

# Conservative Texas judge weighs challenge to abortion pills

March 15 2023, by SEAN MURPHY and MATTHEW PERRONE



Boxes of the drug mifepristone sit on a shelf at the West Alabama Women's Center in Tuscaloosa, Ala., on March 16, 2022. A federal judge will hear arguments Wednesday, March 15, 2023, in a high-stakes court case that could threaten access to abortion medication and blunt the authority of U.S. drug regulators. Credit: AP Photo/Allen G. Breed, File

A conservative federal judge in Texas heard arguments Wednesday from a Christian group seeking to overturn the Food and Drug Administration's more than 2-decade-old approval of an abortion medication, in a case that [could threaten](#) the most common form of abortion in the U.S.

Lawyers for the Alliance for Defending Freedom asked Judge Matthew Kacsmaryk during the hearing in Amarillo, Texas, to issue an immediate order that would revoke or suspend the drug [mifepristone](#)'s approval. Such a step would be an unprecedented challenge to the FDA, which approved mifepristone in combination with a second pill as a safe and effective method for ending abortion in 2000.

During a 90-minute presentation to the court, alliance attorney Erik Baptist told the judge that removing mifepristone from the market "would restore proper policing power to the states"—a reference to last summer's U.S. Supreme Court ruling that overturned *Roe v. Wade* and left it to states to decide on the legality of abortion.

Mifepristone, when combined with a second pill, has become the most common method of abortion in the U.S. and has been increasingly prescribed since *Roe* was overturned.

Acknowledging the significance of the case, Kacsmaryk, who was appointed by then-President Donald Trump, asked Baptist if he could cite a prior example of a court removing an FDA-approved drug after many years on the market.

# Abortion drug challenged

Opponents of abortion are seeking a U.S. ban on mifepristone, one of two drugs commonly used in combination to induce abortion, arguing in federal court that the Food and Drug Administration approved the drug in 2000 without adequate evidence it was safe. How the two-drug regimen works:

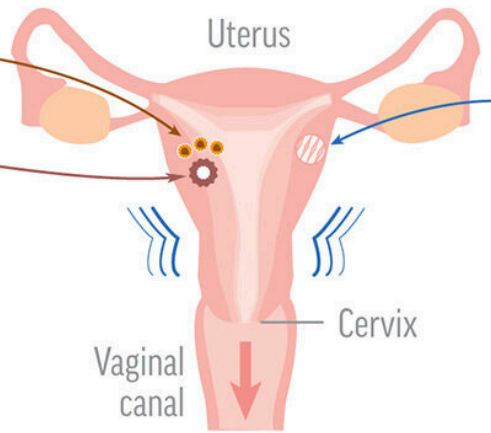
## THE DRUGS

**Mifepristone** and **misoprostol** are available by prescription and taken 24 to 48 hours apart. They are intended for use up to the 10th week of pregnancy, as measured from the start of the last menstrual period.

	6				
1	7				
2	8				
3	9				
4	10				
5					

## IN THE BODY

**Mifepristone** blocks the effectiveness of **progesterone**, a hormone key to maintaining pregnancy. This causes the lining of the uterus to thin, preventing the embryo from staying implanted in the uterine wall.



Misoprostol **triggers muscle contractions** in the uterus while also softening and dilating the cervix. The contractions expel the embryo and uterine tissues through the vagina.

Bleeding and cramping begin within 2 to 24 hours of taking the misoprostol. Health care providers should give instructions on follow-up checks for any complications and to be sure the pregnancy has ended.

Source: American College of Obstetricians and Gynecologists



A drug used as part of a medication abortion regimen is being challenged in federal court by abortion opponents. Credit: AP Graphic

Baptist acknowledged that there are no prior examples, but he blamed the drug's longevity on the FDA's "stonewalling" of his group's prior requests to remove the drug. The group petitioned the FDA in 2002 and in 2019 seeking to curb access to the pill.

Lawyers for the FDA are expected to argue that pulling mifepristone would upend reproductive care for U.S. women and undermine the government's scientific oversight of [prescription drugs](#).

Kacsmaryk gave each side two hours to make their arguments—with time for rebuttal—in the high-stakes case. Mifepristone's manufacturer, Danco Laboratories, will join the FDA in arguing to keep the pill available.

