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

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Author: Chenelle Hammonds, chenelle@progressivecaucuscenter.org

Introduction

On September 8th, the Department of Justice (DOJ) petitioned the Supreme Court to review Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration (AHM v. FDA). At issue, is the FDA’s 23-year-old approval of mifepristone—the first of two medications used for an abortion. In early April, a Trump-appointed U.S. District judge’s ruling halted approval of mifepristone. After subsequent appeals to higher courts, the case now rests in the hands of the U.S Supreme Court, who will decide whether to take up the case in their 2023-24 term that begins in October. For now, the FDA’s approval and guidelines for mifepristone remain unchanged.

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 the latest rulings by the Fifth Circuit Court of Appeals that attempt to restrict access to mifepristone, 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 the 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 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

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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.
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 data\(^3\) have continued to confirm using mifepristone as a safe and effective way for people to end an early pregnancy on their own terms.

### 4. What is the latest decision from this case?

On August 16th, the Fifth Circuit Court of Appeals issued a decision on the appeal to challenge the FDA’s approval of mifepristone. The ruling declined to halt the FDA’s approval of mifepristone entirely, vacating this component of Judge Kaczmaryk’s initial ruling. However, the decision nullifies previous loosened restrictions on the abortion pill by upholding other restrictions from the lower court ruling. This includes the reinstatement of restrictions before 2016, which expanded the gestational limits for mifepristone from 49 days to up to 70 days of pregnancy, doubling the proportion of eligible medication abortions. The decision would also reverse a 2021 modification by the FDA to allow for the dispensing of mifepristone by mail to reduce burdensome in-person dispensing requirements.

### 5. What happens next?

The Supreme Court’s 7-2 decision to grant an emergency stay in AHM v. FDA means mifepristone will remain on the market and accessible while the DOJ’s challenge to the Fifth Circuit’s latest ruling remains in the appeals process. The Supreme Court will now decide whether to review the case in full or deny the appeal, allowing the Fifth Circuit decision reinstating restrictions to go into effect.

### 6. How could abortion access be impacted?

If the appeals court ruling were to remain in place, access to medication abortion would be severely disrupted for several months. According to the manufacturer of mifepristone, reversing FDA protocols for the drug would require the revision of "product labels, packaging, and promotional materials; the recertification of

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\(^3\) 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.
providers; and amendments to “supplier-and distributor-contracts and policies.” The appeals court ruling would also mean that patients would again be subject to burdensome requirements contradicting scientific evidence regarding mifepristone’s safety and efficacy. Moreover, any decision to reverse a drug previously approved by the FDA has policy implications beyond abortion. Such a decision could significantly undermine legal precedent and the FDA's decision-making authority. This could result in potentially disastrous ramifications for drug innovation and the health of the general public.

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.

A decision that would effectively halt access to medication abortion, could also 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 abortions 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.
Meanwhile, some abortion providers have raised the possibility of shifting to an off-label\(^4\) 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 access to medication abortion remains in place.

**7. 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. Accordingly, 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.

In Congress, 147 Republican lawmakers filed an amicus brief with the Supreme Court to support the 5th Circuit’s ruling reinstating restrictions on mifepristone. Moreover, Republican lawmakers have sought to restrict abortion pill access as budget negotiations remain ongoing. In the latest iteration of the 2024 Food and Agriculture (Ag-FDA) Appropriations bill, House Republicans included an abortion pill policy rider to effectively reverse the FDA’s rule allowing mifepristone to be sold by mail and at retail pharmacies.

Additionally, the FDA’s continuance of a drug safety plan for mifepristone makes the medication more susceptible to political attacks and lawsuits. Despite the FDA removing the in-person dispensing requirement for mifepristone, its REMS (Risk Evaluation and Mitigation Strategy) 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. This safety plan evidently aims to

\(^4\) “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.
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. 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).\(^5\)

8. 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.

9. 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.

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

After the Dobbs v. Jackson Women’s Health Organization 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

\[^5\] As a point of reference, of the 20,000+ drug products the FDA has approved, only 61 have current REMS.
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 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.

Additionally, on the eve of the one-year anniversary of Dobbs, President Biden signed an executive order on **Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services.** The executive order directs the Departments of Treasury, Labor, and Health and Human Services to consider new guidance to ensure that health insurers offering care under the Affordable Care Act (ACA) cover all FDA-approved contraceptives without cost-sharing (deductibles, copayments, or coinsurance). The order also directs agencies to find opportunities to expand access to affordable over-the-counter contraceptives, consider new steps to increase high-quality family planning services and supplies offered through Medicaid, and improve coverage and payment for contraceptives for Medicare beneficiaries to ensure people of reproductive age with disabilities have equal access to contraception.

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 abortion on their terms. Both lower court rulings 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.