CENTER *for* REPRODUCTIVE RIGHTS

Case Backgrounder:

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

Case overview:

On March 26, 2024, the Supreme Court of the United States heard oral arguments in a case designed to upend access to abortion pills nationwide. The case—***U.S. Food & Drug Administration, et al. v. Alliance for Hippocratic Medicine, et al.***—was filed by anti-abortion advocates who are asking the Court to rescind the FDA's approval of the abortion pill mifepristone. Failing that, these groups are also asking the Court to rollback regulatory changes the FDA has made to make mifepristone easier to access—changes that have been critical for abortion access in post-*Roe* America.

The **challenged FDA regulatory changes** include:

- The FDA's 2016 decision to allow advanced practice clinicians like nurse practitioners and physicians assistants to independently prescribe mifepristone.
- A 2021 action allowing patients to get mifepristone via mail. Previously, patients had to get the medication in-person at a clinic, even though most U.S. counties have no abortion clinic.

About mifepristone:

Mifepristone is incredibly safe and effective and has been used by millions since the FDA approved it 24 years ago. In addition to abortion, mifepristone is also used to treat miscarriages. Research studies have consistently shown that mifepristone is safe. In fact, mifepristone is **as safe or safer than Tylenol and Viagra**. The anti-abortion groups that brought this case attempt to cast doubt on the safety of mifepristone by citing nothing more than junk science, including studies that have since been **retracted.**

What's at stake:

Mifepristone is used in most abortions in the U.S., with medication abortion **accounting for 63% of all abortions.** The FDA's decisions to expand access to mifepristone in 2016 and 2021, including allowing medication abortions without an in-person visit, have enabled people to have medication abortions from home and increased access with no safety issues—especially for patients in rural areas or who don't live near a clinic. Most U.S. counties have no abortion clinic, so re-instating the in-person requirement may make it impossible for some to access abortion.

This case could also have impacts far beyond abortion, as it **threatens** the FDA's authority to approve drugs in general. Everyone who cares about access to important medications should

be concerned about this case as it could set a dangerous precedent where ideologues can second-guess the independent scientific judgment of the FDA.

Oral arguments:

During oral arguments on March 26th, a majority of Justices seemed skeptical as to whether the anti-abortion extremists who brought the case have the right to sue the FDA. Many court-watchers are speculating that the Court seems inclined to dismiss the case on grounds that plaintiffs **don't have standing.** The Court will issue its ruling in late June or early July. Access to mifepristone remains unchanged until the Court issues its opinion.

Timeline of the case:

- On November 18, 2022, Alliance for Hippocratic Medicine filed this case in Amarillo, TX.
- The federal district court in Amarillo issued a decision on April 7, 2023, **attempting to block the long-standing FDA approval** of mifepristone.
- On April 21, 2023, the **Supreme Court granted a stay of the lower court decision**, leaving mifepristone on the market.
- On August 16, 2023, the **Fifth Circuit Court of Appeals reinstated** burdensome pre-2016 restrictions on mifepristone, but did not remove the drug from the market entirely. Due to the U.S. Supreme Court's earlier stay order, mifepristone remains available under current regulations until the case is decided.
- On September 8, 2023, the U.S. Department of Justice asked the U.S. Supreme Court **to review the Fifth Circuit ruling.**
- On December 13, 2023, the U.S. Supreme Court agreed to review the case.
- On January 30, 2024, the Center for Reproductive Rights, along with the American Civil Liberties Union and the Lawyering Project, **submitted an amicus brief** to the Supreme Court highlighting the junk science and uncredible witnesses that the lower courts based their opinions on. Other notable briefs include a brief submitted by 263 Democratic members of Congress and a brief on behalf of dozens of pharmaceutical companies supporting the FDA.
- Eight days later, Sage Perspectives **retracted two research papers** on the safety and efficacy of mifepristone that the Fifth Circuit referenced in its decision. The publisher retracted the studies for their flawed research and authors' conflicts of interest.
- The U.S. Supreme Court heard oral arguments on March 26, 2024, and will issue an opinion in June this year.

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