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FDA v. Alliance for Hippocratic Medicine: The Supreme Court could devastate nationwide access to a safe and effective medication used in over 60% of all abortions.

A current case¹ before the United States Supreme Court will determine if access to the most common form of abortion in the U.S. will be significantly restricted, which would result in harmful and far-reaching consequences for both patients and providers. Mifepristone is safe, effective, and has greatly expanded access to abortion care for nearly twenty-five years.

Anti-abortion extremists brought this case with the goal of taking away access to medication abortion nationwide.

Just one month after the erroneous and devastating Supreme Court decision to overturn *Roe v. Wade*² in *Dobbs v. Jackson's Women's Health Organization*,³ a collective of anti-abortion groups formed a new organization—Alliance for Hippocratic Medicine (AHM)—for the purpose of eliminating access to mifepristone, a medication abortion pill.⁴ Mifepristone is one of two medications (along with misoprostol) that is used in over 60% of all abortions in the U.S.⁵ Mifepristone is also critical to the full spectrum of reproductive healthcare, including miscarriage management and the treatment of uterine fibroids and other reproductive health conditions.⁶

On November 18, 2022, AHM filed a lawsuit against the U.S. Food and Drug Administration (FDA) seeking to overturn the FDA's approval of mifepristone. AHM relied on junk science and bogus claims about the medication's safety record,⁷ in direct conflict with a wealth of studies and data demonstrating that mifepristone is safe, effective, and critical to filling the gaps in abortion access for communities with limited access to healthcare and other resources.⁸

In bringing this lawsuit, AHM cherry-picked a notoriously anti-abortion judge,⁹ who in April 2023 delivered the extreme and unprecedented result they wanted: invalidating the FDA's original approval of mifepristone, effectively instituting a nationwide ban on its use.¹⁰ An appeals court reversed that extreme result, but instead put back in place harmful restrictions on mifepristone that are not medically necessary and impede access to the medication.¹¹

The Biden administration and the drug's manufacturer appealed to the Supreme Court. The Court stayed the lower court's decision and agreed to hear the case. The Supreme Court will hear oral arguments in *Alliance for Hippocratic Medicine v. FDA* on March 26, 2024,¹² with a decision expected in June 2024.

While the case proceeds, mifepristone is still approved as safe and effective, and available without the restrictions that the appeals court tried to reinstate.¹³

Mifepristone—which is currently still available—is safe, effective, and more critical now to bridging the gaps in abortion access, especially for communities with limited access to health care and other resources.

Mifepristone was first approved by the FDA in 2000 after an in-depth review of the evidence, and mifepristone's substantial record of safety and efficacy has only grown more compelling over time.¹⁴ Since its approval, more than five million people in the U.S. have used mifepristone for medication abortion and miscarriage management.¹⁵ The two-drug medication abortion regimen approved by the FDA, which involves taking one mifepristone pill and then—up to 48 hours later—taking four misoprostol pills,¹⁶ accounts for most abortions in the U.S. today.¹⁷ This FDA-approved medication abortion process has a 95% effective rate and has maintained a consistent safety record for nearly 25 years.¹⁸ Leading medical and scientific organizations recognize it as safe and effective, including the American Medical Association and the American College of Obstetricians and Gynecologists.¹⁹

Despite mifepristone's consistent safety record, when the FDA first approved mifepristone, it imposed unnecessary and burdensome Risk Evaluation and Mitigation Strategy (REMS) restrictions.²⁰ The REMS operated as a burdensome requirement specific to abortion-related medication that was not applied to medications with similar—or worse—safety records. For instance, mifepristone has a better safety record than household medications such as Viagra, penicillin, and acetaminophen (Tylenol).²¹ Over time, the REMS imposed on mifepristone have been modified by the FDA—including in 2016²² and 2023²³—resulting in an incremental elimination of these unnecessary restrictions on access.

