TuSalud

At Stake in Mifepristone Case: Abortion, FDA's Authority, and Return to 1873 Obscenity Law

Court rulings could upend the drug regulatory scheme established by Congress and implemented by the Food and Drug Administration.

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Lawyers from the conservative Christian group that won the case to overturn Roe v. Wade are returning to the U.S. Supreme Court on Tuesday in pursuit of an urgent priority: shutting down access to abortion pills for women across the country.

The case challenges the FDA's regulation of mifepristone, a prescription-only drug approved in 2000 with a stellar safety record that is used in 63% of all U.S. abortions.

Viewed across decades of anti-abortion activism, the case brought by the Alliance Defending Freedom represents a "moonshot" couched in technical arguments about pharmaceutical oversight and the resuscitation of an 1873 anti-obscenity law. A victory would lay the groundwork for a de facto nationwide abortion ban.

Abortion is illegal in 14 states, but abortion pills have never been more widely available.

During the covid-19 pandemic, the FDA suspended — and later formally lifted — the requirement that patients be at a health care facility when taking mifepristone, the first of two pills used in medication abortion. Physicians can now prescribe the drug online through telemedicine and pharmacies can dispense it through the mail.

"You don't need to be handed the pill in the office," said Linda Prine, a family medicine physician, sitting on a couch in her Manhattan apartment answering texts and calls from patients about abortion care.

"It's very effective," she said. "I don't even have medications that are 98 to 99% effective. Our blood pressure medicines aren't effective like that."

Prine, a co-founder of the Miscarriage and Abortion Hotline, works with other doctors operating under New York state's shield law to prescribe and send abortion pills to people across the country. A review of Prine's call log, stripped of personal information, showed hundreds of requests

for pills from Texas, Louisiana, Tennessee, and other states where it is illegal for women to stop a pregnancy.

Anti-abortion groups unsuccessfully petitioned the FDA at least twice before, in 2002 and 2019, to revoke mifepristone's approval and curtail its availability. But in November 2022, following its victory in overturning federal abortion rights, the Alliance Defending Freedom filed a federal lawsuit in Amarillo, Texas, claiming the FDA's safety review of mifepristone was flawed.

U.S. District Judge Matthew Kacsmaryk, who was appointed by President Donald Trump and openly opposes abortion, ruled to invalidate the FDA's approval of mifepristone. An appeals court later said the drug should remain available, but it reinstated restrictions, including prohibitions on telehealth prescriptions and mailing the medication. That ruling was put on hold while the Supreme Court considers the case.

The Biden administration and a manufacturer of mifepristone, Danco Laboratories, have argued in legal filings to the Supreme Court that federal judges do not have the scientific and health expertise to evaluate drug safety and that allowing them to do so undermines the FDA's regulatory authority.

That view is supported by food and drug legal scholars who wrote in court filings that the lower courts had replaced the "FDA's scientific and medical expertise with the courts' own interpretations of the scientific evidence." In doing so, they wrote, the courts "upend the drug regulatory scheme established by Congress and implemented by FDA."

In his ruling, Kacsmaryk cited two studies purporting to show an increase in emergency room visits and a greater risk of hospitalizations from medication abortion. They were retracted in February by medical publisher Sage Perspectives. The journal said the researchers erred in their methodology and analysis of the data and invalidated the papers "in whole or in part."

The research, supported by the Charlotte Lozier Institute, an anti-abortion group that filed a brief in the mifepristone case, "made claims that were not supported by the data," said Ushma Upadhyay, a professor of reproductive sciences at the University of California-San Francisco.

Legal scholars say the Supreme Court's conservative justices have demonstrated a willingness to accept discredited abortion-related health claims. Justice Samuel Alito, writing the majority opinion in Dobbs v. Jackson Women's Health Organization, which overturned the constitutional right to abortion, cited statements about harm to maternal health presented by the state of Mississippi that contradict mainstream medical consensus.

"If this case is successful, it will be because the Supreme Court decided to ignore evidence that demonstrated mifepristone's safety and said to a federal agency, the expert on drug safety, 'You were wrong,'" said Rachel Rebouché, dean of Temple University Beasley School of Law.

The mifepristone case crystallizes "the politicization of science" in abortion regulation, Rebouché said. "But the stakes are getting higher as we have courts willing to strip federal agencies of their

ability to make expert decisions."

Rebouché said that if the Supreme Court overrides the FDA's expertise in regulating a 24-year-old drug like mifepristone, anti-abortion groups, like Students for Life of America, could find judges receptive to false claims that birth control pills, intrauterine devices, emergency contraception, and other forms of hormonal birth control cause abortion. They do not, according to reproductive scientists and U.S. and international regulatory agencies.

Justice Clarence Thomas wrote in his concurring opinion in Dobbs that the Supreme Court should reconsider the 1965 decision that guaranteed a constitutional right to contraception, Griswold v. Connecticut, and decide whether to return the power to allow or regulate access to birth control to the states.

Tucked into the Alliance Defending Freedom's filings is what scholars describe as an audacious legal strategy once on the fringes of the conservative Christian movement: an appeal to the Supreme Court's conservative members to determine that the Comstock Act, a dormant 1873 anti-vice law, effectively bans medical and procedural abortion nationwide.

Passed at a time when the federal government did not give women the right to vote and the prevailing medical literature summed up women's sexuality by saying that "the majority of women (happily for them) are not very much troubled with sexual feelings of any kind," the long unenforced law carried a five-year prison sentence for anyone mailing "every article, instrument, substance, drug, medicine or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion."

References to the Comstock Act appear throughout anti-abortion legal filings and rulings: Kacsmaryk wrote that the act "plainly forecloses mail-order abortion in the present"; the 5th Circuit Court of Appeals wrote if Comstock was "strictly understood" then "there is no public interest in the perpetuation of illegality"; Republican attorneys general threatened legal action against Walgreens and CVS last year citing Comstock as did anti-abortion cases in New Mexico and Texas.

"State attorneys general need to go after and prosecute those who are illegally mailing abortion drugs into their state," said Kristan Hawkins, president of Students for Life of America.

"It's very simple. If your state has passed a law saying that preborn human beings deserve, at the very minimum, the right not to be starved and killed," she said, "then those who are committing those crimes and violating the federal Comstock Act by shipping chemical abortion pills over state lines, there should be consequences."

Tracking abortion pills by mail is difficult — and that's the point, Rebouché said.

"These more diffuse and mobile ways to terminate a pregnancy," she said, "really threaten the control that anti-abortion advocates seek to exercise over who and where and how someone can seek an abortion."

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