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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 increasing 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 now the subject of litigation that may affect access to these products. This Legal Sidebar discusses federal and state regulation of medication abortion drugs, recently filed lawsuits concerning medication abortion, 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 sponsor of the application (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 requires compliance with distribution controls pursuant to a risk evaluation and 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; 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 specified that mifepristone had to be

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dispensed in-person in certain specified health care settings, but a January 2023 update to the REMS enables 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 my prescribe medication abortion drugs. The report also identifies many states that require health care providers to be in the physical presence of the patient 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, and questions have arisen about the interaction between these federal and state regulatory regimes.

Litigation over Medication Abortion Access

In recent months, plaintiffs have filed least three cases that involve the availability of medication abortion drugs. Two of the lawsuits challenge the validity of state medication abortion restrictions, while the third case concerns federal mifepristone regulation and claims that FDA's review and approval of the drug was unlawful.

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 seventy-two-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."

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. The North Carolina and West Virginia state defendants have not yet filed briefs in these cases, though reports indicate that the North Carolina Attorney General will argue that federal law preempts the state's abortion restrictions. On the other hand, in previous communications with FDA, several state attorneys general have expressed that 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.

Challenge to Federal Approval of Mifepristone

In *Alliance for Hippocratic Medicine v. FDA*, 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's approval, in an effort to take the drug off the market. Plaintiffs make several arguments about the agency's initial approval and subsequent administrative actions of the drug. The plaintiffs claim, among other things, that the agency (1) impermissibly used 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) 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.

In its reply brief, FDA counters that the plaintiffs lack standing to sue and that the majority of their claims are untimely. Further, the agency claims that it properly exercised its FD&C Act authority to approve mifepristone and applied its scientific expertise to make determinations about the drug that are entitled to "substantial deference." The agency also points to the uniqueness of the lawsuit, noting that the plaintiffs have 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 maintains 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 a sender of the products intends for the product to be used lawfully. Danco Laboratories, the company that sells the brand-name version of mifepristone, filed a motion to intervene and is now a party to the litigation, and numerous states have filed amicus briefs in the case in support of the plaintiffs or defendants.

Considerations for Congress

Any forthcoming judicial decisions in the *Bryant*, *GenBioPro*, or *Alliance for Hippocratic Medicine* lawsuits may affect the conditions under which medication abortion drugs are accessible to pregnant patients. While the *Bryant* and *GenBioPro* cases concern particular state laws and thus may be limited in application, plaintiffs in *Alliance for Hippocratic Medicine* are seeking, among other things, a preliminary and permanent injunction to vacate mifepristone's FDA approval, potentially removing the legal basis for the drug's sale and distribution nationwide. 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 clarify the degree to which federal regulation of medication abortion drugs preempts state measures inconsistent with federal policy. Such legislation could clarify 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 it "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 on these products.

Congress may also 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.

Alternatively, Congress could pass legislation that addresses the status of mifepristone as an FDA-approved drug or codifies 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, from the 117th Congress, would have taken a dissimilar approach: the Protecting Access to Medication Abortion Act (S. 4467) would have generally required the mifepristone REMS to expressly indicate that patients may access prescriptions for mifepristone via telehealth and that certified pharmacies may dispense the drug through the mail to patients.

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