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Legal Sidebar

Medication Abortion Access Remains Unchanged as Supreme Court Rejects Legal Challenge on Standing Grounds

June 26, 2024

On June 13, 2024, the Supreme Court issued its decision in the consolidated cases *U.S. Food and Drug Administration (FDA) v. Alliance for Hippocratic Medicine* and *Danco Laboratories L.L.C. v. Alliance for Hippocratic Medicine* (*Alliance*), a pair of high-profile legal challenges to FDA's regulation of mifepristone, a commonly used abortion drug. In *Alliance*, the Supreme Court unanimously held that a group of physicians and medical organizations lacked standing to sue FDA regarding the conditions under which mifepristone is accessible to pregnant patients. The Court did not reach the merits of the challenge, and FDA's most recent conditions for mifepristone (which allow qualified health care practitioners to prescribe and dispense the drug via telemedicine) remain intact. This Legal Sidebar provides background on federal regulation of medication abortion, discusses the Court's *Alliance* decision, and concludes with selected legal considerations for Congress.

Background on Medication Abortion Regulation and Litigation

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 FDA as an abortifacient), followed by a second drug, misoprostol, to terminate an early pregnancy. Like other prescription drugs available on the market, the medication abortion drugs were evaluated and approved by FDA pursuant to Federal Food, Drug, and Cosmetic Act (FD&C Act) requirements.

With respect to new drugs, the FD&C Act, as amended, creates a comprehensive federal system of premarket approval for such drugs. Under current law, to market a new drug, a manufacturer must file a new drug application with FDA. The application 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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LSB11183

In 2000, FDA first approved mifepristone for use under certain conditions. As originally approved, mifepristone was available for use for women in the first seven weeks of pregnancy, when prescribed by a qualified physician and dispensed over the course of three in-person office visits with the prescribing doctor. FDA also required mifepristone prescribers to report to the drug sponsor certain serious adverse events, such as hospitalizations and blood transfusions. However, FDA has scaled down these conditions over time. Most relevant to the *Alliance* litigation are two main FDA actions to change the drug's distribution controls:

- In 2016, FDA reviewed and approved a supplemental drug application submitted by Danco Laboratories, the company that sells the brand-name version of mifepristone. In approving this application, FDA concluded that safety and efficacy data supported changes to the drug's conditions of use. These changes included altering the dosing amounts for mifepristone and misoprostol as part of the approved regimen; increasing the gestational age limit from seven to ten weeks of pregnancy; reducing the number of required in-person doctor's visits from three to one; allowing qualified nonphysician health care professionals, such as nurse practitioners, to prescribe mifepristone; and revising the adverse event reporting requirements to allow for periodic reporting as part of an adverse event reporting system used for other prescription drugs and medical products. These changes were implemented through a Risk Evaluation and Mitigation Strategy (REMS), a drug safety plan for mifepristone.
- In 2021, after a lawsuit was filed over the enforcement of the in-person dispensing requirements during the COVID-19 pandemic, FDA stated that it would suspend enforcement during the public health emergency. Subsequently, in response to other litigation related to the mifepristone REMS, FDA indicated that data supported longer-term modifications to mifepristone's distribution controls that would eliminate the in-person prescribing and dispensing requirements. In January 2023, an update to the mifepristone REMS allowed patients to obtain the drug without an in-person visit to a clinician, including through the mail from certified prescribers or pharmacies.

In 2022, a group of doctors and medical organizations with members that assert they have religious or moral objections to providing elective abortion services sued FDA, the FDA Commissioner, and other federal officials, asking the U.S. District Court for the Northern District of Texas to vacate FDA's original approval of mifepristone and subsequent actions relating to the drug. As part of a preliminary injunction request, the plaintiffs challenged the validity of FDA's mifepristone regulation, arguing, in part, 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 intervened as a defendant in the case.

Responding to these arguments, FDA countered that the plaintiffs lacked standing to sue, that the majority of their claims were 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, thus suspending the legal basis for the drug's sale and distribution nationwide. Subsequently, the Supreme Court granted an application to stay the district court's decision pending appeal, and mifepristone remained on the market under FDA's most recent distribution controls while the litigation continued.

On appeal, the Fifth Circuit vacated the district court's order concerning FDA's approval of mifepristone, holding that the plaintiffs' claims were likely time-barred. As the court explained, FDA originally approved mifepristone in 2000, and that action was subject to the generally applicable six-year statute of

limitations period related to federal administrative actions. However, the court sustained the plaintiffs' challenges to FDA's 2016 and 2021 actions related to the drug. The appeals court agreed with the district court that FDA failed to adequately consider relevant scientific data in relaxing these controls.

The federal defendants and Danco Laboratories petitioned the Supreme Court for review of the Fifth Circuit's decision related to FDA's 2016 and 2021 mifepristone actions. In response, the plaintiffs submitted a conditional cross-petition, asking the Court to also review FDA's original approval of mifepristone if the government's petition was granted. The Court then granted review of the government's and Danco Laboratories' petitions, but denied the plaintiffs' request.