A ruling could come any time after arguments conclude. A decision against the drug would be swiftly appealed by U.S. Department of Justice attorneys representing the FDA, who would also likely seek an emergency stay to stop it from taking effect while the case proceeds.





People march through downtown Amarillo to protest a lawsuit to ban the abortion drug mifepristone on Feb. 11, 2023, in Amarillo, Texas. A federal judge will hear arguments Wednesday, March 15, 2023, in a high-stakes court case that could threaten access to abortion medication and blunt the authority of U.S. drug regulators. Credit: AP Photo/Justin Rex, File

One of the alliance's chief arguments against the FDA is that it misused its authorities when it originally approved the pill.

The FDA reviewed the drug under its so-called accelerated approval program, which was created in the early 1990s to speed access to the first HIV drugs. Since then, it's been used to expedite drugs for cancer and other "serious or life-threatening diseases."

The alliance, which was also involved in the lawsuit that led the Supreme Court to overturn Roe, argues that pregnancy is not a disease and therefore mifepristone should not have been considered for accelerated approval.

"The contrast between these illnesses and the FDA jamming pregnancy into ... the FDA regulations could not be more stark," Baptist told Kacsmark.

But the FDA says the group's argument is flawed on multiple counts. First, FDA regulations make clear that pregnancy is considered a "medical condition" that can be serious and life-threatening in some cases.



A women's march group member dons a kangaroo mask and judicial robe, Wednesday, March 14, 2023 in Amarillo, Texas. A federal judge in Texas appointed by former President Donald Trump is considering a request by a Christian conservative group to overturn the Food and Drug Administration's more than 2-decade-old approval of the abortion pill mifepristone. Credit: AP Photo/David Erickson

Second, while the FDA reviewed the drug under its accelerated approval regime, it didn't expedite the drug's review. In fact, approval only came after four years of deliberation. Instead, the FDA used regulatory powers under the accelerated program to add extra safety restrictions to mifepristone, including requiring physicians to be certified before prescribing it.

The hearing is the first in the case and is being closely watched by groups on both sides of the abortion issue in light of the reversal of Roe.. Removing mifepristone from the market would curtail access to abortion even in states where it's legal.

If Kacsmaryk rules against the FDA, it's unclear how quickly access to mifepristone could be curtailed or how the process would work. The FDA has its own procedures for revoking drug approvals that involve public hearings and scientific deliberations, which can take months or years.

If mifepristone is sidelined, clinics and doctors that prescribe the combination say they would switch to using only misoprostol, the other drug used in the two-drug combination. That single-drug approach has a slightly lower rate of effectiveness in ending pregnancies but is widely used in countries where mifepristone is illegal or unavailable.





Bottles of the drug misoprostol sit on a table at the West Alabama Women's Center, March 15, 2022, in Tuscaloosa, Ala. Misoprostol induces uterus contractions that expel an embryo or fetus and other tissue. A federal judge in Texas will hear arguments Wednesday, March 15, 2023, in a high-stakes court case that could threaten access to abortion medication and blunt the authority of U.S. drug regulators. The lawsuit from Christian conservatives aimed at overturning the Food and Drug Administration's approval of the abortion pill mifepristone. The drug, when used with a second pill, misoprostol, has become the most common method of abortion in the U.S. Credit: AP Photo/Allen G. Breed, File

In addition to challenging mifepristone's approval process, the lawsuit takes aim at several later FDA decisions that loosened restrictions on the



pill, including eliminating a requirement that women pick it up in person.

Lawyers for the FDA have pointed out that [serious side effects](#) with mifepristone are rare, and the agency has repeatedly affirmed the drug's safety by reviewing subsequent studies and data. Pulling the [drug](#) more than 20 years after approval would be "extraordinary and unprecedented," the government stated in its legal response.

© 2023 The Associated Press. All rights reserved. This material may not be published, broadcast, rewritten or redistributed without permission.

Citation: Conservative Texas judge weighs challenge to abortion pills (2023, March 15) retrieved 25 April 2024 from <https://medicalxpress.com/news/2023-03-texas-abortion-pills.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.