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Legal Sidebar

FDA Regulation of Medication Abortion: Recent Legal Developments

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Regulation of medication abortion drugs is a salient issue for federal policymakers, particularly amid continued litigation over the conditions in which these drugs may be available to pregnant patients. Some of the more prominent pending cases involve claims that the Food and Drug Administration's (FDA's) actions relating to the medication abortion drug mifepristone, are unlawful. Plaintiffs in these cases seek changes to current federal prescribing and dispensing requirements. The claims in these cases vary widely: while some suits allege that FDA improperly considered the risks of mifepristone and unlawfully approved or set controls for the drug that are too relaxed, others contend that FDA inappropriately limited access to mifepristone and that the medication should be easier to obtain. In *Louisiana v. FDA*, the U.S. Court of Appeals for the Fifth Circuit (Fifth Circuit) granted a motion to stay FDA's current mifepristone requirements that allow patients to obtain the drug via remote prescribing and dispensing. The Supreme Court paused this stay as the litigation continues, and remote prescribing and dispensing of mifepristone remains available. This Legal Sidebar provides background on federal regulation of mifepristone, explores recent litigation over how FDA regulates the drug, and concludes with selected legal considerations for Congress.

Background on Federal Regulation of Medication Abortion

According to CDC data published in 2022, medication abortions represent roughly half of U.S. abortions. A more recent survey of abortion provider data by the Guttmacher Institute concluded that medication abortion has grown as a percentage of procedural abortions since that time. A typical medication abortion regimen involves using the prescription drug mifepristone (the only drug approved by 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.

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In 2000, FDA first approved mifepristone for use under certain conditions. Since 2007, controls on mifepristone have been imposed through 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 the risks." In some circumstances, FDA may also impose more stringent controls on access to drugs through a REMS, and such controls must "be commensurate with the specific serious risk listed in the labeling of the drug" and, considering such risk, cannot "be unduly burdensome on patient access to the drug."

The mifepristone REMS has been modified on several occasions. The most recent version issued in September 2025 compels health care professionals who prescribe the drug, and pharmacies that dispense 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 imposed additional, more stringent controls on prescribing and dispensing mifepristone (including a requirement to prescribe and dispense the drug over the course of three in-person office visits with the prescribing doctor). Over time, FDA has reviewed data related to mifepristone and scaled down these controls. Most central to the medication abortion litigation are two series of actions.

First, in 2016, FDA reviewed and concluded that mifepristone safety and efficacy data supported changes to the drug's conditions of use. These changes included reducing the number of required in-person office visits for obtaining the drug from three to one; allowing qualified nonphysician health care professionals, such as nurse practitioners, to prescribe mifepristone; and easing adverse event reporting requirements to those that allow for reporting of only fatalities as part of an adverse event reporting system used for other prescription drugs and medical products (in a prior version of the REMS, mifepristone prescribers had to also report to the drug manufacturer certain serious adverse events, such as hospitalizations and blood transfusions).

Second, in 2021, after a lawsuit was filed over the enforcement of the in-person prescribing and dispensing requirements during the COVID-19 pandemic, FDA stated that it would suspend enforcement during the public health emergency. The agency also announced that data supported longer-term modifications to mifepristone's distribution controls that would eliminate the in-person prescribing and dispensing requirements. In 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. However, FDA reversed course in September 2025, announcing that it will re-examine the 2023 REMS, and that this reconsideration was based on "the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered." FDA's review of the 2023 mifepristone REMS is ongoing.

Lawsuits to Restrict Mifepristone Access

Several states and other plaintiffs have sued FDA over its regulation of medication abortion, claiming that FDA approved and set distribution controls for mifepristone in a way that does not reflect the drug's risks. To defend the legality of FDA's actions, mifepristone manufacturers, Danco Laboratories and GenBioPro, Inc., have intervened in these cases as parties to the litigation.

