

Appeals court keeps abortion pill available, with restrictions

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A federal appeals court on Wednesday said the abortion pill

mifepristone could remain available for now. But the court's judges added some provisions to their ruling: A block on mailing the pill to patients as well as stays on other measures the federal government has taken recently to boost access to the medication.

The three-member panel partially overruled [Judge Matthew Kacsmaryk's](#) ruling in Texas last week, which said the U.S. Food and Drug Administration's approval of mifepristone back in 2000 was invalid.

Mifepristone is typically given as the first of two drugs used during a medication [abortion](#).

The U.S. Justice Department had filed its [appeal](#) of the Texas ruling on Monday. "If allowed to take effect, the court's order would thwart FDA's scientific judgment and severely harm women, particularly those for whom mifepristone is a medical or practical necessity," the appeal stated.

In its [preliminary ruling](#) filed on Wednesday, the [federal appeals court](#) suggested a statute of limitations bars any legal challenge to the FDA's approval of mifepristone. The court also seemed to consider the government's view that removing a long-approved drug from the market would have "significant public consequences."

But it left in place parts of Kacsmaryk's ruling that rolled back a loosening of restrictions on mifepristone by the FDA in recent years. That includes a 2016 move to allow the drug to be used through 10 weeks of pregnancy instead of the initial seven weeks, as well as a decision this year to allow retail pharmacies to dispense the pills.

The Justice Department is likely to appeal the latest order to the Supreme Court.

The battle over mifepristone was launched late last week.

The [Texas ruling](#) was swiftly followed by a ruling from Washington state federal judge [Thomas Rice](#) that ordered a halt to "any action to remove mifepristone from the market or otherwise cause the drug to become less available."

The two opposing rulings suggest that any final decision on the availability of mifepristone, which is typically given alongside misoprostol, may end up at the Supreme Court.

The [Washington state lawsuit](#) originated with Democratic attorneys general who were challenging restrictions in place that made it difficult to obtain mifepristone.

The Texas decision involves a lawsuit filed by a coalition made up of doctors and anti-abortion groups who sought an end to the use of mifepristone, claiming that the FDA's decision 23 years ago to approve the drug was made hastily and without proper regard for its overall safety.

In his decision, Kacsmaryk said that, "The court does not second-guess [the] FDA's decision-making lightly. But here, FDA acquiesced on its legitimate safety concerns—in violation of its statutory duty—based on plainly unsound reasoning and studies that did not support its conclusions. There is also evidence indicating FDA faced significant political pressure to forgo its proposed safety precautions to better advance the *political* objective of increased 'access' to chemical abortion."

'Not just Texas'

In a [statement](#) released Monday, President Joe Biden warned that

Kacsmark's ruling could affect medicines beyond mifepristone and affect Americans nationwide.

"If this ruling were to stand, then there will be virtually no prescription, approved by the FDA, that would be safe from these kinds of political, ideological attacks," he said.

Biden added that the ruling "does not just affect women in Texas—if it stands, it would prevent women in every state from accessing the medication, regardless of whether abortion is legal in a state."

And in an open letter published on Monday, hundreds of pharmaceutical executives also weighed in on the ruling, warning about the impact to their industry if the Texas order was to take effect.

"If courts can overturn drug approvals without regard for science or evidence, or for the complexity required to fully vet the safety and efficacy of new drugs, any medicine is at risk for the same outcome as mifepristone," the letter stated.

Medical abortion now accounts for about half of all abortions in the United States. With the overturning of *Roe v. Wade* last June, obtaining mifepristone and misoprostol for a [medical abortion](#) has been seen as a viable option for women who live in states affected by bans who might still want to obtain an abortion.

Mifepristone works by suppressing a hormone that's necessary for pregnancy to continue. The second drug, misoprostol, induces contractions similar to those seen in a miscarriage. In countries where mifepristone is hard to obtain, medical abortions often involve the use of misoprostol alone, although experts believe the efficacy of misoprostol alone is less than the two-drug combo, and side effects such as nausea become more common.

Doctors' groups concerned

Reaction to last week's Texas ruling from abortion rights proponents and opponents was swift.

The American College of Obstetricians and Gynecologists (ACOG) condemned the Texas ruling. In a [joint statement](#), ACOG president [Dr. Iffath Abbasi Hoskins](#) and CEO [Dr. Maureen Phipps](#) called the decision " a grievous legal overstep into America's well-established regulatory system."

"Mifepristone has been used safely and effectively for medication abortion for more than two decades," Hoskins and Phipps said. "That safety and efficacy is backed up by robust, evidence-based, clinical data and its observed use by millions of people with support from clinicians, including obstetrician-gynecologists. Regardless of the opinion of one judge on this matter, mifepristone is a safe, effective part of comprehensive health care."

"Today's decision is clearly a transparent effort to make it harder for people to access medication abortion," they added. "It will force people to turn to other means of accessing abortion care; it will force clinicians to prescribe less safe, less effective regimens for medication abortion; and it will impose greater harm on those who already struggle to access needed reproductive health care, thus increasing health inequities."

The American Medical Association (AMA) issued a similar [statement](#).

"There is no evidence that people are harmed by having access to this safe and effective medication," said AMA president [Dr. Jack Resneck Jr.](#) "To the contrary, there is substantial evidence that the denial of needed abortion care without justification carries a psychological, physical and economic toll."

Resneck added that any decision by the courts to rescind FDA approval of mifepristone could set a dangerous precedent for other medications Americans use every day.

"This decision introduces the extraordinary, unprecedented danger of courts upending longstanding drug regulatory decisions by the U.S. Food and Drug Administration [FDA]. Doing so goes against the established scientific process that leads to those decisions and puts other drugs at risk of being subject to similar efforts," he said.

Future uncertain

In a [statement](#) issued Friday [Carol Tobias](#), president of National Right to Life, a group opposing abortion access, supported Kacsmark's decision.

"This decision shines a light on something that the Biden Administration wants to sweep under the rug—that these drugs do not treat or cure disease but kill unborn children and expose their mothers to dangerous side effects. The FDA should be in the business of ensuring safety, not in taking lives," she said.

For its part, Danco Laboratories, one of two companies that make mifepristol, said it will fight to provide its drug (Mifeprex) to women.

"Danco affirmatively joined the case as a defendant to protect the availability of Mifeprex for pregnant women and the company's only product, recognizing the importance of mifepristone as the only [drug](#) approved for medication abortion," the company said in a [statement](#).

The company estimates that over 5 million women have used Mifeprex to undergo medical abortion since its approval in 2000, noting that it is 97% effective in terminating early pregnancy.

Even if the decision to rescind [mifepristone](#)'s FDA approval is ultimately upheld, experts believe most American women could still access medical abortion, since misoprostol would still remain legal.

More information: Find out more about medical abortion at the [Cleveland Clinic](#).

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