The 2016 change to the REMS lifted the requirement that only physicians can prescribe mifepristone, allowing nurse practitioners, physician's assistants, and other providers to become certified to dispense mifepristone.²⁴ In 2021, in response to the COVID-19 pandemic, the FDA temporarily suspended enforcement of the REMS requirement that mifepristone be dispensed in person.²⁵ After years of continued safe and effective use of mifepristone, the FDA made these changes permanent in 2023, eliminating the

in-person dispensing requirement and making it possible for patients to access the drug at certified pharmacies.²⁶

The nationwide reliance on expanded medication abortion access, particularly following the loss of *Roe v. Wade*, cannot be overstated. According to data released on March 19, 2024, use of medication abortion has risen substantially between 2020 and 2024. Now, more than three out of five abortion patients in the U.S. use medication abortion.²⁷

Medication abortion allows patients to access care in regions where providers are limited, avoid the financial and logistical challenges of traveling long distances, and to have an abortion at a place of their choosing with the support of their community members and loved ones.²⁸ Medication abortion has been vital to bridging the gaps in care for communities facing the most obstacles to care, in particular through telehealth access in states where abortion is limited or severely restricted.²⁹ If the Supreme Court allows the reimposition of restrictions— as the Fifth Circuit Court of Appeals tried to do – it would have a drastic and immediate impact,³⁰ with the greatest effect on those communities, including Black, Indigenous, other people of color, people with low incomes, LGBTQ+ people, young people, immigrants, people with disabilities, and people living at the intersection of those identities.³¹ Individuals unable to access mifepristone may be forced to either undergo procedural abortions—which are also very safe but require in-person care—or forced to carry unwanted pregnancies to term.³²

The claims in this case are baseless and the case never should have been allowed to move forward, but it was purposely brought before sympathetic extremist judges.³³

AHM put forward baseless claims about the FDA's approval of mifepristone, citing discredited anti-abortion researchers and unreliable studies to assert that mifepristone is unsafe,³⁴ which flies in the face of mifepristone's overwhelming safety record and more than 100 peer-reviewed articles documenting its safety.³⁵

Not only is the litigation without merit, but the plaintiffs should not even have standing to bring this case.³⁶ AHM members do not provide abortion care, and AHM is not regulated by the FDA. The hypothetical circumstances they posit—of *maybe* having to provide emergency care to patients who take mifepristone—are speculative and unsupported by any evidence.³⁷

AHM strategically picked judges who would approve of these unsupported claims. AHM was purposely incorporated in Amarillo, Texas in order to bring a case before Judge Matthew Kacsmaryk,³⁸ a Trump-appointed with an extensive record³⁹ of hostility towards reproductive rights who has been willing to impose sweeping rulings with nationwide implications.⁴⁰ The lawsuit was filed in the Amarillo division of the Northern District of Texas, a single-judge division where the cases are automatically assigned to Judge Kacsmaryk.⁴¹

Instead of throwing out this baseless case, the extremist district court judge issued an unprecedented and far-reaching ruling that effectively banned mifepristone nationwide.

As expected, Judge Kacsmaryk sided with AHM on April 7, 2023, issuing an unprecedented and far-reaching ruling that the FDA's approval of mifepristone was unlawful, effectively imposing a nationwide ban on mifepristone.⁴² Judge Kacsmaryk stayed the FDA's nearly 25-year-old approval of the medication, but delayed enforcement for seven days to allow the government to appeal.⁴³ This decision created nationwide chaos, leaving clinics unclear on whether they would be able to provide medication abortion pills to patients if the ruling was enforced.⁴⁴

Judge Kacsmaryk relied on junk-science and since-retracted studies⁴⁵ from AHM's complaint to support his decision.⁴⁶ Judge Kacsmaryk took no efforts to conceal his anti-abortion biases throughout his decision, opting to forgo standard medical terms in favor of ideological terminology: calling medication abortion "chemical abortion," referring to abortion providers as "abortionists," and describing a fetus or embryo as an "unborn human" or "unborn child."⁴⁷

On appeal, the Fifth Circuit Court reinstated harmful and unnecessary barriers to medication abortion that, if upheld, would drastically restrict access.

