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Legal Sidebar

Medication Abortion: New Litigation May Affect Access

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The Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* has spurred significant debate over federal and state regulation of medication abortion—a pregnancy termination method involving the use of prescription drugs. Recent attention has centered on how these drugs may provide broader access to elective abortion, particularly for those residing in areas with few or no abortion providers. The scope of federal and state authority to regulate medication abortion is the subject of a number of high-profile lawsuits that raise questions about the future availability of these products. This Legal Sidebar explores federal and state regulation of medication abortion drugs, ongoing litigation concerning medication abortion access, and selected legal considerations for Congress.

Background on FDA and State Regulation of Medication Abortion

According to recent data, medication abortions represent roughly half of all U.S. abortions. The medication abortion regimen typically involves using the prescription drug mifepristone (the only drug approved by the Food and Drug Administration [FDA] as an abortifacient), followed by a second drug, misoprostol, to terminate an early pregnancy. Like other prescription drugs available on the market, FDA evaluated and approved the medication abortion drugs pursuant to Federal Food, Drug, and Cosmetic Act (FD&C Act) requirements. Under current law, to market a new brand-name drug, a manufacturer must file a new drug application with FDA, which must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." FDA may approve an application if the application's sponsor (e.g., a drug manufacturer or marketer) demonstrates, among other things, that the drug is safe and effective under the conditions prescribed, recommended, or suggested in the product's labeling.

As a condition of mifepristone's approval, FDA currently requires compliance with distribution controls pursuant to a risk evaluation and mitigation strategy, or REMS. In general, a REMS is a drug safety plan that FDA may impose upon a determination that, among other things, the plan is "necessary to ensure that the benefits of the drug outweigh its risks." While the mifepristone REMS has been modified over time, the most recent version compels health care professionals who prescribe the drug to be certified; meet specified qualifications (e.g., the ability to assess the duration of a pregnancy accurately); and ensure that patients receive and sign a patient agreement form relating to mifepristone use. Earlier REMS versions

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also imposed more stringent controls on prescribing and dispensing mifepristone, including three mandatory in-person office visits to health care providers in certain specified health care settings (reduced to one in-person visit in 2016). In January 2023, an update to the REMS allowed patients to obtain the drug without an in-person visit to a clinician, including through the mail from certified prescribers or pharmacies.

Aside from FDA's regulation of mifepristone, several states have enacted measures to limit access to medication abortion drugs. Relying on their police powers to regulate for health, safety, and welfare, states have established requirements related to the types of health care providers who may prescribe mifepristone and the conditions under which the drug may be available. For instance, according to one recent report, numerous states provide that only licensed physicians may prescribe medication abortion drugs. The report also identifies many states that require health care providers to be in the patient's physical presence when prescribing these drugs or otherwise restrict the use of telehealth. Additionally, some states have adopted stricter requirements on medication abortion, including measures that prohibit access to these drugs except under narrow circumstances (e.g., following rape or incest). These types of state provisions aim, at least in some cases, to impede medication abortion access beyond what federal law would otherwise permit. Questions have arisen about the interaction between these federal and state regulatory regimes.

Litigation over Medication Abortion Access

In recent months, plaintiffs have filed cases that target medication abortion regulation. Among these cases, some involve federal mifepristone regulation and claims that FDA's actions relating to the drug are unlawful. Others challenge the validity of state medication abortion restrictions.

Challenges to Federal Regulation of Mifepristone

Some lawsuits contest FDA's actions with respect to mifepristone, but the basis for their claims is widely inconsistent. At least one suit alleges that FDA unlawfully approved mifepristone and that the drug should be removed from the market, while other suits contend that FDA inappropriately restricted access to mifepristone and that the medication should be easier to obtain.

