the court case about?

- This case is an attempt to ban mifepristone nationwide and limit access to abortion.
- Official name: **Alliance for Hippocratic Medicine v. FDA**
  - The plaintiffs are challenging the FDA's approval process and the modifications of the conditions for distributing mifepristone - claiming that the FDA went beyond its authority.
    - The FDA approval process includes a team of physicians, chemists, pharmacologists, and other scientists who review tests and data from the manufacturer, who must conduct numerous studies and clinical trials in order to provide sufficient evidence regarding the safety and effectiveness of the drug.
    - After the first approval, the FDA continues to conduct periodic reviews and closely monitor the drug for any safety issues or "adverse events."

- Some drugs like mifepristone also have a **risk evaluation and mitigation strategy (REMS)**, which is intended to “mitigate the risk of serious complications” by subjecting the distribution of the drug to certain restrictions.
- Plaintiffs are also claiming that an 1873 anti-obscenity law, **the Comstock Act**, prohibits the mailing of any medication used for abortion.
  - This act criminalizes mailing contraceptives or any other items that can be considered “obscene.”

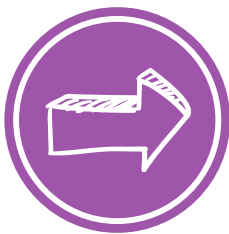
## What were the rulings?

- The case was first taken up in the U.S. District Court for the Northern District of Texas Amarillo Division, where **Judge Mathew Kacsmaryk issued a preliminary injunction in the case blocking the FDA’s approval of mifepristone**
  - Judge Kacsmaryk’s ruling directed the FDA to suspend its approval of the mifepristone as the litigation continued, but gave the FDA seven days to appeal the case to the 5th Circuit before the order took effect. This ruling would block the sale and distribution of mifepristone in the entire country and block access to the drug in states where abortion is legal and protected.
- Less than an hour after Judge Kacsmaryk issued his ruling, **Judge Thomas O. Rice of the U.S. District Court for the Eastern District of Washington** blocked the FDA from slowing down any access to the drug in 17 states and the District of Columbia
- The Biden administration immediately appealed the Texas ruling, and the U.S. Court of Appeals for the Fifth Circuit said that mifepristone could remain available as the case is being reviewed, but with restrictions.
  - Biden administration went to the Supreme Court, and the justices stated that the availability of mifepristone should remain as it is for now (full access, without the restrictions) – until the Fifth Circuit hears arguments and makes a decision.



**Key Point: The Supreme Court’s decision to grant the stay means mifepristone will remain accessible for now.**

- Specifically, this means that the Texas judge's decision to suspend mifepristone can't happen before his decision is reviewed in an "appeal." The Supreme Court's stay does not mean that they have issued a ruling in this case. If the Texas Judge's decision is upheld in the appeal, the FDA will likely appeal the decision again, this time to the Supreme Court
- Oral arguments for the case were heard on May 17, 2023 in the Fifth Circuit Court of Appeals and the **decision** was made on August 16. The decision reinstated pre-2016 restrictions on the abortion medication mifepristone (though it did not revoke the initial approval of the drug).
  - Restrictions include having to obtain the drug in person and prohibiting access through mail or telemedicine, which would make abortion care more difficult for people in many states, especially those who have difficulty traveling or who are at high risk for viruses, like COVID.
- **The US Department of Justice has appealed this decision to the Supreme Court, which has taken on the case and will hear oral arguments on March 26, 2024.**
  - This is the first time an abortion-related case is back in the Supreme Court since the Dobbs decision that overturned Roe v. Wade



**As of right now mifepristone remains available until the Supreme Court makes a final ruling, which will likely be in the summer of 2024.**



**Why is this important to the disability community?**

- **Medication abortion accounted for more than half of abortions across the country – this includes disabled people attempting to get abortions.**



- Abortion rights are also disability rights – disabled people face a greater risk of pregnancy-related complications and maternal mortality, and we should have the right to end a pregnancy, if we choose to.
- The attempt to ban mifepristone will impact disabled people beyond the potential restrictions to abortion. **Mifepristone can also be used in the management and treatment** of chronic conditions and disabilities, such as for the treatment of Cushing’s syndrome and uterine fibroids.
- Mifepristone can help regulate blood pressure, blood sugar, metabolism, inflammation, and sleep cycles. It may be the best or only treatment option for some people.
  - A ban on mifepristone means denying people with disabilities access to treatment.
  - Trials are being conducted to see the potential mifepristone has in treating conditions like **breast cancer, brain cancer, prostate cancer, alcoholism, post-traumatic stress disorder, depression, and more**
    - If availability is blocked, then the trials may be impacted, and a potential treatments could be lost.
- If the Texas ruling is upheld and the authority of the FDA is undermined, other drugs used to manage many different illnesses could be restricted, and people with disabilities could be denied treatment.



## How can you get involved?

- **Share our factsheet!**
- Urge your members of Congress to **Pass the Women’s Health Protection Act**
- Read the **amicus brief** for the case filed by various disability organizations, including AAPD
- Use the Bans Off Our Bodies **Mifepristone case toolkit**