## US Supreme Court protects access to abortion medication



Justices did not address claims that mifepristone endangered patients and that its approval by the FDA was flawed. Opponents vow to continue the legal fight. Susan Jaffe reports.

In a rare unanimous ruling on June 13, the US Supreme Court allowed continued distribution by mail of an abortion drug in a lawsuit filed by anti-abortion doctors seeking to restrict its use. The justices decided the case on narrow grounds, claiming that the doctors did not prove they were injured by the drug and so had no right to sue. The court's dodge all but guarantees that another legal challenge will be heading their way.

The court did not address opponents' claims that the Food and Drug Administration (FDA) erred by approving the drug mifepristone (Mifeprex) in 2000 and by easing some prescription requirements in 2016 and 2021. It also did not consider claims that the 1873 Comstock Act, a largely ignored federal anti-obscenity law, prohibits mailing drugs or other materials used for an abortion.

"Mifepristone is accessible and does not have any new restrictions in states where it is legal", Jacqueline Ayers, Senior Vice President of Policy Campaigns and Advocacy for the Planned Parenthood Action Fund, told reporters.

"We breathe a sigh of relief knowing that millions of people who rely on this essential medication every day in states across the country will continue to get the care they need and that they deserve", said Ayers.

"We should not be dazzled by the fact that the Supreme Court did the right thing here", said Julia Kaye, a senior staff attorney at the American Civil Liberties Union's (ACLU's) reproductive freedom project. "The question of whether these anti-abortion groups had legal standing to bring this case was an easy one."

The ruling comes 2 years after the court's decision in Dobbs v Jackson Women's Health Organization overturning Roe v Wade,

which established a constitutional right to abortion in 1973. Since the *Dobbs* case, 14 states have enacted a total ban on abortion, and another 27 forbid abortions after as little as 6 weeks of pregnancy, and most restrictions allow exceptions to protect the life of the mother. Abortion providers have said such exceptions are difficult to apply in emergency situations.

Last year, federal district court Judge Matthew Kacsmaryk in Texas, known for his anti-abortion views, overturned

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the FDA's approval of mifepristone—the first court to cancel an FDA drug determination. But shortly after, a Washington state federal court judge agreed with 17 states and the District of Columbia that the FDA must not restrict access to medication abortions. The Biden administration appealed Kacsmaryk's ruling to the Supreme Court along with mifepristone's manufacturer, Danco Laboratories.

Despite the convoluted patchwork of state abortion bans and restrictions, medication abortions accounted for 63% of the abortions provided in the USA last year, a 10% increase compared with 2020, said Candice Gibson, Director of State Policy at the Guttmacher Institute. Mifepristone is also used for druginduced abortions in approximately 80 countries, including the UK, Sweden, and France.

"Efforts to second-guess the FDA's scientific judgment and roll back access to mifepristone were based on a sham case that not only lacked standing, but relied on speculative allegations and ideological assertions to undermine decades of rigorous scientific review", said Bobby Mukkamala, President-Elect of the American Medical Association (AMA), in a statement. "The drug is highly safe and effective for both termination of pregnancy and for medical management of miscarriage." The AMA joined the American College of Obstetricians and Gynecologists and ten other medical organisations that filed amicus briefs in support of the FDA.

As the preferred abortion method in the USA, medication abortion will remain a legal target, said Nancy Northup, President and CEO of the Center for Reproductive Rights, in a statement. "The anti-abortion movement sees how critical abortion pills are in this post-Roe world, and they are hell bent on cutting off access. In the end, this ruling is not a 'win' for abortion—it just maintains the status quo, which is a dire public health crisis in which 14 states have criminalized abortion."

President Joe Biden, a Democrat who supports abortion access and is running for re-election, praised the Supreme Court's decision but warned that "attacks on medication abortion are part of Republican elected officials' extreme and dangerous agenda to ban abortion nationwide".

The Republicans' presumptive presidential nominee, former President Donald Trump, has frequently taken credit for the *Dobbs* ruling, citing his appointment of three justices who supported overturning *Roe*. Asked to comment on the mifepristone case, Trump campaign spokesperson Karoline Leavitt said, "President Trump has been very clear—he supports the rights of states to make decisions on

For details on state abortion restrictions and exceptions see https://www.guttmacher.org/state-policy/explore/state-policies-abortion-bans

For more background on the mifepristone lawsuit see World Report Lancet 2023; 401: 1325–26

abortion, and supports exceptions for abortions in cases of rape, incest, and life of the mother."