The Fifth Circuit Court of Appeals is also notoriously hostile to reproductive rights.⁴⁸ On August 16, 2023, a panel of three judges recognized that Judge Kacsmaryk went too far in overturning the FDA's initial 2000 approval of mifepristone, but took the extraordinary and unprecedented step of reinstating the outdated pre-2016 REMS restrictions that had been lifted by the FDA.⁴⁹ The pre-2016 REMS were modified

for a reason, as the restrictions were deemed unnecessarily burdensome for—among other things—prohibiting people from receiving mifepristone in the mail or via telemedicine and significantly narrowing the scope of medical providers who may prescribe the medication, and requiring patients to go to three appointments in order to take the drug that can be safely administered at home.⁵⁰ The Fifth Circuit's flawed and dangerous decision parroted the same biased distortions of science and medicine that AHM put forth in their complaint, and accepted AHM's unsupported standing arguments.⁵¹

The Fifth Circuit's decision was wrong. It contradicts fundamental principles of law, ignores scientific and medical evidence, and would impede patient care and undermine patient safety, disrupting care nationwide.

The Biden Administration and the drug's manufacturer appealed this outrageous decision to the Supreme Court, and the court agreed to hear the case this term. The Court also decided on April 21, 2023, to maintain the status quo with respect to availability of mifepristone, including the FDA's decision to lift the prior REMS, for the duration of the litigation.

This decision could have major implications for drug approval and research.

If the Supreme Court upholds the Fifth Circuit decision, it could set a dangerous precedent that undermines FDA's authority for purely political reasons, with far-reaching implications for research and approval of new drugs.⁵² As the American Medical Association has said about this case, "[a]llowing courts to upend drug regulatory decisions by the FDA based on speculation, opinion or ideology goes against the long-established scientific process that leads to those careful decisions and puts every other drug at risk of finding itself subject to similar efforts."⁵³ That is why more than 350 representatives of drug companies and patient support groups, as well as a number of former FDA Commissioners, have weighed in with amicus briefs challenging the lower courts' decisions.⁵⁴

Ultimately, if the Supreme Court approves of this judicial interference with the FDA's expertise, it will mark a departure from the statutory framework created by Congress in which administrative agencies are vested with the power to regulate matters of public health.⁵⁵

Pregnant people deserve access to critical, safe, and effective medication, free of fear and baseless attacks on care.

If the Supreme Court upholds the Fifth Circuit decision, more than 64.5 million people will face increased barriers that will severely limit their access to a critical medication that is part of the most commonly used form of abortion care.⁵⁶ Mifepristone is safe and effective, and should be available to all who need it, so that they can make their own decisions about their bodies, lives, and futures.