The Supreme Court's Decision

In a unanimous decision authored by Justice Brett Kavanaugh, the Supreme Court held that the plaintiffs lacked standing to challenge FDA's 2016 and 2021 actions related to mifepristone. Before any court can render a decision on the issues before it, it must first determine whether it has jurisdiction to examine the issues in the case. As part of this threshold inquiry, plaintiffs proceeding in federal courts must demonstrate that they have standing under Article III of the Constitution to bring the legal action. Standing requirements compel a plaintiff to prove, among other things, an injury that is "concrete and particularized," and that affects the plaintiff "in a personal and individual way." Additionally, a plaintiff's injury must be "fairly traceable," i.e., it is likely caused, or will be caused, by the allegedly unlawful conduct at issue.

In its opinion, the Court first pointed out that the plaintiffs did not prescribe or use mifepristone, and that the group consisted of "unregulated parties who seek to challenge FDA's regulation of *others*." The Court then rejected certain theories of standing advanced by the plaintiffs. Among these theories, the group claimed that FDA's actions to loosen the regulatory controls on mifepristone made it more difficult for doctors to diagnose harmful conditions such as ectopic pregnancies, and increased the likelihood that emergency care would be needed. As emergency room doctors, members of the group argued they suffered an injury because they could be compelled to perform an abortion or other emergency treatment for these patients, in violation of their religious or moral beliefs. However, the Court disagreed, explaining that existing federal conscience laws prevent doctors from being required to perform treatments to which they have a religious or moral objection.

The plaintiffs also asserted financial and other related injuries caused by FDA's 2016 and 2021 actions (e.g., the diversion of resources to treating patients suffering complications from mifepristone, and heightened liability risks in treating these patients). In declining to accept this reasoning, the Court declared that the alleged injuries could not be causally linked to FDA's actions and were "highly speculative." The Court further declared that "allowing doctors or other healthcare providers to challenge general safety regulations as unlawfully lax would be an unprecedented and limitless approach" inconsistent with the Constitution's standing requirements. Additionally, the Court rejected the medical associations' argument that they had standing to sue based on associational standing (or organizational standing) principles. The Court maintained that an organization cannot sue solely on the basis of the "intensity of the litigant's interest" or "strong opposition to the government's conduct."

While the Court recognized that the plaintiffs had sincere objections to elective abortion, the Court ultimately concluded that such objections alone do not make a claim justiciable, and that the plaintiffs failed to demonstrate how FDA's relaxed conditions for mifepristone would cause an injury sufficient to confer standing. Noting that access to the courts is constrained by the Article III standing requirement, the Court stated that "plaintiffs may present their concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process."

Justice Clarence Thomas penned a concurring opinion in *Alliance*, expressing concerns about the Court's existing associational-standing doctrine and the ability of an association to sue solely based on a single

member's injury. He suggested the Court should revisit this doctrine and explain how the doctrine comports with Article III of the Constitution.

Considerations for Congress

In the wake of the Supreme Court's decision in *Alliance*, it appears the case leaves federal mifepristone regulation in place. However, other current and future legal battles related to this regulation may continue. For instance, questions have been raised about possible next steps for the attorneys general of Missouri, Kansas, and Idaho, who sought to intervene in the *Alliance* litigation while the federal defendants' and Danco Laboratories' petitions for Supreme Court review were pending. The attorneys general sought involvement in the case because of, among other things, alleged economic harm caused by increased costs to state-funded insurance and hospitals, and the district court allowed the states to become parties to the litigation. As new parties to the case, the attorneys general then asked the Supreme Court to intervene and assess the states' standing to sue, in order for the Court to "more easily reach the merits." The Court denied this request. It remains to be seen whether these states will seek to continue challenging FDA regulation of mifepristone, perhaps through a new lawsuit.

Other cases concerning federal mifepristone regulation remain ongoing, including cases in which plaintiffs 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 hamper access to the drug and are "arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law" in violation of the APA. In April 2023, the U.S. District Court for the Eastern District of Washington determined that FDA failed to appropriately consider the drug's safety profile in imposing the REMS and 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." After 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. The district court declined 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. On June 13, 2024, the Ninth Circuit issued an order for the litigation parties in *Washington* to submit supplemental briefs regarding the effect of the *Alliance* case on the litigation.

In light of *Alliance* and other lawsuits challenging federal mifepristone regulation, Congress may choose to enact legislation that could affect or respond to 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, require in-person dispensing requirements. 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 controls for mifepristone that would allow patients to access prescriptions for the drug via telehealth and certified pharmacies to dispense the drug through the mail to patients (though the requirements would be able to be modified or removed based on "sound scientific evidence").

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