

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, which pregnancies need to continue. Due to its ability to block the hormone,



mifepristone is used to end pregnancies. It 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: <u>Alliance for Hippocratic Medicine v. FDA</u>
 - The plaintiffs were 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, and 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 <u>risk evaluation and mitigation</u> <u>strategy (REMS)</u>, which is intended to "mitigate the risk of serious complications" by subjecting the distribution of the drug to certain restrictions.
- Plaintiffs were also claiming that an 1873 anti-obscenity law, <u>the Comstock Act</u>, 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 brought in the U.S. District Court for the Northern District of Texas Amarillo Division, where <u>Judge Mathew Kacsmaryk issued a preliminary</u> <u>injunction blocking the FDA's approval of mifepristone</u>
 - 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, <u>Judge Thomas O.</u> <u>Rice of the U.S. District Court for the Eastern District of Washington</u> 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 was for now (full access, without the restrictions).
 - 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 did not mean that they have issued a ruling in this cuse.



- The Fifth Circuit Court of Appeals heard oral arguments for the case on May 17, 2023, and made a <u>decision</u> 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-19.
- The US Department of Justice appealed this decision to the Supreme Court, which heard oral arguments on March 26, 2024.
 - This is the first time an abortion-related case was back in the Supreme Court since the Dobbs decision that overturned Roe v. Wade
- On June 13, 2024 the Supreme Court unanimously decided that Alliance for Hippocratic Medicine had no legal standing and rejected their challenge to the FDA's approval of mifepristone.



Key point: Mifepristone will remain on the market, accessible, and without any new restrictions in states where abortion is legal

• The flight is not over. The case will return the first court in Texas, which has already allowed the states of Kansas, Missouri, and Idaho to intervene, meaning the case could continue at the district court with these states as plaintiffs.

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.



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- 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 would impact disabled people beyond the potential restrictions to abortion. <u>Mifepristone can also be used in the management and treatment</u> 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. For some people, it may be the best or only treatment option.
 - 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 <u>breast cancer, brain cancer, prostate cancer,</u> <u>alcoholism, post-traumatic stress disorder, depression, and more.</u>
 - The trials may be impacted if availability is blocked, and potential treatments could be lost.
- If 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 <u>amicus brief</u> for the case filed by various disability organizations, including AAPD
- Join the Bans Off Our Bodies movement and use their <u>Mifepristone case</u>
 <u>toolkit</u>