In 2022 in *Alliance for Hippocratic Medicine v. FDA*, a group of doctors and medical organizations with religious or moral objections to providing elective abortion services sued FDA and several federal officials, asserting, in part, that the agency violated the Administrative Procedure Act (APA) by failing to examine and inappropriately disregarding scientific evidence in regulating the drug. Responding to the plaintiffs' arguments, FDA claimed, among other things, that the plaintiffs lacked standing to sue, and that the agency properly exercised its FD&C Act authority and applied its scientific expertise to make

determinations about mifepristone. The U.S. District Court for the Northern District of Texas sided with the plaintiffs and ordered a stay of FDA's approval of mifepristone and other FDA actions, thus suspending the ability for mifepristone to be on the market nationwide. On appeal, the Fifth Circuit vacated the district court's order concerning FDA's initial approval of mifepristone in 2000, on the basis that the claim was time-barred because of a generally applicable six-year statute of limitations period related to federal administrative actions. However, the Fifth Circuit sustained the plaintiffs' challenges to FDA's 2016 and 2021 actions to change the REMS program.

In its opinion, the appeals court agreed with the district court that FDA failed to adequately consider relevant scientific data in relaxing these drug controls. With respect to the changes to the 2016 REMS, the court expressed that FDA violated APA requirements because the agency did not consider the effects of implementing all of the changes to the REMS simultaneously. While FDA and Danco Laboratories contended FDA was not required to study the drug under the precise conditions under which it may be used, the court rejected this argument, concluding that failure to study the "cumulative effect" of the 2016 revisions demonstrated that the agency engaged in flawed decisionmaking under the APA. Additionally, with respect to the 2016 and 2021 actions, the appeals court took issue with the agency's decisions related to its collection of adverse-events data. The court declared that FDA "likely" violated the APA when it did not take into account that it was relaxing mifepristone's conditions of use, while at the same time it decided to loosen adverse event reporting requirements on mifepristone prescribers.

In June 2024, the Supreme Court unanimously held that the plaintiffs lacked standing to sue FDA regarding the conditions under which mifepristone is accessible to pregnant patients and did not address the merits of the Fifth Circuit opinion. The Court stated that "general legal, moral, ideological, or policy objection to a particular government action" are not sufficient to satisfy constitutional standing requirements; plaintiffs must show they have or will likely suffer a "concrete" injury as a result of the defendant's conduct. The Court explained, in part, that the plaintiff physician group did not prescribe or use mifepristone, and that the group consisted of "unregulated parties who seek to challenge FDA's regulation of *others*." The arguments the plaintiffs raised to make a causal link from the FDA's regulatory actions to the plaintiffs' alleged injuries were, in the Court's view, "too speculative or otherwise too attenuated to establish standing."

Following the Supreme Court's decision, the case continued in the lower courts. The States of Idaho, Kansas, and Missouri intervened in the lawsuit as plaintiffs and generally assert, among other things, that FDA's 2016 and subsequent actions related to mifepristone interfere with their "sovereign interests" by impeding enforcement of their laws that restrict access to medication abortion, and trigger increased costs to states' Medicaid programs. The case has been transferred to the U.S. District Court for the Eastern District of Missouri. In a separate lawsuit, the States of Texas and Florida are challenging FDA's approval and other actions related to mifepristone. The lawsuit is pending before the U.S. District Court for the Northern District of Texas.

In October 2025, the State of Louisiana and a state resident sued FDA and other federal officials in a separate lawsuit, asking the court to vacate the most recent 2023 mifepristone REMS, including FDA's authorization of remote prescribing and dispensing. As part of their suit, the plaintiffs filed a motion to preliminarily stay the 2023 REMS during the course of the litigation. Responding to this preliminary motion, the U.S. District Court for the Western District of Louisiana first determined that Louisiana had standing to sue, in part because of "sovereign harm," based on the idea that the REMS facilitated the shipment of medication abortion to patients in the state under circumstances that violated abortion restrictions under state law. Turning to the merits of the preliminary injunction motion, the court indicated that the plaintiffs demonstrated a likelihood of prevailing on the merits of their challenge to the 2023 REMS. The court pointed in part to FDA's 2025 decision to revisit the REMS because of safety concerns. Nevertheless, the district court declined to preliminarily stay the REMS. The plaintiffs appealed to the Fifth Circuit, which granted the motion to stay. Danco and GenBioPro then asked the Supreme Court to

stay the judgment of the Fifth Circuit (or grant certiorari in the case), and the Court agreed to pause this stay during the pendency of the litigation, over the dissents of Justices Alito and Thomas. The result is that the 2023 REMS remains in effect during the course of this lawsuit.