ENDNOTES

- 1 For purposes of this factsheet, we will use FDA v. Alliance for Hippocratic Medicine to refer to a consolidation of two cases: Danco Laboratories, LLC, v. Alliance for Hippocratic Medicine and FDA v. Alliance for Hippocratic Medicine. Alliance for Hippocratic Medicine (AHM) are the lead appellees and are joined by three anti-abortion groups—American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), the American College of Pediatricians, and Christian Medical and Dental Associations—and their members as well as four individual doctors in challenging the FDA's approval of mifepristone. The Alliance Defending Freedom—an anti-abortion organization—is representing AHM and its fellow litigants. *U.S. Food and Drug Admin. v. All. for Hippocratic Med.*, ALL. DEFENDING FREEDOM (Mar. 6, 2024), <https://adfmmedia.org/case/us-food-and-drug-administration-v-alliance-hippocratic-medicine>. When AHM sought a preliminary injunction blocking the FDA's approval of mifepristone, Danco Laboratories, a manufacturer and distributor of mifepristone, intervened in the case. Brief for Danco Laboratories, LLC at 12, U.S. Food and Drug Admin. v. All. for Hippocratic Med., Nos. 23-235, 23-236 (petition for cert. filed Sept. 08, 2023) (Nos. 23-235, 23-236); https://www.supremecourt.gov/DocketPDF/23/23-236/279177/20230908115843401_2023-09-08%20Danco%20Cert%20Petition%20Final.pdf.
- 2 *Roe v. Wade*, 410 U.S. 113 (1973), overruled by *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022).
- 3 *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2284 (2022).
- 4 Jordan Smith, *The Shadow Medical Community Behind the Attempt to Ban Medication Abortion*, THE INTERCEPT (Mar. 6, 2024), <https://theintercept.com/2023/02/28/medication-abortion-lawsuit/>.
- 5 *Medication Abortions Accounted for 63% of All US Abortions in 2023, an Increase from 53% in 2020*, GUTTMACHER INST. (Mar. 19, 2024), <https://www.guttmacher.org/news-release/2024/medication-abortions-accounted-63-all-us-abortions-2023-increase-53-2020>.
- 6 Elise W. Boos, MD, et al., *Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020*, JAMA, 766, 766 (Jul. 21, 2003), <https://jamanetwork.com/journals/jama/article-abstract/2807775> (determining that mifepristone plus misoprostol is more effective in early miscarriage management than misoprostol alone, with a success rate of 84% compared to 67%); Priyanka R., et al., *Efficacy of mifepristone in the management of fibroid*, 11 INT. J. OF REPRODUCTION, CONTRACEPTION, OBSTETRICS & GYNECOLOGY 1214, 1218 (Apr. 2022), <https://www.ijrcog.org/index.php/ijrcog/article/view/11504/7264> (finding that mifepristone significantly improved the symptoms and health outcomes of patients suffering from Uterine fibroids). See also Dr. Kristyn Brandi, *What to Know About Abortion and Miscarriage With or Without Mifepristone*, THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (Mar. 6, 2024), <https://www.acog.org/womens-health/experts-and-stories/the-latest/what-to-know-about-abortion-and-miscarriages-with-or-without-mifepristone>.
- 7 Complaint, All. for Hippocratic Med. v. U.S. Food and Drug Admin., 668 F.Supp.3d 507 (N.D. Tex., 2023) (No. 2:22-cv-00223); <https://clearinghouse.net/doc/135215/>.
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- 9 Bridget Winkler, *Any Day Now, Extremist Trump-Appointed Judge Matthew Kacsmaryk Could End a Critical Abortion Option for People Nationwide*, NAT. WOMEN'S LAW CTR. (Mar. 1, 2023), <https://nwl.org/any-day-now-extremist-trump-appointed-judge-matthew-kacsmaryk-could-end-a-critical-abortion-option-for-people-nationwide/>.
- 10 *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 668 F. Supp. 3d 507, 560 (N.D. Tex 2023).
- 11 A three-judge panel of the Fifth Circuit granted, in part, a motion for a stay pending appeal on April 12, 2023, blocking the district court's ruling as it pertained to the initial 2000 approval of mifepristone but allowing the portions of the court's ruling on the 2016 and 2023 modifications to the approval to go into effect. *All. for Hippocratic Med. v. Food & Drug Admin.*, No. 23-10362, 2023 WL 2913725 (5th Cir. Apr. 12, 2023). On August 16, 2023, the Fifth Circuit upheld the district court's preliminary injunction with regard to the 2000 approval but reversed with regard to the 2016 and 2023 amendments. *All. For Hippocratic Med. v. Food & Drug Admin.*, No. 23-10362, 2023 WL 5266026 (5th Cir. Aug. 16, 2023).
