FACTSHEET: Threats to Medication Abortion

Alliance for Hippocratic Medicine et al v. U.S. Food and Drug Administration et al

Just days after the midterm elections in which voters overwhelmingly demonstrated support for abortion rights, on November 18, 2022, several anti-abortion groups sued the U.S. Food and Drug Administration (FDA) over its approval of mifepristone, one of the two drugs used in medication abortion. The lawsuit asks the court to order the FDA to withdraw the approval of mifepristone in order to remove it from the market and ban medication abortion nationwide. This is just the next step in anti-abortion groups' plan to attempt to ban abortion in every state in the country.

This case could result in a devastating nationwide ban on one of the two medications used in medication abortion — *even in states where abortion is protected*. Medication abortion is a method of abortion used for more than half of all abortions in the U.S. and study after study has found this method to be an exceedingly safe and effective way to end a pregnancy.

THE CASE

- The case was filed by groups that advocate for making abortion a crime, including Alliance Defending Freedom, which has been labeled a hate group by the Southern Poverty Law Center.
- This case was deliberately filed in the Northern District of Texas, a single-judge court house where the cases are automatically assigned to Judge Matthew Kacsmaryk.
    - Since his appointment to the bench by former President Trump in 2019, Judge Kacsmaryk has issued multiple major anti-immigrant, anti-LGBTQ+, and anti-birth control opinions.
    - Judge Kacsmaryk recently ruled that teenagers can be barred from accessing contraception without parental consent and questioned whether the right to contraception survives the *Dobbs* decision.
- Plaintiffs have asked the court to order FDA to rescind its approval of mifepristone. **This could block the use of the drug for medication abortion and miscarriage care nationwide as early as February.**
- The lawsuit incorrectly argues that the FDA exceeded its authority when approving mifepristone over 20 years ago.
    - Plaintiffs falsely claim that the FDA did not sufficiently study the drug's safety and efficacy – despite the drug's exceptional record of safe use both in the United States and internationally.

NEXT STEPS

- The case will be fully briefed on February 10, 2023, after which point the district court could issue its decision at any time. Judge Kacsmaryk could schedule oral arguments on the claims brought in the case or simply rule without hearing further from the parties.

- Although the case has many legal defects and the claims lack merit, Judge Kacsmaryk's record indicates that he could rule in any number of ways that would deny people throughout the country access to mifepristone.
- In addition, the case could move very quickly to the Fifth Circuit Court of Appeals and, if the plaintiffs are successful there, it could be before the Supreme Court as early as March or April.

BACKGROUND ON MEDICATION ABORTION

- Mifepristone is the first drug in a two-medication regimen that has been used safely and effectively by millions of people for over 20 years for early abortion care and more recently for miscarriage management.
- Medication abortion is incredibly safe and effective, and there are countless studies that back the science. Here's why:
    - Mifepristone was approved by the FDA in 2000. It has since been used by more than 4 million women in the U.S.
    - A robust audit by the Government Accountability Office in 2008 found that the FDA's approval of mifepristone was consistent with other drugs.
    - The FDA has conducted in-depth analyses on mifepristone over the years which repeatedly demonstrate the drug's safety and efficacy, including during initial approval in 2000, follow-up review in 2016, and as recently as this year.
    - Medication abortion accounts for more than half (54%) of all abortions in the U.S and is the preferred method for many patients because of mifepristone's safe and effective track record.
- More information on the safety and real-world use of medication abortion can be found here, courtesy of the EMAA Project.

IMPLICATIONS OF THE CASE

This case poses a major threat to people's ability to access abortion across the country.

- Mifepristone is used in more than half of all the abortions in this country. If it is no longer available, clinics could not come close to meeting the patients' needs.
- Clinics are already overwhelmed by the influx of patients from states that have banned abortion.
- This also threatens the health of patients who need treatment for miscarriage management.
- Leading medical organizations have repeatedly expressed concern over the lack of access to abortion—including medication abortion—on patients' health.
    - American College of Obstetricians and Gynecologists (ACOG) and the American Medical Association (AMA) predict that the country's maternal mortality crisis will worsen without access to abortion care, including medication abortion.
    - Pharmacy groups said that patients' health is at risk without access to mifepristone, which is also used to treat ectopic pregnancies, miscarriages, and other medical conditions.

The impact of this lawsuit also goes beyond medication abortion access. It threatens the FDA's authority over the drug approval process, which could severely limit the development of new drugs overall and have far-reaching repercussions on patients' access to FDA-approved medications.

CASE TIMELINE

- September 2000 – FDA approves the use of mifepristone albeit with medically unnecessary restrictions. Subsequent reviews over the next 20 years consistently find mifepristone safe and effective; the FDA takes steps to lessen restrictions in 2016 and again in 2023.
- Nov. 18, 2022 – Anti-abortion groups filed their challenge and request for emergency relief
- Jan. 13, 2023 – DOJ filed its opposition to the plaintiffs' request for a preliminary injunction and Danco, the company that holds the initial approval of mifepristone, requested to join the case on the side of the FDA.
- Feb. 10, 2023 – ADF will file its final brief on the preliminary injunction request. Groups on both sides will file amicus briefs.
- Late February/March 2023 – The decision could come at any time after February 10, but will likely take several weeks. It will likely be somewhat longer if the court decides to hold oral arguments on the motion.
    - An appeal to the Fifth Circuit after a ruling is likely. If the FDA loses, we expect them to file an emergency appeal.
- March/April 2023 – Earliest date that the case could be in front of the Supreme Court.