In *Alliance for Hippocratic Medicine v. FDA (Alliance)*, plaintiff medical organizations and doctors sued FDA and Biden Administration officials, asking the U.S. District Court for the Northern District of Texas to vacate FDA's approval of mifepristone and other actions relating to the drug. Plaintiffs made several arguments about the validity of FDA's mifepristone regulation, including that the agency violated the Administrative Procedure Act (APA) by failing to examine and inappropriately disregarding scientific evidence in approving and setting distribution controls for the drug. Danco Laboratories, the company that sells the brand-name version of mifepristone, moved to intervene in the litigation and is also a defendant in the case. In response to these arguments, FDA countered that the plaintiffs lack standing to sue, the majority of their claims are untimely, and that the agency properly exercised its FD&C Act authority and applied its scientific expertise to make determinations about mifepristone that are entitled to "substantial deference." The agency also stressed the lawsuit's uniqueness, noting that FDA identified no other example "where a court has second-guessed FDA's safety and efficacy determination and ordered a widely available FDA-approved drug to be removed from the market."

The Texas district court sided with the plaintiffs and ordered a stay of FDA's approval of mifepristone and other FDA actions related to the mifepristone REMS, thus suspending the legal basis for the drug's sale and distribution nationwide. On appeal, the Fifth Circuit vacated the district court's order concerning FDA's approval of mifepristone, on the basis that the plaintiff's claims were likely time-barred. As the court explained, FDA originally approved mifepristone in 2000, and there was nothing that stalled the application of a six-year statute of limitations period related to federal administrative actions. However,

the court sustained the plaintiff's challenges to FDA's 2016 REMS amendments and subsequent actions that loosened requirements for obtaining the drug. The appeals court maintained that FDA failed to adequately consider relevant safety data in relaxing these distribution controls, and, as a result, the court reinstated the former, more rigorous pre-2016 controls on mifepristone. Following the Fifth Circuit's decision, the Justice Department announced it would petition the Supreme Court for review of the case. In the meantime, the Fifth Circuit's decision is stayed as the litigation proceeds, and mifepristone remains on the market under FDA's most recent controls for the drug (i.e., the 2023 REMS) during the pendency of the litigation.

In contrast, other suits claim that the 2023 mifepristone REMS unlawfully *constrains* access to the drug. For instance, in *State of Washington v. FDA*, attorneys general of 17 states and the District of Columbia filed suit, alleging, in part, that FDA's 2023 changes to the mifepristone REMS improperly hampers access to the drug and is "arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law" in violation of the APA. The state plaintiffs contended that the REMS restrictions are unduly burdensome to patients and unwarranted, particularly in light of what the plaintiffs describe as ample evidence regarding the drug's safety and effectiveness. In response, FDA and other federal defendants countered that FDA met its FD&C Act and APA obligations in concluding that the REMS is scientifically justified, necessary to ensure the drug's benefits outweigh its risks, and not unreasonably burdensome.

On April 7, 2023, the U.S. District Court for the Eastern District of Washington issued a preliminary injunction barring FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 [REMS] in Plaintiff States." The Washington district court determined that FDA failed to appropriately consider the drug's safety profile in imposing the REMS and clarified that regardless of a ruling in *Alliance*, FDA cannot alter the "the status or rights of parties" under the 2023 mifepristone REMS in the plaintiff states. In the wake of the district court's decision, a separate group of seven other states asked to intervene in the litigation in an effort to preserve abortion restrictions within their borders. On April 21, 2023, the court rejected this request, and the states appealed this decision regarding their participation in the lawsuit to the U.S. Court of Appeals for the Ninth Circuit.

Challenges to State Law Restrictions

In late January 2023, plaintiffs filed separate cases in North Carolina and West Virginia federal district courts, alleging, among other things, that the FD&C Act preempts state restrictions on medication abortion. Under federal preemption doctrine, federal law may implicitly override state law when, for instance, 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." In *Bryant v. Stein*, a North Carolina physician sued North Carolina's Attorney General and others, asserting that federal law preempts the state's medication abortion controls, including an in-person counseling requirement and a 72-hour waiting period. In the complaint, the physician claims that FDA developed a precise, data-driven set of regulatory controls for mifepristone and that the state "cannot stand in the shoes of FDA to impose restrictions on medication access . . . that upset the careful balance FDA was directed by Congress to strike." After the North Carolina Attorney General sided with the plaintiffs in *Bryant* and argued that federal law preempts the state's abortion restrictions, two North Carolina legislators intervened in the case to defend the state's medication abortion laws. The state legislators in the *Bryant* case have generally argued that the state restrictions on medication abortion are permissible as a way to promote and protect public health and that nothing in the REMS negates state laws that prohibit the prescription, administration, or use of these drugs. The district court has not yet issued a ruling on the preemption issues raised in this lawsuit.

