Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

Medication Abortion: A Changing Legal Landscape

Updated July 1, 2022

Following the Supreme Court's recent decision in *Dobbs v. Jackson Women's Health Organization*, questions have been raised about continued access to medication abortion, a pregnancy termination method involving the use of prescription drugs regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Recent attention has centered on the availability of these drugs, as the drugs' availability may allow those residing in areas with few or no abortion providers to have access to an elective abortion. The Food and Drug Administration (FDA) regulates the distribution of mifepristone (sold under the brand name Mifeprex), and the agency's current policies allow the drug to be prescribed via telehealth and sent to patients through the mail under specified conditions. At the same time, state legislatures have taken steps to regulate access to medication abortion, including, since the Court's decision in *Dobbs*, proposing specific bans on medication abortion drugs under particular circumstances. Prior to *Dobbs*, such restrictions may have been subject to legal challenge based on the Court's abortion decisions in *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, as well as other cases that recognized a woman's constitutional right to terminate a pregnancy. Now that the Court's majority opinion in *Dobbs* has overruled *Roe* and *Casey*, a state's ability to restrict or prohibit access to these drugs may solely depend on the interplay between state and federal law. This Legal Sidebar explores federal regulations of medication abortion drugs under the FD&C Act, state efforts to regulate access to medication abortion and issues regarding federal preemption, and considerations for Congress.

FDA Regulation of Medication Abortion

According to recent data published by the Centers for Disease Control and Prevention, medication abortions represented approximately 42% of all U.S. abortions by 2019. The medication abortion regimen involves using the prescription drug mifepristone, followed by a second drug, misoprostol, to terminate an early pregnancy. Similar to other prescription drugs available on the market, FDA evaluated and approved the medication abortion drugs pursuant to the agency's authority under the FD&C Act. As a condition of mifepristone's approval, FDA requires compliance with a risk evaluation mitigation strategy, or REMS. In general, a REMS is an FDA-imposed drug safety plan designed to ensure that the benefits of a drug with serious potential safety concerns outweigh its risks. While the mifepristone REMS has been modified over time, the current version requires health care professionals who prescribe the drug to be certified,

Congressional Research Service
https://crsreports.congress.gov
LSB10706

meet particular qualifications (e.g., the ability to accurately assess the duration of a pregnancy), and ensure that patients receive and sign a patient agreement form relating to mifepristone use.

The 2019 version of the REMS specified that mifepristone could only be dispensed in certain clinics, medical offices, and hospitals, or under the supervision of a certified prescriber (although a patient could take the drug in a different location, including the patient's home). After a lawsuit was filed over the enforcement of the REMS in-person dispensing requirements during the Coronavirus Disease 2019 (COVID-19) pandemic, FDA stated that it would suspend enforcement during the COVID-19 public health emergency. As enforcement remains currently on hold, FDA announced that data support long-term modifications to the REMS and that future modifications would remove the in-person dispensing requirements and add a new certification requirement for pharmacies that dispense mifepristone. While this REMS modification has not been formally implemented, it appears FDA's decision to modify the REMS was intended to allow patients to obtain medication abortion drugs without an in-person visit to a clinician and through the mail from certified prescribers or retail pharmacies.

State Restrictions on Medication Abortion

Aside from mifepristone regulation under the FD&C Act, numerous states have enacted laws that aim specifically to restrict access to medication abortion drugs. Using their police powers to regulate for public health, safety, and welfare, these states have established requirements related to the types of health care providers who may prescribe mifepristone and the conditions under which it must be prescribed. According to one recent report, 33 states provide that medication abortion drugs may only be prescribed by a licensed physician. In addition, the report identifies 19 states requiring the physician to be in the physical presence of the patient when prescribing these drugs, or place restrictions on the use of telehealth.

State restrictions on medication abortion have occasionally been subject to legal challenge. In 2012, the Supreme Court of Oklahoma invalidated Oklahoma's law barring persons in the state from using mifepristone in ways that contravened FDA's protocol on dosage and use of the drug. The court held that the state law impermissibly infringed on a person's right to obtain an abortion. The U.S. Supreme Court agreed initially to review *Oklahoma Coalition for Reproductive Justice v. Cline*, but it later dismissed the state's petition for certiorari as improvidently granted, preserving the state Supreme Court's judgment.

Following the *Dobbs* decision, a court reviewing a medication abortion law like the one at issue in *Cline* may now reach a different conclusion. In overruling *Roe* and *Casey*, the majority opinion in *Dobbs* not only held that the U.S. Constitution does not guarantee a right to abortion but also changed the standard under which laws restricting abortion are to be evaluated. Abortion restrictions will now be evaluated under rational basis review that is generally more deferential to lawmakers. Applying rational basis review, a court might conclude that a law prohibiting the use of mifepristone in ways that contravene FDA protocol is rationally related to a legitimate government interest, such as an interest in promoting patient safety and maternal health.

