10 Things to Know About Alliance for Hippocratic Medicine v. FDA

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Introduction

On April 7, a Trump-appointed U.S. District judge ruled in Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration (AHM v. FDA) that the FDA’s 23-year-old approval of mifepristone— one of the first of two medications in a medication abortion— is suspended. At the current time of publication, the Department of Justice has appealed the ruling to the Supreme Court.

This decision follows the Dobbs v. Jackson Women’s Health Organization ruling in June 2022, in which the Supreme Court eliminated the federal constitutional right to abortion. Since Dobbs, bans have eliminated some or all abortion rights in 19 states, forcing people seeking abortions to find the resources to travel or carry a pregnancy to term. Additionally, Wyoming became the first state to ban abortion pills, effective July 1, ahead of the Texas court decision on mifepristone's approval.

Mifepristone is a safe and effective option for people seeking abortion care that millions of people have used over the past 20 years. Taking it off the market would significantly compromise abortion access across the country—even in states with protections for abortion access. As a result of this latest decision, there is increased uncertainty about the state of abortion access and rights nationwide.

This explainer provides context to and answers common questions surrounding AHM v. FDA, and the broader implications for the future of medication abortion access.

1. Who filed the lawsuit?
In November 2022, the Alliance Defending Freedom filed a federal lawsuit against the U.S. Food and Drug Administration (FDA) in the U.S. District Court for the Northern District of Texas, Amarillo Division. The organization—which the Southern Poverty Law Center designates as a hate group—filed the lawsuit on behalf of the Alliance for Hippocratic Medicine, a recently formed coalition of anti-abortion national medical associations and doctors. The group alleged the FDA lacked the authority to approve mifepristone, that studies regarding drug’s safety were insufficient, and that mifepristone’s approval violates a 150-year-old anti-obscenity law. The Alliance for Hippocratic Medicine sought an injunction requesting that the drug’s FDA approval be reversed while the case plays out in court. The judge granted the plaintiff’s request, and the FDA’s approval of mifepristone was halted.

2. Why was this lawsuit filed in Amarillo, TX?

The Alliance for Hippocratic Medicine (AHM) is a Tennessee-based organization incorporated in Amarillo, TX, three months after the Dobbs decision. AHM proceeded with the lawsuit in Amarillo shortly after the group’s relocation, raising the question of whether the organization was legitimately established or founded due to a political calculation.

Congress gives U.S. federal district courts discretion to create their own procedures dividing cases among judges. Most district courts assign cases randomly to be distributed among a roster of judges, but in Texas, federal courts assign cases based on geographic location. Among Texas’ four district courts, there are 27 smaller jurisdictional divisions, of which nine have one single judge and 10 others have two. This means that a plaintiff filing a lawsuit in certain jurisdictions knows which judge will likely hear their case and can choose to file where it is politically advantageous.

In September 2022, Northern District of Texas Chief Justice David Godbey issued a special order assigning 100% of cases filed in the Amarillo division to Judge Kacsmaryk—a staunch conservative who has drawn controversy over his legal opinions on civil liberties, including access to contraceptives for minors. In addition, the Northern District faces increased scrutiny over its judicial assignments and single-judge divisions, as it has become a common jurisdiction for Republican state attorneys general to file legal challenges for a favorable outcome (Democratic state attorneys general do this in other jurisdictions). This practice is called “forum

1 Nationwide injunctions are orders used by federal courts to prevent an action, rule, or regulation from going into effect nationally. For a more in-depth analysis on nationwide injunctions, read CPCC’s explainer here.

2 See map of Texas’ federal judicial districts.
shopping” or “judge shopping” and is generally discouraged in modern law, as it can undermine the democratic process.

3. What is medication abortion and what is it used for?

Medication abortion is the process of ending a pregnancy by taking pills. The FDA authorizes two medications—mifepristone and misoprostol as a medication regimen to induce an abortion for the first 10 weeks of pregnancy (it can also safely be used in later pregnancies). Mifepristone is the first medication taken. According to the Guttmacher Institute, medication abortion was used in 54 percent of all abortions in the United States in 2022, and has a safety record of over 99 percent. The FDA also authorizes additional uses for mifepristone, and both medications offer the most effective regimen for managing a miscarriage.

Despite the ruling in AHM v. FDA, decades of research and data³ have continued to confirm using mifepristone as a safe and effective way for people to end an early pregnancy on their own terms.

4. How many people will this decision affect?

Rulings by district court judges can have national implications when they are issued to block an FDA-approved medication, as described below. According to a study by NARAL Pro-Choice America, this decision could impact as many as 64.5 million people of reproductive age. This data includes people residing in states where abortion access has been protected or expanded, like New York, California, and Vermont.