On August 24, 2023, the U.S. District Court for the Southern District of West Virginia issued an opinion in *GenBioPro v. Sorsaia*, a legal challenge to West Virginia provisions that largely prohibit abortion

(including access to mifepristone) except under limited circumstances and bar health care providers from prescribing medication abortion drugs via telemedicine. In *Sorsaia*, a pharmaceutical company that sells the generic version of mifepristone sued West Virginia officials, claiming, in part, that federal law supersedes West Virginia's requirements because they impermissibly conflict with FDA's regimen for mifepristone and frustrate Congress's objectives in giving FDA authority to address prescription drug risks.

In responding to the defendant's motion to dismiss, the district court rejected the plaintiff's claims regarding the state's abortion prohibition, concluding that despite FDA's actions to regulate mifepristone, the prohibition withstood federal preemption. The court, however, sustained the plaintiff's challenge to West Virginia's telemedicine restriction because it "dictates the manner in which mifepristone may be prescribed," a decision Congress gave to FDA. The court's decision regarding the motion to dismiss may not have an immediate impact on the availability of mifepristone, and the litigating parties may choose to appeal this decision to the U.S. Court of Appeals for the Fourth Circuit. However, the recent decision is notable, in that it demonstrates a court's willingness to allow states to place limits on which pregnant patients may obtain this FDA-approved drug, but not the prescribing conditions under which those state-selected patients may receive the medication (i.e., via a telemedicine appointment).

Considerations for Congress

The cases discussed above may transform the legal landscape surrounding medication abortion and affect the conditions under which these drugs are accessible to pregnant patients. However, at least for now, mifepristone remains on the market, and the current federal regulatory framework (i.e., the 2023 mifepristone REMS) remains in place as the litigation proceeds. With respect to application of state law, future judicial decisions may clarify the extent to which states may impose their own requirements on medication abortion, given that FDA has established access controls for the drug. Congress may choose to await further legal developments in the litigation or may enact legislation that could affect the outcome of these cases.

Among possible legislative options, Congress could pass legislation that addresses the status of mifepristone as an FDA-approved drug or otherwise codifies federal standards for the prescribing or dispensing of medication abortion drugs. An example of this type of bill is the Protecting Life from Chemical Abortions Act (H.R. 384), which would, among other things, reinstate in-person dispensing requirements as part of the mifepristone REMS. Another example takes a different approach: the Protecting Access to Medication Abortion Act (S. 237 and H.R. 767) would generally require FDA to maintain the mifepristone REMS to allow patients to access prescriptions for mifepristone via telehealth and certified pharmacies to dispense the drug through the mail to patients (though the REMS would be able to be modified or removed based on "sound scientific evidence").

Congress could also clarify the degree to which federal regulation of medication abortion drugs preempts state measures inconsistent with federal policy. Such legislation could speak to the extent to which states may set controls on medication abortion drugs subject to FDA oversight. For example, the Protecting Reproductive Freedom Act from the 117th Congress (H.R. 8976) would have limited states' ability to impose restrictions on mailing medication abortion drugs across state lines or requirements that would compel the in-person prescribing or dispensing of the drugs. Additionally, at the end of the 117th Congress, the House passed H. Res. 1434. This resolution does not have the force of law but "reaffirms" that FDA can regulate reproductive health care products; that those federal requirements have a preemptive effect on state or local laws that limit access to those products; and that the U.S. Attorney General has the authority to take legal action against states or localities that restrict access to these products.

Alternatively, Congress may choose to pass legislation that expressly preserves a state's ability to regulate medication abortion drugs. For instance, the Protecting Pain-Capable Unborn Children from Late-Term Abortions Act (117th Congress, S. 4840) would have prohibited abortion, through the use of drugs or otherwise, under certain circumstances. The bill also would have specified that it could not be "construed to preempt or limit any Federal, State, or local law that provides greater protections for an unborn child" as compared to the relevant provisions under the legislation.

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