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- 16 *Medication Guide Mifepristone tablets* at 18, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/media/164654/download?attachment> (last visited Mar. 7, 2024).
- 17 *The Availability and Use of Medication Abortion*, KFF (Sept. 28, 2023), <https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/>.
- 18 Ushma D. Upadhyay, et al., *Effectiveness and safety of telehealth medication abortion in the USA*, NATURE MEDICINE (Feb. 15, 2024), <https://www.nature.com/articles/s41591-024-02834-w>. See Nat'l Acad. of Sci., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 45, 56-68, 79 (2018) ("National Academies Report"), <http://nap.edu/24950>; ANSIRH, *Safety of Abortion in the United States*, Univ. of Cal., S.F.: Issue Brief # 6, 1, 1-2 (Dec. 1, 2014), <https://bit.ly/3JmawgA> (wisdom tooth complication rate is roughly 7%, compared to 2.1% of abortions; complication for tonsillectomies is approximately 4x higher than abortions); FDA Ctr. for Drug Eval. & Rsch., *Medical Review(s), Application No. 020687Orig1s020* at 5, 14-17 (Mar. 29, 2016) ("2016 FDA Approval"), <https://bit.ly/3n5zUzZ>, at 1, 50, 56. See also *A Private Choice for Early Abortion*, Danco, <https://www.earlyoptionpill.com/> (last visited Jan. 24, 2024) (brand name mifepristone has been used by over 5 million patients in the U.S.); *The Availability and Use of Medication Abortion*, KAISER FAMILY FOUND. (Sept. 28, 2023), <http://bit.ly/3nOLUme> (2.75 million people between 2000 and 2016 used brand-name mifepristone for an abortion).
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- 23 [Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=The%20January%202023%20modification%20to,Program%20is%20eligible%20for%20certification](https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=The%20January%202023%20modification%20to,Program%20is%20eligible%20for%20certification) (content current as of Sept. 9, 2023).
- 24 Laurie Sobel, et al., *Legal Challenges to the FDA Approval of Medication Abortion Pills*, KFF (Mar. 13, 2023), <https://www.kff.org/report-section/legal-challenges-to-the-fda-approval-of-medication-abortion-pills-key-findings/>.
- 25 Pam Belluck, *F.D.A. Will Permanently Allow Abortion Pills by Mail*, N.Y. TIMES (Dec. 16, 2021), <https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html>.
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- 30 *Alliance for Hippocratic Medicine v. FDA Court Case*, REPRODUCTIVE FREEDOM FOR ALL BLOG, <https://reproductivefreedomforall.org/resources/alliance-for-hippocratic-medicine-v-fda-court-case/> (last updated Feb. 15, 2024); *The Safety of Medication Abortion Care*, EMAA PROJECT, <https://emaaproject.org/wp-content/uploads/2023/07/Fact-Sheet-Medication-Abortion-20230717.docx.pdf> (last visited March 20, 2023).
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- 33 Jordan Smith, *The Shadow Medical Community Behind the Attempt to Ban Medication Abortion*, THE INTERCEPT (Mar. 6, 2024), <https://theintercept.com/2023/02/28/medication-abortion-lawsuit/>.
- 34 Press Release, Am. C. L. Union, *ACLU Calls Out Junk Science at the Heart of the Supreme Court Medication Abortion Case* (Jan. 30, 2024), <https://www.aclu.org/press-releases/aclu-calls-out-junk-science-at-the-heart-of-the-supreme-court-medication-abortion-case>; Sofia Resnick, *Study cited by Texas judge in abortion pill case retracted*, WASHINGTON STATE STANDARD (Feb. 6, 2024), <https://washingtonstatestandard.com/2024/02/06/study-cited-by-texas-judge-in-abortion-pill-case-retracted/>.
- 35 Amy Schoenfeld Walker, et al., *Are Abortion Pills Safe? Here's the Evidence*, N.Y. TIMES (Apr. 7, 2023), <https://www.nytimes.com/interactive/2023/04/01/health/abortion-pill-safety.html>.
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- 52 *Three Ways Patients Will Pay The Price*, EMAA PROJECT, <https://emaaproject.org/wp-content/uploads/2024/03/Patient-Access-to-other-FDA-approved-Medications.pdf>, (last visited March 20, 2024).
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