5. How will this case impact abortion access?

This decision could significantly impede abortion access, partly due to the high number of health care centers that rely on mifepristone as a primary service method. According to data from the University of San Francisco’s Advancing New Standards in Reproductive Health, a collaborative research group, around 40 percent of clinics nationwide offer medication abortions only. The share of medication abortions also drastically varies by state, meaning this decision would impact people living in certain states more heavily. To put this into perspective, the data collected from 2022 reflects that about half of Pennsylvania clinics offered medication and procedural abortions nearly equally. In contrast, the share of

³ Prior to the approval of mifepristone in 2000, the FDA conducted an in-depth review of the drug’s safety and has conducted additional reviews of the evidence in the decades since. The Government Accountability Office also conducted two separate reviews—one in 2008 and another in 2018—confirming that the FDA followed standard practice when it approved use of the drug.
abortion provided via medication in states like Colorado, Maine, Iowa, and Vermont was 70 percent or higher. In Wyoming, 100 percent of abortions reported were via medication only. For providers of only medication abortion, it may also be difficult to completely switch to procedural abortions, since in-clinic abortions require more time and resources for clinic staff. Traveling to health care centers for an abortion is also not an option for all patients, which will only create an additional and possibly insurmountable barrier for patients.

If clinics can switch to offering more procedural abortions, this will likely not come without consequence. Since Roe v. Wade was overturned, many abortion clinics that border states with heavy restrictions or bans have been overwhelmed by the influx of patients. As more people are forced to cross state lines to receive care, this will further increase the strain on abortion providers and their staff to meet the demand for services.

6. Why and how is medication abortion being targeted?

Medication abortion has consistently been a target of attacks because it makes abortion care more accessible across the country. Attacks on medication abortion underscore efforts by anti-choice organizations to end abortion care by any means. Additionally, the FDA’s continuing drug safety plan for mifepristone makes the medication more susceptible to political attacks and lawsuits.

Risk Evaluation and Mitigation Strategy, or REMS, is a drug safety plan that the FDA can sometimes require for medications that have serious health concerns. This safety plan aims to take extra precautions to ensure a drug’s therapeutic benefit outweighs its risks. Yet, the abundance of evidence indicating mifepristone safe usage (it is safer than drugs like Tylenol), calls into question why a REMS plan for mifepristone is required. Before recently loosened restrictions, the drug had to be dispensed in-person by a certified medical provider, preventing patients from having the option to access mifepristone via mail or a retail pharmacy. Since the FDA permanently removed this restriction effective January 2023, the mifepristone REMS program still maintains requirements for medical provider certification and prescriber-patient agreement forms—additional provisions that can mislead patients into believing the drug is unsafe. The updated REMS also adds a certification requirement for pharmacies dispensing mifepristone, creating another barrier for pharmacies to stock it. As a point of reference, of the 20,000+ drug products the FDA has approved, only 61 have current REMS. The list of drugs containing REMS includes those with serious side effects or high risk for abuse, like cancer therapies and opioid painkillers.
It is important to also note that while Alliance for Hippocratic Medicine used the presence of REMS restrictions to challenge mifepristone’s safety, many practitioners and groups have questioned whether a REMS protocol for mifepristone is necessary based on scientific evidence—or the result of politicization of medication abortion. For example, the drug Korlym uses mifepristone at a higher dosage to treat Cushing’s syndrome, yet it is not subject to the same restrictions as Mifeprex (the brand-name drug used for abortion care).

Many states that restrict abortion access have also imposed restrictions on medication abortion. For example, several states have established requirements that limit the types of health care providers who may prescribe medication abortion, restrictions against its use in telehealth, gestational limits that run counter to the FDA’s approved usage and measures that prohibit entire access altogether. Essentially, these restrictions aim to limit access to medication abortion beyond what the FDA dictates.

**7. What legal authority does the FDA have to approve mifepristone?**

A federal statute—the Federal Food, Drug, and Cosmetic Act (FDCA)—authorizes the FDA to regulate the safety and effectiveness of drug products in the U.S. The Food and Drug Administration Amendments Act (FDAAA) of 2007 gave the FDA authority to require REMS for certain drugs, though prior restrictions were in place since the drug entered the U.S. market in 2000.

**8. Has a court ever ordered the FDA to withdraw an approved drug?**

This is the first time a court has ever ordered the FDA to withdraw a drug’s approval. The ruling defies the logic of federal preemption and the six-year statute of limitations to challenge any action by a federal agency, and undermines Congress’ delegated authority to the FDA to approve and regulate drug products that could have far-reaching implications beyond mifepristone. As a result, hundreds of U.S. pharmaceutical executives signed an open letter supporting the FDA’s legal authority to approve and regulate medicines and called for reversing this decision that would undermine the “evidence-based and legislatively sanctioned authority” of the FDA.