Lawsuits to Expand Mifepristone Access

In contrast to the cases mentioned above, other suits involve claims that the 2023 mifepristone REMS unlawfully *constrains* access to mifepristone. For instance, in *State of Washington v. FDA*, attorneys general of 17 states and the District of Columbia filed suit in the U.S. District Court for the Eastern District of Washington, alleging, in part, that FDA's 2023 mifepristone REMS improperly hampers access to the drug and violates 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 July 2025, the district court sided with FDA and granted its motion for summary judgment of the case. The court determined that FDA properly reviewed the controls on the drug and came to a reasonable conclusion in setting controls for the drug as part the 2023 REMS.

By comparison, in *Purcell v. Kennedy*, a suit brought by physician prescribers of mifepristone and other parties, the U.S. District Court for the District of Hawaii held that FDA violated the APA when crafting the 2023 REMS. The court decided that the agency failed to provide a reasoned explanation for imposing the drug's distribution controls and neglected to consider the statutorily mandated requirements of the REMS provision in the FD&C Act. In general, the court determined that the agency did not analyze the necessary factors for imposing the REMS, and did not provide adequate justifications for its decisionmaking related to the prescriber certification, the patient agreement form, and the pharmacy certification components of the REMS. The court also concluded that FDA failed to consider certain data in its REMS review (such as statements from "preeminent medical societies urging elimination of the mifepristone REMS"). The court declared the mifepristone REMS unlawful, but it left the REMS in place while the FDA performs its review. Another case in which plaintiffs are seeking removal of the mifepristone REMS, *Whole Woman's Health Alliance v. FDA*, is pending in the U.S. District Court for the Western District of Virginia.

Legal Considerations for Congress

The legal landscape surrounding FDA regulation of medication abortion is complex and changing. While mifepristone remains on the market under the current federal regulatory framework (i.e., under the 2023 mifepristone REMS) as the litigation proceeds, changes may be on the horizon, perhaps in light of FDA's review of the REMS. Any forthcoming administrative changes to the mifepristone REMS may alter the procedural posture of the ongoing cases, or spur new litigation. As FDA reviews the mifepristone REMS, it is possible that some of the cases challenging FDA regulation of medication abortion may be placed on hold (for example, the States of Florida and Texas have expressed support for a time-limited stay in their case based on FDA's REMS review), and other cases, such as the *Louisiana* lawsuit, may continue.

Aside from lawsuits over FDA regulation of medication abortion, legal challenges related to state regulation of medication abortion continue. Several states have enacted measures designed to govern 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. Such laws have been subject to challenge, including on federal preemption grounds.

For example, in *Bryant v. Stein*, a physician sued North Carolina's Attorney General and others, asserting that federal law preempts the state's medication abortion controls, including physician only, in-person prescribing, dispensing, and administering requirements; in-person counseling requirements with a 72-

hour waiting period before prescribing mifepristone; and ultrasound requirements. In the case, the plaintiff physician claimed, in part, 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 April 2024, the U.S. District Court for the Middle District of North Carolina concluded that while some state provisions related to patient health and welfare, other provisions imposed safety-related restrictions on medication abortion drugs. The court characterized the first type of state requirements (including the in-person advance consultation requirements and the ultrasound requirements) as related to regulation of pregnancy-related health issues, and held that they withstood federal preemption and remained valid. Conversely, the court determined that the second type of provisions, including the in-person prescribing, dispensing, and administering requirements, were preempted by federal law, as these requirements directly related to drug regulation and interfered with Congress's goal of creating a comprehensive federal framework for mifepristone. The *Bryant* case is pending before the U.S. Court of Appeals for the Fourth Circuit. Should the federal regulatory regime for mifepristone change, such changes could affect the outcome in *Bryant* or any future cases challenging state laws relating to medication abortion.

Finally, in light of recent judicial and administrative developments regarding federal regulation of medication abortion, Congress may choose to amend federal law to specify the conditions in which these products are available to patients, or clarify the degree to which federal regulation of medication abortion drugs preempts state measures inconsistent with federal policy. 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 prescribing or dispensing medication abortion drugs. An example of this type of bill in the 119th Congress is the Safeguarding Women from Chemical Abortion Act (S. 4066 and H.R. 7902), which, among other things, would withdraw FDA's approval for mifepristone for use as an abortifacient and remove the legal basis for the drug's sale and distribution. Another example, during the 118th Congress, would have taken a different approach: the Protecting Access to Medication Abortion Act (S. 237 and H.R. 767) would have generally required 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.

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