CENTER *for* REPRODUCTIVE RIGHTS

January 17, 2023

Case Backgrounder:

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

Case background:
In November, several anti-abortion groups sued the U.S. Food and Drug Administration (FDA) over its approval of mifepristone, one of the drugs used in medication abortion (abortion by pills). Filed in a federal court in Texas, the lawsuit *Alliance for Hippocratic Medicine v. FDA* is seeking to revoke FDA approval of mifepristone and remove it from the market nationwide. If the court grants plaintiffs' request, **access to medication abortion would be eradicated in every single state in the country, even states where abortion is legal**. Currently medication abortion accounts for more than half of the abortions in the U.S.

Who is involved:
The case was brought by anti-abortion organizations and doctors including the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG). They are represented by the Alliance Defending Freedom (ADF), which is designated as a hate group by the Southern Poverty Law Center.

The case was filed in federal court in Amarillo, Texas, where 95% of cases are automatically assigned to Judge Matthew J. Kacsmaryk. He recently ruled that teenagers can be prohibited from using contraception without parental consent. Judge Kacsmaryk has also issued opinions allowing for discrimination against the LGBTQ community and limiting the rights of immigrants.

Timeline:
Briefing will be complete on February 10, after which point the district court could issue its decision at any time. The judge may schedule a hearing after briefs are submitted or rule without a hearing.

Claims:
The lawsuit incorrectly argues that the FDA exceeded its authority and did not use the proper process when approving mifepristone over 20 years ago. Plaintiffs also falsely claim that the FDA did not sufficiently study the drug's safety and efficacy and attacks the agency's decision to allow patients to receive mifepristone through the mail via telehealth.

The reality is that medication abortion is incredibly safe and effective, and there are countless studies that back the science. Here's why:

- Medication abortion 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.
- FDA's decision to allow patients to obtain medication abortion via mail was made after a comprehensive review in line with evidence.
- Medication abortion accounts for more than half (54%) of all abortions in the U.S and is the preferred method for many patients.

More information on the safety and real-world use of medication abortion can be found here.

Implications:
This case poses a major threat to people's ability to access abortion across the country. Blocking access to mifepristone would force all patients to have procedural abortions and inundate clinics. Many clinics are already overwhelmed by the influx of patients from states that have banned abortion.

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.

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MEDIA CONTACT: center.press@reprorights.org