The Court's decision in *Dobbs* is also likely to have an impact on the availability of medication abortion in states that broadly prohibit all abortion methods. For instance, as of the date of this Sidebar, 13 states have adopted so-called trigger laws that prohibit abortion and take effect once a constitutional right to abortion is no longer recognized. Because many of these laws seem to apply to both surgical and medication abortions, the availability of mifepristone could be severely restricted in these states.

Medication Abortion After *Dobbs*: Considerations for Congress

Following the Court's decision in *Dobbs*, the evolving legal landscape surrounding medication abortion is increasingly complex. The mifepristone REMS and federal requirements relating to the conditions under

which the drug may be prescribed and dispensed to patients remain in effect. Against this backdrop, state provisions that limit the availability of these drugs (e.g., through telehealth or other measures) aim, in at least some instances, to restrict the drug's access beyond what federal law would otherwise permit. Some states are seeking to take these restrictions further and prohibit use of medication abortion generally. Questions may arise about federal preemption of these state laws and the extent to which states may impose requirements on medication abortion drugs that are subject to FDA regulation.

Pursuant to the Constitution's Supremacy Clause, federal preemption occurs when a validly enacted federal law supersedes an inconsistent state law. Preemption may occur in a variety of circumstances, including when it is "impossible for a private party to comply with both state and federal requirements," or if implementation of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

With respect to medication abortion drugs, a preemption inquiry may involve an analysis of the relationship between a state's police power to regulate health and safety matters, and FDA's central oversight role in determining the safety and efficacy of prescription drugs that are marketed in the United States. In a 2014 case that addressed these issues, *Zogenix, Inc. v. Patrick*, a federal district court examined a Massachusetts order that generally barred prescribing and dispensing an opioid medication, ZohydroER, based on concerns about diversion, overdose, and abuse. Despite the Commonwealth's argument that the order was a permissible exercise of its traditional state police powers, the district court issued a preliminary injunction against implementation of the order, concluding that Massachusetts' ban on the drug was an "obstruction" that undermined FDA's authority in making "drugs available to promote and protect the public health." Massachusetts later established other requirements for ZohydroER prescribers to take certain actions when prescribing the drug and pharmacies to take specified steps to prevent diversion of the drug, and the district court declined to enjoin the new requirements.

Other state requirements governing medication abortion may also be examined by courts. In an ongoing federal district court case, *Genbiopro, Inc. v. Dobbs*, a pharmaceutical company that markets and sells mifepristone is challenging Mississippi state provisions that, among other things, direct physicians authorized to prescribe an "abortion-inducing drug" to perform a physical examination of the pregnant patient and compel patients to ingest the medication in a physician's presence. The company argues, in part, that federal law preempts Mississippi's requirements, as they impermissibly conflict with FDA's established regimen for mifepristone and frustrate Congress's objectives in giving FDA authority to determine measures to address prescription drug risks. Mississippi, on the other hand, contends that Congress did not give FDA the power to override a state's authority to regulate the circumstances under which an abortion may be performed.

In *Dobbs*, the majority opinion maintained that it was returning the authority to regulate abortion "to the people and their elected representatives." Following the Court's decision, additional state abortion restrictions seem likely, and Congress may also consider federal legislation to regulate the procedure. Legislation that specifically addresses medication abortion has been in introduced in the 117th Congress. The Teleabortion Prevention Act of 2021 (H.R. 5136 and H.R. 626) would require an abortion provider to be "physically present at the location" of a medication abortion. A provider who violates the act would be fined not more than $1,000 or imprisoned for not more than two years, or both.

Those who support a right to abortion and access to medication abortion may promote legislation that would establish such a right in federal statute. If enacted, the Women's Health Protection Act of 2021 (WHPA) (H.R. 3755/S. 4132), introduced in the 117th Congress, would guarantee health care providers a statutory right to provide abortion services and preempt any state law that would limit or restrict that right. The bill would also establish a corresponding right for patients to obtain abortion services unimpeded by state law restrictions, such as pre-viability abortion prohibitions. The House passed the WHPA in September 2021, but the Senate has twice rejected cloture motions to proceed with consideration of the bill. A second bill introduced this Congress, the Reproductive Choice Act (S. 3713),

would codify the "essential holdings" of *Roe* and *Casey*, and provides that a state may not impose an undue burden on a woman's ability to have an abortion before fetal viability. If enacted, it appears that the bill would allow abortion restrictions to be evaluated under the standard established by *Casey*.

Questions involving the relationship between existing state medication abortion requirements and FDA's mifepristone regimen may also prompt additional federal legislation that clarifies the degree to which federal regulation of medication abortion drugs preempts state or local measures inconsistent with federal policy. To date, it appears that this kind of legislation has not been introduced.

Author Information

Jennifer A. Staman
Legislative Attorney

Jon O. Shimabukuro
Legislative Attorney

Disclaimer