The decision, written by Associate Justice Brett Kavanaugh, appointed by Trump in 2018, came in a lawsuit against the FDA by the Alliance for Hippocratic Medicine, a coalition of anti-abortion medical groups, and four doctors. The drug's manufacturer, Danco Laboratories, joined Biden administration lawyers to defend the FDA.

The plaintiffs asked the court to reverse the agency's rules that made the drug more accessible, including allowing patients to receive mifepristone in the mail, without seeing a health-care provider in person. Because the doctors contended that the drug was unsafe, they claimed they would eventually have to provide emergency treatment to patients experiencing complications after taking it. Delivering that type of care would violate their right to refuse to participate in medical procedures that go against their religious beliefs or moral convictions.

"We are disappointed that the Supreme Court did not reach the merits of the FDA's lawless removal of commonsense safety standards for abortion drugs", Erin Hawley, senior counsel for the alliance, said in a statement. "The FDA recklessly leaves women and girls to take these highrisk drugs all alone in their homes or dorm rooms, without requiring the ongoing, in-person care of a doctor."

But Kavanaugh found that patients were not a party to the lawsuit and the anti-abortion doctors were not a good substitute. He said they neither prescribed nor used mifepristone. He continued: "The plaintiffs have not identified any instances where a doctor was required, notwithstanding conscience objections, to perform an abortion or to provide other abortion-related treatment that violated the doctor's conscience since mifepristone's 2000 approval."

Kavanaugh also defined those federal conscience-based protections more broadly than previous court interpretations, said Mary Ziegler, a law professor at the University of California, Davis School of Law, who has written extensively about the legal history of abortion. "According to Justice Kavanaugh, the physician can just say 'I don't want to do that', regardless of what interests the patient has, or who else is present to treat the patient", she said. The protections apply to the doctor's beliefs not particular procedures, Kavanaugh wrote, "even in a socalled health care desert, where other doctors are not readily available".

The FDA approved mifepristone in 2000, and it is usually taken in combination with misoprostol to complete an abortion. Mifepristone is also used to induce labour and treat miscarriages. In 2016, the FDA allowed nurse practitioners and other health-care providers to prescribe the drug, permitted use up to 10 weeks of pregnancy instead of 7 weeks, and required one in-person visit with a health-care provider instead of two. In 2021, during the COVID-19 pandemic, the FDA lifted the in-patient visit requirement.

Even if the plaintiffs had proven they had suffered harm due to the FDA mifepristone rules, the solution they demanded was extreme, said Associate Justice Ketanji Brown Jackson, appointed by President Joe Biden, during oral arguments in March. The plaintiffs essentially argued that "because we object to having to be forced to participate in this procedure, we're seeking an order preventing anyone from having access to these drugs at all", she said. "And I guess I'm just trying to understand how they could possibly be entitled to that given the injury that they have alleged".

Ziegler said that the court's decision does not settle the issue. "In theory, other plaintiffs with standing could still bring those claims to the Supreme Court", she said. The plaintiffs most likely to resurrect the case against mifepristone are state officials in Idaho, Kansas, and Missouri. Kacsmaryk granted the states' request to intervene in the doctors' lawsuit but the Supreme Court did not. The states had argued in the district court that their injuries were financial because some residents who received medication abortions elsewhere would require medical care funded by the state Medicaid programme for complications experienced when they returned home.

The states could also argue that the availability of medication abortion elsewhere allows their citizens to circumvent their home states' abortion restrictions. "But it's not clear that it's a slam dunk", said Ziegler. It depends on whether a state can prove it incurred financial losses or that its residents disobeyed local abortion laws. Kansas Attorney General Kris Kobach said the states have such evidence. "It is essential that this case continue in order to ensure that the FDA operates within the law", he said in a statement.

States opposing mifepristone may be more persuasive in court than the doctors, Sarah Parshall Perry, Senior Legal Fellow for the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation, told reporters. "A state in bringing suit on behalf of, for example, a number of women who may have been injured from complications of the use of mifepristone might have more success", she told reporters on a conference call. States could also claim increased costs for injured women insured under the state Medicaid programme.

But the ACLU's Julia Kaye disagrees. Like the anti-abortion groups who failed to convince the Supreme Court last week, the states "rely on speculative chains of hypotheticals", she said. "The states also cannot show that whatever harms they are alleging are actually caused by the FDA's actions".

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