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Appeals court keeps abortion pill on the market but sharply limits access

The court blocked the use of mifepristone beyond seven weeks of pregnancy and barred its distribution by mail.

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Mifepristone has been used for decades as part of a two-drug regimen to induce an abortion in the first trimester of pregnancy — in combination with the drug misoprostol. | Phil Walter/Getty Images

A federal appeals court ruled late Wednesday that an abortion pill can remain on the market but only under strict conditions that prohibit its use beyond seven weeks of pregnancy and bar its distribution by mail.

In a [42-page order](#), a three-judge panel of the 5th Circuit Court of Appeals agreed to temporarily block the central aspect of a Texas-based federal judge's ruling that [suspended the FDA's 2000 approval](#) of the drug, mifepristone. But by a 2-1 vote, the panel permitted other aspects of that ruling to take effect that would block a seven-year effort by the FDA to widen access to the drug.

Among the policies temporarily blocked by the court's order: the FDA's decision to expand mifepristone's availability until the 10th week of pregnancy; authorization for retail pharmacies to dispense the drug; eliminating the requirement for in-person office visits to obtain a mifepristone prescription and allowing physicians to prescribe the pills via telemedicine; allowing non-physicians to prescribe or administer the drug; and ending a requirement for prescribers to report "non-fatal adverse events" related to mifepristone.

Reining in the drug's availability while keeping it on the market is likely to dramatically diminish its usefulness to patients seeking to terminate pregnancies in Republican-led states where severe restrictions on abortion kicked in or were passed after the Supreme Court overturned the federal constitutional right to abortion last June. The decision will also significantly hamper access in blue states that have sought to maintain broad access to the pills — both for their own residents and for the surge of patients traveling across state lines to terminate their pregnancies.

Mifepristone has been used for decades as part of a two-drug regimen to induce an abortion in the first trimester of pregnancy — in combination with the drug misoprostol. It now accounts for more than half of all abortions in the United States.

The Biden administration and abortion rights activists have sought to ease access to abortion medication by mail as an alternative to surgical abortion, which is easier for states to restrict as a practical matter.

Anti-abortion groups, aware that the drug is being used to circumvent state bans, sued to revoke the 23-year-old federal approval of the drug as well as the FDA's more recent policies to expand its access. Last week, Judge Matthew Kacsmaryk, a Texas-based appointee of former President Donald Trump, suspended both the original approval and the expanded-access policies, setting up what is likely the most consequential legal battle over abortion since the high court's 5-4 decision last June overturning *Roe v. Wade* after nearly half a century.

The Biden administration is expected to ask the Supreme Court to intervene immediately. It can ask the justices to grant an emergency order putting all aspects of Kacsmaryk's ruling on hold while the appeals process continues.

Justice Department spokespeople, representatives for the drug's main manufacturer, Danco Laboratories, and for the anti-abortion groups seeking to block access to the medication, did not immediately respond to requests for comment early Thursday.

Without the high court's intervention, the 5th Circuit's ruling limiting access to the drug will take effect at the end of this week. The appeals court panel consisted of Judges Andrew Oldham and Kurt Engelhardt, who are both Trump appointees, and Judge Catharina Haynes, an appointee of former President George W. Bush. Haynes indicated she would have kept Kacsmaryk's entire ruling on hold until a subsequent panel had a chance to consider the merits of the case.

Oldham and Engelhardt said suspending the original approval of mifepristone would have untenable consequences, but in a ruling issued shortly before midnight on

Wednesday, they defended their decision to allow the other portions of Kacsmaryk's ruling to stand.

"This is an exceedingly unusual regime," the judges wrote, referring to the FDA's relaxation of restrictions around the drug. They said the agency "chose to cut out doctors from the prescription and administration of mifepristone." And they disputed the agency's contention that the drug is just as safe as ibuprofen.

The Justice Department defended the drug's safety record earlier this week in [court papers](#). "FDA made those changes after fifteen years of adverse event data that showed 'known risks occurring rarely,'" the government's lawyers wrote. "By that point, mifepristone's 'well-characterized safety profile' was firmly established. Serious adverse events were 'exceedingly rare,' as demonstrated by eleven different studies and data from 'well over 30,000 patients.'"

The appeals court opinion — like Kacsmaryk's ruling last week — frequently deployed language more commonly associated with anti-abortion advocates, such as referring to the medication as "chemical abortion" and the follow-up procedure sometimes needed after a patient takes the pills in the first few weeks of pregnancy as "remov[ing] an unborn child."

Kacsmaryk's ruling appeared to be the first time that a judge ever suspended the FDA's approval of a drug, according to legal experts. Few conservative legal authorities stepped forward to defend the ruling, which the the Justice Department faulted for an "extravagant" interpretation of legal standing.

At an event Wednesday focused on reproductive rights, Vice President Kamala Harris said Kacsmark's decision amounted to "what could very righteously be considered a nationwide ban."

Flanked by Attorney General Merrick Garland and Health and Human Services Secretary Xavier Becerra, Harris stopped just short of accusing Kacsmark of acting for political, rather than legal, reasons.

"We have, in effect, a situation where politicians and politics have driven lawyers to go to a court of law where a judge who is not a medical professional is making a decision to undo the ruling 20 — over 20 — years ago of the FDA that declared a specific medication safe and effective for the American people," the vice president said.

Garland also warned that permitting judges to second-guess drug approval decisions would invite future challenges going far beyond the abortion drug in question.

"This could happen to any medication that Americans rely on, no matter how essential it is. And no matter how long ago it was approved," the attorney general said.

The president of the American Medical Association, Jack Resneck Jr., issued a similar warning Thursday morning in response to the 5th Circuit's ruling, saying the decision "would still roll back mifepristone access, favor ideology and pseudoscience over facts, harm patients and establish dangerous precedent of judges without scientific training overriding FDA expertise."

Anti-abortion groups cheered the middle-of-the-night ruling as an endorsement of their core criticisms of the FDA.

"From a pro-life perspective, this very evidence-based rejection of Biden's weakened health and safety standards for chemical abortion pills is good news for women," Kristi Hamrick, the spokesperson for Students for Life, said in a statement. "A sloppy, Roe v. Wade mentality allowed the drug to proceed as it impacted the preborn in the first months of life. But those issues are being looked at now."

Kacsmark's decision last week was handed down just minutes before another federal judge, who sits in Spokane, Wash., issued an order requiring the FDA to maintain current procedures for access to the drug in 17 states and Washington, D.C. U.S. District Court Judge Thomas Rice acted at the request of state attorneys general who [filed a suit](#) challenging the FDA's remaining restrictions on mifepristone as unnecessary and unjustified.

[The dueling decisions appeared to pull federal authorities in different directions](#), although it was unclear whether they were in direct conflict.

On Monday, Justice Department attorneys asked Rice to clarify his order in light of the ruling from Texas. He has not yet responded to the request.

The 5th Circuit panel said Rice's order did not impact their ruling. "We cannot embrace an argument that would, in effect, allow the decision of an out-of-circuit district court to impel us towards 'extraordinary' relief that would be otherwise inappropriate," the appeals court panel's majority wrote.

Abortion providers around the country say they are preparing to administer medication abortions using misoprostol alone if courts cut off access to mifepristone. While misoprostol-only abortions have been common in other countries for many years and groups including the American College of Obstetricians and Gynecologists consider them safe and effective, they carry a higher rate of complication and more severe side effects than the two pills used together.

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