**9. What happens next?**

Within days following the ruling, the Department of Justice (DOJ) filed a motion seeking an emergency stay on the injunction while immediately looking to appeal the case to the Fifth U.S. Circuit of Appeals. On April 13, the federal appeals court partially granted this request, pausing the initial ruling until the full case can be
heard. The decision maintained that mifepristone could remain on the market, but rolled back the FDA's previous removal of REMS restrictions that increased the gestational age for approved use from 7 to 10 weeks, expanded the category of health professionals able to prescribe and administer mifepristone, lifted requirements on in-person office visits, and removed additional reporting requirements that misguided patients about the safety of the medication. In addition, the order blocks mail delivery of mifepristone. The DOJ has appealed this ruling to the Supreme Court, citing the Fifth Circuit’s decision to reinstate restrictions on mifepristone, and awaits a decision. Both rulings set a dangerous precedent for ignoring decades of research and the FDA’s scientific judgment regarding the safety and efficacy of medications.

Nevertheless, some abortion providers have raised the possibility of shifting to an off-label⁴ misoprostol-only protocol for medication abortion as a result of this decision. Misoprostol-only abortion is commonly used in other countries to terminate a pregnancy and has long been a safe and effective option for a person to self-manage an abortion. In many parts of the world, misoprostol is the primary method of medication abortion care due to the unavailability of mifepristone and other barriers. In light of this decision, many Democratic governors have ordered doses of misoprostol to ensure that people maintain access to medication abortion.

Two additional court cases involving mifepristone—GenBioPro v. Sorsaig and Bryant v. Stein—await litigation. A lower court ruling in Washington v. FDA that directly conflicts with the ruling in AHM v. FDA likely means that both cases will end up at the Supreme Court for a full review.

10. What have Congress and the Administration done to protect access to medication abortion?

After the Dobbs decision, the Biden Administration took a number of steps to protect abortion access, including issuing a series of executive orders directing agencies to use their authorities to protect reproductive rights and access. Some of these directives include: guidelines obligating hospital physicians to provide life-saving abortions if medically necessary; protections against the illegal use of medical data sharing; prohibitions against pharmacy denials of medication to pregnant people; guidance on increased flexibility of Medicaid waivers to be used to fund out-of-state travel; and the establishment of a pathway to receive contraceptive coverage notwithstanding an employer’s religious exemption. In response to Judge

⁴ “Off-label” refers to the practice of a healthcare provider using an FDA approved drug for another use besides its authorized indication, i.e., a different dosage, population, treatment for disease. Many prescriptions are written for off-label purposes (approximately 1 in 5) and it is common in clinical practice.
Kacsmaryk’s ruling in *AHM v. FDA*, the Biden Administration proposed a new rule prohibiting health care organizations from sharing personal medical records with law enforcement by expanding language to current HIPPA laws covering people crossing state lines to seek an abortion. This step may be crucial to reinforcing patients’ protection of privacy as more states move to enact legislation that criminalizes providers for administering abortion care, and seek to ban interstate travel for minors seeking an abortion.

Beyond these actions, Senators Elizabeth Warren (D-MA) and Mazie Hirono (D-HI) led calls for the Biden Administration to take additional steps to protect reproductive rights. Concerning medication abortion, the Senators urged the Administration to “continue to evaluate remaining restrictions on medication abortion” and whether the FDA’s current restrictions on mifepristone are medically unnecessary. This largely echoes the views of abortion rights advocates and leading medical groups, who have continuously called on the FDA to permanently remove these restrictions. In addition, following an announcement by Walgreens that they would no longer sell abortion pills in certain states after legal threats, Senators Patty Murray (D-WA), Debbie Stabenow (D-MI), and Tammy Baldwin (D-WI) also led a letter asking Walgreens for clarification on its plan to ensure that medication abortion remains available. Additionally, 240 members of Congress filed a bicameral amicus brief urging the U.S. Court of Appeals for the Fifth Circuit to protect the availability of mifepristone for reproductive care. At this time, there are limited actions Congress can take on this issue as litigation continues.

**For now, approval of mifepristone remains protected.** Yet ultimately, *AHM v. FDA* aims to create additional cruel and unnecessary obstacles to prevent people from exercising their right to have an abortion on their own terms. Both rulings, in this case, set a dangerous precedent for undermining the FDA’s authority to determine the safety and efficacy of all drugs, and threaten patients’ access to other life saving medications. Mifepristone has allowed patients to make their own private medical decisions and expanded access to reproductive health care. As the right to abortion remains under attack, any actions to remove or restrict access to mifepristone would significantly compromise access to abortion nationwide and eliminate people’s freedom and bodily autonomy to make the best decisions for their own health and well-being.