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Legal Sidebar

Medication Abortion: New Litigation May Affect Access

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After the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, there has been greater focus on federal and state regulation of medication abortion—a pregnancy termination method involving the use of prescription drugs. Recent attention has centered on how medication abortion 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 high-profile litigation that raises questions about the future availability of these products. Recently, two federal district courts issued conflicting decisions in litigation over current federal requirements for medication abortion. On April 21, 2023, the Supreme Court stayed enforcement of an order issued by a district court in one of those cases, leaving the current federal regulatory framework in place as the litigation proceeds. This Legal Sidebar explores federal and state regulation of medication abortion drugs, 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 requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). 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,

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the most recent version compels health care professionals who prescribe the drug to be certified; meet particular 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 also imposed other 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 the FDA's regulation of mifepristone, several states have enacted measures to limit access to medication abortion drugs. Using 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 more stringent 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 at least four cases that target the regulation of medication abortion. Two of the lawsuits concern federal mifepristone regulation and assert claims that FDA's actions relating to the drug are unlawful. The other two cases challenge the validity of state medication abortion restrictions.

Challenges to Federal Regulation of Mifepristone

Two lawsuits making their way through the court system contest FDA's actions with respect to mifepristone, but the basis for their claims are widely inconsistent. While one suit alleges that FDA unlawfully approved the use of mifepristone for terminating a pregnancy, the other suit claims that the 2023 mifepristone REMS unlawfully restricts access to the drug.

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 mifepristone approval in an effort to take the drug off the market. Plaintiffs made several arguments about the agency's initial approval and subsequent administrative actions related to the drug, including that FDA violated the Administrative Procedure Act (APA) when it (1) impermissibly used the so-called Subpart H regulations, a regulatory approval pathway that is only available for treating serious or life-threatening illnesses (and that pregnancy is not such an illness); (2) failed to examine or inappropriately disregarded scientific evidence in approving and setting distribution controls for the drug; and (3) improperly ignored the so-called Comstock Act, federal criminal provisions that restrict the distribution of drugs or other abortion-related articles through the mail or other carriers. 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." Additionally, FDA maintained that the agency need not consider the Comstock Act in regulating mifepristone, and that, in accordance with earlier judicial decisions and as addressed in a recent Justice Department memorandum, the Act is inapplicable when the product's sender intends for the product to be used lawfully.

On April 7, 2023, the Texas district court ordered a stay of FDA's approval of mifepristone, thus suspending the legal basis for the drug's sale and distribution nationwide. The court held, among other things, that in initially approving mifepristone under the Subpart H regulations, FDA overstepped its authority and improperly relied on "plainly unsound reasoning and studies that did not support its conclusions." The court also determined that the Comstock Act's restrictions on mailing abortion drugs prevent FDA from removing the in-person dispensing requirement, as included in the REMS. Defendants filed a notice to appeal with the U.S. Court of Appeals for the Fifth Circuit, as well as emergency motions to stay the district court's order while the appeal is ongoing.

The Fifth Circuit granted the defendants' motions in part. Noting that the court grants emergency stays in "extraordinary circumstances," the appeals court found that the defendants successfully made this "extraordinary" showing with respect to FDA's approval of mifepristone in 2000. The court suggested that because of a six-year statute of limitations provision, the plaintiffs' challenge to the drug's approval may be time-barred. However, the court declined to stay the district court's order relating to FDA's 2016 REMS change and subsequent actions on mifepristone. In other words, under the Fifth Circuit's order, FDA's approval of mifepristone would remain in effect pending appeal, along with the more stringent, pre-2016 distribution controls in place (including in-person dispensing requirements). The Justice Department, on behalf of FDA and Danco Laboratories, then petitioned the Supreme Court for an emergency stay of the district court's order pending appeal of the case.

On April 21, 2023, the Supreme Court granted this request, allowing mifepristone to remain on the market under FDA's most recent controls for the drug (i.e., the 2023 REMS) during the pendency of the litigation. In granting the stay, the Court's majority issued no opinion, while Justice Clarence Thomas indicated he would deny the stay. Justice Samuel Alito penned a dissent, expressing that he would have denied the stay on the basis that the petitioners failed to demonstrate they were likely to suffer irreparable harm as the case continues. The Fifth Circuit scheduled oral arguments in the *Alliance* case for May 17, 2023.

In contrast, attorneys general of 17 states and the District of Columbia filed suit in *State of Washington v. FDA*, alleging, in part, that FDA's imposition of the 2023 mifepristone REMS unlawfully 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 contend 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, approximately 20 minutes after the Texas district court handed down its order in *Alliance*, 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. Given the conflicting nature of the *Alliance* and *Washington* opinions, FDA quickly filed a motion for clarification of the ruling, asking the district court to clarify the agency's obligations assuming the order in the *Alliance* case takes effect. The district court granted the motion, reiterating that regardless of a ruling in the Fifth Circuit, 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. The district court's rulings in *Washington* may be appealed to the U.S. Court of Appeals for the Ninth Circuit (or potentially the Supreme Court).

Challenges to State Law Restrictions

In late January 2023, plaintiffs filed separate cases in North Carolina and West Virginia federal district courts, alleging 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 dispensing 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.

In *GenBioPro v. Sorsaia*, a pharmaceutical company that sells the generic version of mifepristone sued West Virginia officials, challenging state provisions that, among other things, ban abortion generally (including access to mifepristone) except under limited circumstances. The company claims, in part, that federal law preempts West Virginia's requirements, as they are alleged to 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. Defendants in these cases have generally argued that state restrictions on medication abortion drugs, even bans, 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 medication abortion. District courts have not yet issued a ruling on the preemption issues raised in these lawsuits.

Considerations for Congress

Judicial decisions in the *Alliance*, *Washington*, *Bryant*, and *GenBioPro* lawsuits could potentially transform the legal landscape surrounding medication abortion regulation and affect the conditions under which medication abortion drugs are accessible to pregnant patients. Most immediately, the conflicting decisions in *Alliance* and *Washington* have created uncertainty as to the current availability of mifepristone. However, given that the Supreme Court has stayed the Fifth Circuit's order pending appeal, the immediate consequences of the decisions are likely minimal. 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.

Author Information

Jennifer A. Staman
Legislative Attorney

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